

FDA Adverse Event Reporting System (FAERS) FOIA Case Report Information

Disclaimers:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Esub Case ID(s) Printed:

9681215 10511270 10511962

Run by: STEPPERH

Date - Time: 04-NOV-2016 08:34 AM

Total number of cases (Esub): 3



FOIA Case Report Information

Case ID: 9681215

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Application Type: NDA Country: CAN Event Date: Outcomes: DE,

DAY)

FDA Rcvd Date: 11-Nov-2013 Mfr Rcvd Date: 07-Nov-2013 Mfr Control #: CA-ASTRAZENECA-2013SE82130 Application #: 018240

Patient Information:

Age: 40 YR Sex: Male Weight:

| Sus | spect Products: | Compounded | Dose/ | | | | | | | |
|-------|-----------------------------|------------|-----------|--------------------|-------------------------------------|----------------|----------|----|-------|------|
| # | Product Name | Drug ? | Frequency | Route | Dosage Text | Indications(s) | Start Da | te | End [|)ate |
| 1 | ATENOLOL | | | Oral | | | | | | |
| 2 | CAMPRAL | | | Unknown | | | | | | |
| 3 | CREATINE | | | Unknown | | | | | | |
| 4 | EPHEDRINE HYDROCHLORIDE | | | Unknown | | | | | | |
| 5 | ETHANOL | | | Unknown | | | | | | |
| 6 | HOMEOPATHICS | | | Unknown | | | | | | |
| 7 | HYDRASHRED | | | Unknown | | | | | | |
| 8 | HYLANDS TEETHING TABLETS | | | Unknown | | | | | | |
| 9 | LITHIUM CARBONATE | | | Unknown | | | | | | |
| 10 | PANTOPRAZOLE | | | Unknown | | | | | | |
| 11 | RAPID LEAN | | | Unknown | | | | | | |
| 12 | RIPPED FREAK | | | Unknown | | | | | | |
| 13 | SEROQUEL | | | Oral | | | | | | |
| 14 | SUPER VITA VIM | | | Unknown | | | | | | |
| 15 | VITAMIN B1 | | | Unknown | | | | | | |
| 16 | VITAMIN D | | | Unknown | | | | | | |
| Print | Time: 04-NOV-2016 08:34 / | AM | | If a field is blar | nk, there is no data for that field | | Page | 1 | of | 12 |



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FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 9681215

| | Product Name | Compounded Drug ? | Dose/ Frequency | Route | e Dosage Text | | Indication | s(s) | Start Date | End Date |
|----|------------------------------|-------------------|--------------------|-------|---------------|----------|------------|-----------|------------|----------|
| 17 | WELLBUTRIN XL | | | Unkno | own | | | | | |
| 18 | XENADRINE EFX | | | Unkno | own | | | | | |
| | | Interval 1st | | | | | | | | |
| # | Product Name | Dose to Event | DeC | ReC | Lot# | Exp Date | NDC # | MFR/Label | er | |
| 1 | ATENOLOL | | NA | NA | | | | ZENECA | | |
| 2 | CAMPRAL | | NA | NA | | | | | | |
| 3 | CREATINE | | NA | NA | | | | | | |
| 4 | EPHEDRINE | | NA | NA | | | | | | |
| 5 | HYDROCHLORIDE ETHANOL | | NA | NA | | | | | | |
| 6 | HOMEOPATHICS | | NA | NA | | | | | | |
| 7 | HYDRASHRED | | NA | NA | | | | | | |
| 8 | HYLANDS TEETHING | | NA | NA | | | | | | |
| 9 | TABLETS LITHIUM CARBONATE | | NA | NA | | | | | | |
| 10 | PANTOPRAZOLE | | NA | NA | | | | | | |
| 11 | RAPID LEAN | | NA | NA | | | | | | |
| 12 | RIPPED FREAK | | NA | NA | | | | | | |
| 13 | SEROQUEL | | NA | NA | | | | ZENECA | | |
| 14 | SUPER VITA VIM | | NA | NA | | | | | | |
| 15 | VITAMIN B1 | | NA | NA | | | | | | |
| 16 | VITAMIN D | | NA | NA | | | | | | |
| 17 | WELLBUTRIN XL | | NA | NA | | | | | | |
| | | | | | | | | | | |



FOIA Case Report Information

Case ID: 9681215

| Product Name | Compounded Drug ? | Dose/ Frequency | Route | Dosag | je Text | Indicatio | ons(s) | Start Date | End Date |
|------------------|-------------------------------|--------------------|-------|-------|----------|-----------|----------|------------|----------|
| Product Name | Interval 1st Dose to Event | DeC | ReC | Lot# | Exp Date | NDC # | MFR/Labe | eler | |
| 18 XENADRINE EFX | | NA | NA | | | | | | |

Event Information:

| Preferred Term (MedDRA 🖨 Version: | 17.0 |) | ReC |
|--|------|---|-----|
| Antipsychotic drug level above therapeutic | | | NA |
| Drug interaction | | | NA |
| Toxicity to various agents | | | NA |

Event/Problem Narrative:

Print Time: 04-NOV-2016 08:34 AM

A report had been received from a health professional via health Canada concerning a 40 year old male patient. Medical history and concomitant medications of the patient were not reported. The patient had been receiving oral Atenolol (atenolol) started on an unknown date, oral seroquel (quetiapine fumarate) started on an unknown date, unknown campral (acamprosate calcium) started on an unknown date, unknown creatine (creatine) started on an unknown date, unknown ephedrine hydrochloride (ephedrine hydrochloride) started on an unknown date, unknown ethanol (ethanol) started on an unknown date, unknown hoodia (homeopathic nos) started on an unknown date, unknown hydrashred (no match) started on an unknown date, unknown hydroxycut (no match) started on an unknown date, unknown pantoprazole (pantoprazole) started on an unknown date, unknown pmslithium carbonate (lithium carbonate) started on an unknown date, unknown rapid lean (no match) started on an unknown date, unknown ripped freak (no match) started on an unknown date, unknown super vita vim (vitamins nos) started on an unknown date, unknown vitamin B1 (thiamine hydrochloride) started on an unknown date, unknown vitamin D (ergocalciferol) started on an unknown date, unknown wellbutrin XL (bupropion hydrochloride) started on an unknown date and unknown xenadrine (acetylcarnitine, citrus aurantium, ephedra spp., Levothyroxine, pantothenic acid, paullinia cupana, salix alba, zingiber officinale) started on an unknown date. It was reported that the patient experienced drug interaction (preferred term: drug interaction), toxicity to various agents (preferred term: toxicity to various agents) and antipsychotic drug level above therapeutic (preferred term: antipsychotic drug level above therapeutic). Action taken with all interacting drugs was not applicable. The following products were considered to be interacting: atenolol, seroquel, campral, creatine, ephedrine hydrochloride, ethanol, hoodia, hydrashred, hydroxycut, pantoprazole, pms-lithium carbonate, rapid lean, ripped freak, super vita vim, vitamin b1, vitamin d, wellbutrin xl and xenadrine. The patient died from the event of drug interaction, toxicity to



FOIA Case Report Information

Case ID: 9681215

various agents and antipsychotic drug level above therapeutic on an unspecified date. An autopsy performed was unknown. The reporter considered the events drug interaction, toxicity to various agents and antipsychotic drug level above therapeutic to be serious due the serious criteria of death.

| Relevant Medical His | tory: | | | | | | | |
|------------------------|--------------------|-------------------|-------------|------------------|-------------|--------------|----------|-------------------------------|
| Disease/Surgical Proce | dure | : | Start Date | End Date | Continuing? | , | | |
| Medical History Produc | t(s) | • | Start Date | End Date | Indications | | Eve | ents |
| Relevant Laboratory | Data: | | | | | | | |
| Test Name | | Result | Unit | Normal Low Range | Norma | l High Range | Info A | Avail |
| Concomitant Product | es: | | | | | | | |
| # Product Name | Dose/ Frequency | Route | Dosage Text | Indi | cations(s) | Start Date | End Date | Interval 1st Dose to Event |
| Reporter Source: | | | | | | | | |
| Study Report?: No | Sender Or | ganization: ASTRA | ZENECA | | | 503B Compo | | |



FOIA Case Report Information

Case ID: 9681215

Literature Text:

5



FOIA Case Report Information

Case ID: 10511270

Case Information:

Application Type: NDA Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: Outcomes: HO.

DAY)

FDA Rcvd Date: 10-Oct-2014 Mfr Rcvd Date: 03-Oct-2014 Mfr Control #: US-PFIZER INC-2014275842 Application #: 019833

Patient Information:

Suspect Products:

Age: 3 YR Sex: Male Weight:

| | Product Name | Compounded Drug ? | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date |
|---|--------------|----------------------|--------------------|-------|-------------|----------------|------------|----------|
| 1 | INFANT ADVIL | | | | UNK | Teething | | |

CONCENTRATED DROPS 2 BABY ORAJEL UNK Teething

NIGHTTIME FORMULA

3 BABY ORAJEL TEETHING UNK Teething PAIN MEDICINE

| # | Product Name | Interval 1st Dose to Event | DeC | ReC | Lot# | Exp Date | NDC # | MFR/Labeler |
|---|--------------|-------------------------------|-----|-----|------|----------|-------|-------------|
| 1 | INFANT ADVIL | | Unk | NA | | | | PFIZER |

CONCENTRATED DROPS 2 BABY ORAJEL Unk NA NIGHTTIME FORMULA

3 BABY ORAJEL TEETHING Unk NA PAIN MEDICINE

Event Information:

Print Time: 04-NOV-2016 08:34 AM

ReC Preferred Term (MedDRA @ Version: 17.0

NA Dyspnoea

NA Eye movement disorder

NA Moaning



FOIA Case Report Information

Case ID: 10511270

Event/Problem Narrative:

This is a spontaneous report from a contactable consumer. A 3-year-old male patient of an unspecified ethnicity started to receive ibuprofen (INFANT ADVIL CONCENTRATED DROPS), benzocaine (BABY ORAJEL TEETHING PAIN MEDICINE), HYLAND TEETHING TABLETS, and benzocaine (BABY ORAJEL NIGHTTIME FORMULA) via an unspecified route of administration from an unspecified date to an unspecified date at unspecified doses for teething. Medical history included Kawasaki's disease from (b) (6) and they used scalpel to deliver her son and they were able see where a little tissue had built up where the scalpel had entered his skin but did not enter his brain. It was kind of in between the scalp and the skull. She stated his head was oddly shaped. Concomitant medication included ibuprofen (CHILDREN'S ADVIL). It was reported the patient experienced eyes rolling in back of head and moaning like a Down's Syndrome sort of sound from when he started teething to age 3 years. He also quit breathing a few times for a few seconds. The son is now 5 years old. Mother states the son was taken to the hospital for a bunch of tests and did not receive answers for his experiencing these episodes. The patient underwent lab tests and procedures which included computerised tomogram head results of which were unknown, skull x-ray the results of which were unknown and MRI the results were unknown. The action taken in response to the events for ibuprofen and benzocaine was unknown.

Relevant Medical History:

Print Time: 04-NOV-2016 08:34 AM

Continuing? **End Date** Disease/Surgical Procedure Start Date Kawasaki's disease (b) (6) UNKNOWN Head deformity Incision site complication Start Date Medical History Product(s) **End Date** Indications Events Relevant Laboratory Data: **Test Name** Info Avail Result Normal High Range Unit Normal Low Range CT brain scan Unknown N Head X-ray Unknown N MRI Unknown N



FOIA Case Report Information

Case ID: 10511270

Concomitant Products:

Product Name Dose/ Route Dosage Text Indications(s) Start Date End Date Interval 1st Frequency Dose to Event

CHILDREN'S ADVIL UNK

Reporter Source:

Study Report?: No Sender Organization: PFIZER 503B Compounding Outsourcing Facility?:

Literature Text:

Print Time: 04-NOV-2016 08:34 AM

of



FOIA Case Report Information

Case ID: 10511962

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: 19-Sep-2014 Outcomes: OT,

Application Type: NDA

DAY)

FDA Rcvd Date: 19-Feb-2015 Mfr Rcvd Date: 09-Feb-2015 Mfr Control #:US-PFIZER INC-2014274670

Application #: 019833

Patient Information:

Age: 1 YR Sex: Female Weight: 9 KG

| Sus | spect Products: | C | Dose/ | | | | | | | |
|----------------|---------------------------------------|----------------------|-----------|-------|----------|-------------|-----------|----------------|-------------|-------------|
| # Product Name | | Compounded Drug ? | Frequency | Route | Dosage | Dosage Text | | Indications(s) | | End Date |
| 1 | Infant Advil Concentrated Drops | | .625 ML/ | Oral | 0.625 ml | , UNK | Fever | | | |
| 2 | BABY ORAJEL TEETHING PAIN MEDICINE | | | | UNK | | | | | |
| 3 | Infant Advil Concentrated Drops | | 1.25 ML/ | | 1.25 ml, | UNK | Sore thro | pat | 19-Sep-2014 | 01-Oct-2014 |
| # | Product Name | Interval 1st | DeC | DoC. | 1 444 | Eve Data | NDC # | MFR/Labe | la | |
| # | Product Name | Dose to Event | DeC | ReC | Lot# | Exp Date | NDC# | WIFK/Labe | ier | |
| 1 | Infant Advil Concentrated Drops | | Unk | NA | R14186 | | | PFIZER | | |
| 2 | BABY ORAJEL TEETHING PAIN MEDICINE | | Unk | NA | | | | | | |
| 3 | Infant Advil Concentrated Drops | | Unk | NA | | | | PFIZER | | |

Event Information:

Print Time: 04-NOV-2016 08:34 AM

| Preferred Term (MedDRA 🛍 Version: 17.1 |) | ReC |
|---|---|-----|
| Choking | | NA |
| Eye movement disorder | | NA |
| Head deformity | | NA |
| Hypoaesthesia | | NA |
| Local swelling | | NA |
| Moaning | | NA |
| Musculoskeletal stiffness | | NA |



FOIA Case Report Information

Case ID: 10511962

| Preferred Term (MedDRA 🛍 Version: | 18.0 | ReC |
|------------------------------------|------|-----|
| Pyrexia | | NA |
| Seizure | | NA |
| Vomiting | | NA |

Event/Problem Narrative:

Print Time: 04-NOV-2016 08:34 AM

This is a spontaneous report from a contactable consumer on behalf of her daughter. A 13-month-old Caucasian female patient started to receive ibuprofen (INFANT ADVIL CONCENTRATED DROPS), Drug lot number R14186, Expiration date eb2017), oral from an unspecified date at a dose of 0.625 ml and 1.25 ml from 19Sep2014 to 01Oct2014 for fever and sore throat and HYLAND'S TEETHING TABLETS, via an unspecified route of administration at 2 tablets to 03Sep2014 for teething, and benzocaine (BABY ORAJEL TEETHING PAIN MEDICINE), via an unspecified route of administration from an unspecified date to an unspecified date at an unknown dose and frequency for an unspecified indication. Medical history included kawasaki's disease from 09Sep2014 to an unknown date and ear infection from 03Sep2014 to an unknown date. Concomitant medication included amoxicillin since 03Sep2014 5 mg orally twice a day for ear infection, stopped on 09Sep2014 due to yeast infection, paracetamol (LITTLE REMEDIES FOR FEVERS) 1.25 ml for fever since 03Sept2014. Caller states that her daughter has been taking ADVIL 8 hr infant medication since she was born and it works great. Caller reports that daughter has had: bumps coming up on her head since May2014. Caller says she is not able to get clear answers from the doctors. Mother did not provide daughter's height. Caller reports that on 19Sep2014 her daughter's eyes were rolling back in her head, and the doctors say that it is seizures. Caller says she thinks it could be fever related that daughter may have had seizure. The baby was stiff as a board, moaning, had extremely high temperature on 19Sep2014. Caller states her daughter received 9 oz formula and a small amount of baby food and threw it all up on 19Sep2014, and 1.25ml ADVIL 8H infant medicine was given about an hour later because she was really hot, but did not know what her temperature was. Caller says she was doing some research to try and figure out if mixing the ADVIL 8h Infant with HYLAND'S BABY TEETHING TABLETS and/or ORAJEL daytime and ORAJEL night time was causing problems that her daughter was experiencing. Mother states she notices her daughters episodes after she has given ADVIL and 2 teething tablets, but only when adding a teething agent with the ADVIL. Mother also states her son experienced similar symptoms with eyes rolling in back of head and moaning from when he started teething to age 3. The son is now 5 years old. Mother states the son was taken to the hospital for a bunch of tests and did not receive answers for his experiencing these episodes. Suspect Medications: ADVIL 8h infant: NDC number not seen on box. ADVIL 8h infant dose 0.625 ml Physician recommend dosage of 1.25 ml due to her weight, but has been administering a smidge over .625ml. Other medications: AMOXICILLIN 5mg orally twice a day, gave it to her sometimes once a day, started on 03Sep2014 to treat the ear infection, stopped on 09Sep2014 due to a bad yeast infection. Mother states only two dates had both AMOXICILLIN and ADVIL 8H infant on 08SEP2014 and 09SEP2014. LITTLE REMEDYS FOR FEVERS, instant fever pain reliever



FOIA Case Report Information

Case ID: 10511962

last dose 03sept2014 1.25 ml, for fever. BABY ORAJEL mother states this numbed her throat and choked her, and felt not healthy to give it to her so after that 1 time I never gave it to her again. Mother states she has noticed bumps coming up on her head since May2014. Mother states the doctors do not know why and she is just trying to get some answers. On 24Sep2014, the baby had soft area on side of back of head. On 25Sep2014, the baby had soft spot fifty cent size piece on back right side of head. 06May2014 mother states huge whole side of head swelling. Mother states physician thought child had bumped her head. When the mother saw the regular doctor with her daughter the mother reports the regular doctor said the child did not hit her head, as would have to be a hard hit to make that happen. The patient underwent lab tests and procedures which included body temperature: 101.5 on 18Sep2014, body temperature: 102.5 on 29Sep2014, body temperature: 100 on 29Sep2014, body temperature: 100 on 03Oct2014, computerised tomogram head: scalp hematoma on 06May2014. CT scan of Brain: (06May2014) Findings: no mass or midline shift, no acute hemorrhaging, skull unremarkable, minimal mucousal thickening, impression: normal enhanced CT scan of the Brain, paranasal sinus disease. Most suggestive of scalp hematoma, no solid or cyst soft tissue tumor could be identified, there is a compressible fluid collection in right side of the scalp. Mother states there is a MRI scheduled for 04Oct2014. Outcome of all events not reported. The physician reported that the patient did not provide information regarding the reported adverse event with the use of the product. The action taken in response to the events for ibuprofen was unknown was permanently withdrawn on 01Oct2014, for HYLAND'S TEETHING TABLETS was permanently withdrawn on 03Sep2014, and for benzocaine was permanently withdrawn on an unspecified date. The outcome of the events was unknown. This physician denied the patient provide information regarding the reported adverse event with the use of product and could not confirm the occurrence of the events reported by the patient.

Follow-up (22Dec2014): New information received from a contactable physician including physician comment.

Follow-up (09Feb2015): New information from a contactable Physician includes: medical confirmation status.

Relevant Medical History:

Print Time: 04-NOV-2016 08:34 AM

| Disease/Surgical Procedure | Start Date | End Date | Continuing? | |
|----------------------------|-------------|-------------|---------------|-----------------|
| Ear infection | 03-Sep-2014 | | UNKNOWN | |
| Kawasaki's disease | 09-Sep-2014 | | UNKNOWN | |
| Medical History Product(s) | Start Date | End Date | Indications | Events |
| AMOXICILLIN | 03-Sep-2014 | 09-Sep-2014 | Ear infection | Yeast infection |



FOIA Case Report Information

Case ID: 10511962

Relevant Laboratory Data:

| • | | | | | | |
|---|----------------|------|------------------|-------------------|------------|--|
| Test Name | Result | Unit | Normal Low Range | Normal High Range | Info Avail | |
| Body temperature | 101.5 | | | | N | |
| Body temperature | 100 | | | | N | |
| CT brain scan | scalp hematoma | a | | | N | |
| Body temperature | 102.5 | | | | N | |
| Body temperature | 100 | | | | N | |

Concomitant Products:

| # | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|----------------------------|--------------------|-------|--------------|----------------|-------------|----------|-------------------------------|
| 1 | LITTLE REMEDIES FOR FEVERS | 1.25 ML/ | | 1.25 ml, UNK | Fever | 03-Sep-2014 | | 17 DAY |

Reporter Source:

Study Report?: No Sender Organization: PFIZER 503B Compounding Outsourcing Facility?:

Literature Text:

Print Time: 04-NOV-2016 08:34 AM

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Printer: CDPEDQ5
User: STEPPERH

Date - Time: 04-Nov-2016 08:36 AM

Total Number of Cases (Non-Esub): 123

Total Number of Pages: 563
Print Job Number: 12985

Disclaimers:

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| Processed C | Case Id's for | · Images: | | | | | |
|-------------|---------------|-----------|-----------|-----------|------------|-----------|----------|
| 9275207 9 | 9305621 | 9314081 | 9316714 9 | 325460 93 | 325466 934 | 41721 934 | 1729 |
| 9341740 9 | 9341747 | 9342328 | 9342345 9 | 342356 93 | 342360 94° | 10155 941 | 2421 |
| 9412536 | 9412646 | 9412659 | 9412660 9 | 412682 94 | 12689 94 | 12695 942 | 4540 |
| 9461703 9 | 9471241 | 9486434 | 9570361 9 | 570446 96 | 322302 962 | 27012 963 | 0574 |
| 9661367 | 9747541 | 9767440 | 9790085 9 | 820308 99 | 24670 999 | 98991 999 | 9086 |
| 10023432 | 10024252 | 10027923 | 10040722 | 10149861 | 10162192 | 10162223 | 10234825 |
| 10234831 | 10257359 | 10267562 | 10272692 | 10272885 | 10275530 | 10283615 | |
| 10285322 | 10285323 | 10302306 | 10302334 | 10302341 | 10302641 | 10307987 | 10313881 |
| 10314685 | 10359541 | 10384035 | 10387468 | 10390459 | 10395246 | 10402276 | |
| 10412341 | 10430246 | 10436018 | 10436103 | 10483550 | 10486049 | 10486072 | 10501178 |
| 10510040 | 10519215 | 10529024 | 10529055 | 10530766 | 10530771 | 10530789 | |
| 10542710 | 10542735 | 10542775 | 10542937 | 10542971 | 10543066 | 10547547 | 10567790 |
| 10570064 | 10576562 | 10584800 | 10589980 | 10601392 | 10619563 | 10619580 | |
| 10627664 | 10631888 | 10638399 | 10642973 | 10643083 | 10648706 | 10648708 | 10656951 |
| 10678285 | 10678309 | 10678313 | 10684780 | 10691018 | 10723317 | 10792549 | |
| 10855443 | 10862441 | 10866401 | 10877680 | 10901130 | 10945484 | 10984052 | 10993411 |

Failed Case Id's for Images:

Total Failed Cases: 0



CDER

CaseID: 9275207

Empress MB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

DLUNTARY reporting of rents, product problems and product use errors

| | FDA USE ONLY |
|---------------------------|--------------|
| Triage unit sequence # | 510829 |

| 32,320. | product u |
|--|--|
| an ouncey innormation and | Internet Submission |
| Adverse Event Reporting Program | |
| A. PATIENT INFORMATION | |
| 1. Patient Identifier 2. Age at Time of Even | nt, or 3. Sex 4. Weight |
| (b) (6) Date of Birth: | Female 13 lb |
| In confidence 3 Months | Male orkg |
| B. ADVERSE EVENT, PRODUCT | PROBLEM OR ERROR |
| Check all that apply: | |
| | olem (e.g., defects/maifunctions) Different Manufacturer of Same Medicine |
| 2. Outcomes Attributed to Adverse Event | |
| (Check all that apply) | 1 |
| Death: | Disability or Permanent Damage |
| (mm/dd/yyyy) Life-threatening | Congenital Anomaly/Birth Defect |
| Hospitalization - initial or prolonged | Other Serious (Important Medical Events) |
| Required Intervention to Prevent Perma | |
| | |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (mm/dd/yyyy) |
| 03/31/2012 | 04/30/2013 |
| 5. Describe Event, Problem or Product Use | Error |
| After giving my son th | he 2 tablets per hour |
| for 3 doses -the labe. | l says you can give up |
| to 2 tablets for 6 hou | urs-, he became |
| extremely lethargic to | o the point of being |
| unresponsive. His eyes | s glazed over and |
| remained opened but he | e would not make eye |
| contact and looked lil | ke he was in a daze. |
| When I put him on my | knees he began to slide |
| off almost involuntar | ily. He was not moving. |
| I rushed him to the E | R and his heart rate |
| was low but after a f | ew minutes improved. |
| The doctor said it wa | s possibly from the |
| belladonna in this pr | oduct. After getting |
| home. I found out it | has been recalled in |
| the past for very sim | ilar reactions. My son |
| is okay now, but | |
| | 1 |
| | |
| | |
| | |
| | More |
| Detailed in the second Pote Industri | ing Dates |
| 6. Relevant Tests/Laboratory Data, Includi | |
| Not sure how to do la | b test but I saved |
| bottle in case you ca | in |
| | |
| | |
| | |
| · · | |
| | |
| | More |
| | The state of the s |
| 7. Other Relevant History, Including Prees race, pregnancy, smoking and alcohol use | xisting Medical Conditions (e.g., allergies, e, liver/kidney problems, etc.) |
| | |
| None | |
| | |
| 1 | l |

| Page 1/L | | | | |
|---|----------------|-----------------|--------------|---------------------------------------|
| . SUSPECT PRODU | | | | |
| Name, Strength, Manufa | | roduct label) | Ну | land's |
| Hyland's baby ¹ Teething Tablet | 8 | | | |
| 2 | | | | |
| Dose or Amount | | Frequency | | Route |
| 1 2 tablets/hr | | 3 hrs | • | ро |
| | | | | |
| 2 | | <u> </u> | | |
| Dates of Use (If unknown best estimate) | | n) from/to (or | | bated After Use d or Dose Reduced? |
| One da | y 03/ | 31/2013 | #1 \(Ye | |
| #1 00/02/2000 | | | | □ □ Doesn't |
| #2 | | ion) | #2 Ye | es No Apply |
| Diagnosis or Reason for Teething | r use (maica) | ion | | Reappeared After duction? |
| #1 | | | #1 Y | Doesn't |
| #2 | I= = · · · · | | | Apply Doesn't |
| Lot # | 7. Expiratio | n Date | #2 Y | es No Apply |
| 1 115731 | #1 | | 1 | or Unique ID |
| 2 | #2 | | 54973 | -3127-2 |
| . SUSPECT MEDIC | CAL DEVI | CE | | |
| Brand Name | | | | |
| Common Device Name | | - | | CTU |
| Manufacturer Name, Cit | tv and State | | ···· | |
| . manufacturer name, or | ., | | MΔ | Y - 1 2013 |
| | | | -70-1 | |
| . Model # | Lot | • | | 5. Operator of Device |
| Catalog # | Exp | iration Date (n | nm/dd/yyyy) | Health Professional |
| | | <u>'</u> | | Lay User/Patient |
| Serial # | Oth | er# | | Other: |
| . If Implanted, Give Date | (mm/dd/vvvv | 7. If Ex | planted. Giv | ve Date (mm/dd/yyyy) |
| | | | | |
| . Is this a Single-use De | vice that was | Reprocessed | and Reuse | d on a Patient? |
| Yes No | tor Name sa | Address of E | Reprocessor | * |
| . If Yes to Item No. 8, En | ter Name and | Audress of F | reprocesso. | • |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| F. OTHER (CONC | (TNATIMO | MEDICAL | PRODUC | CTS |
| Product names and then | apy dates (e) | cruae treatmer | n or eveni, | |
| | | | | |
| | | | | |
| | | | | More |
| G. REPORTER (S | ee confide | entiality se | ction on | back) |
| Name and Address (b) (6) | | | | |
| (b) (b) | | | | W ₁ |
| | | | | |
| | | le | | |
| Phone (b) (6) | | (b) (6) | | ~ 1 |
| 2. Health Professional? | | | - 1 | 4. Also Reported to: |
| Yes 🗸 No | Consume | r/Non-Hea | lth | Manufacturer |
| 5. If you do NOT want yo | our identity d | isclosed | | User Facility |
| to the manufacturer, p | olace an "X" | n this box: | Ц | / Distributor/Importer |

Yes No

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

Returned to Manufacturer on: __

More

(mm/dd/yyyy)





Ath professionals of adverse events and product problems
Internet Submission - Page 2

B5. Describe event or problem continued

had I given him 3 more doses every hour -totaling 6 doses in 6 hours as label says-, I shudder at the thought of what could have happened to him. Clearly they still have problems with inconsistent dosing as they did the last time they were recalled. This product is dangerous and needs to be pulled off the market.

USS MAY 01 2013 9305621-01-00-01

\mathcal{CDER}

- Page 1

product use errors

DLUNTARY reporting of vents, product problems and

CaseID: 9305621

4B No. 0910-0291, Expires: 10/91/06

See OMB statement on reverse.

| FDA USE ONLY | | | | | | |
|------------------------|--------|--|--|--|--|--|
| Triage unit sequence # | 512921 | | | | | |
| | | | | | | |

| Adverse Event i | Reporting Program | Inter | net/Submission |
|--|--|---------------|-----------------|
| A. PATIENT IN | FORMATION | | |
| 1. Patient Identifier Baby Boy - (b) (6) | 2. Age at Time of Event, or Date of Birth: (b) (6) | 3. Sex Female | 4. Weight 13 lb |
| in confidence | 6 Months | ✓ Male | kg |

| A DATIENT INFORMATION | D. SUSPECT PRO | DDUCT(S) | | | | |
|---|---------------------------------|-----------------------|---------------|-------------|--------------|----------------|
| A. PATIENT INFORMATION | 1. Name, Strength, Man | | duct lahel) | | | |
| Pather Roy Date of Birth: 3. Sex 4. Weight 13 lb | Hyland Teethi | | ouci raber, | ну | land | |
| Baby Boy - (b) (6) | #1Tablets | | | | | |
| in confidence 6 Months William Kg | #2 | | | | | |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR | 2. Dose or Amount | F | requency | | Route | |
| Check all that apply: | | | 4 times | daily | | |
| 1. Adverse Event Product Problem (e.g., defects/mailfunctions) | #1 2-3 tablets | | | | po | |
| Product Use Error Problem with Different Manufacturer of Same Medicine | #2 | | | | | |
| | #2 | | | | | |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) | 3. Dates of Use(If unknown | own, give duration) | from/to (or | | bated After | |
| | best estimate) | | | Stoppe | d or Dose R | |
| Death: Disability or Permanent Damage (mm/dd/yyyy) | #1 10/01/2012 | 11/0 | 1/2012 | #1 🖊 Ye | s No | Doesn't Apply |
| Life-threatening Congenital Anomaly/Birth Defect | | | | | | Doesn't |
| Hospitalization - initial or prolonged Other Serious (Important Medical Events) | #2 | | | #2 ∐ Y€ | s No | Apply |
| Required Intervention to Prevent Permanent Impairment/Damage (Devices) | 4. Diagnosis or Reason teething | n for Use (Indication | 1) | 8. Event F | Reappeared | After |
| | #1 | | | | duction? | |
| 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) | | | | #1 🔲 Ye | s 🔲 No | Doesn't Apply |
| 10/02/2012 05/21/2013 | #2 | | | | | |
| 5. Describe Event, Problem or Product Use Error | 6. Lot # | 7. Expiration | Date | #2 🔲 Ye | es 🗌 No | Doesn't Apply |
| | #1 115007 | #1 | | 0.1100 | Holow - 1 | *** |
| My son, who is now 13 months old, had some | | - | | | or Unique il | |
| unexplained seizure activity for a span of | #2 | #2 | | 54973 | -3127-2 | |
| about 3 months. The events started when he | E. SUSPECT ME | DICAL DEVICE | E | | | |
| was 6 months old. Recently I came across | 1. Brand Name | | | | | |
| information that there has been a link to | | | | | CTU_ | |
| seizure activity. I used Hyland Teething | 2. Common Device Na | me | | | | |
| tablets during this time quite frequently. | | | | | 0 0 0 | |
| My son had a very rough time teething and | 3. Manufacturer Name, | , City and State | | MAY | 2 2 20 | 113 |
| these seemed to help. Unfortunately I am now | | | | | | |
| concerned that in trying to help ease my | | | | | 5 0 | - of Davidso |
| son's pain that I inadvertantly cause other | 4. Model # | Lot# | | | 5. Operator | r of Device |
| medical issues. I still have the same bottle | | | | | Health | n Professional |
| of tablets that I used in October. | Catalog # | Expira | tion Date (m | n/dd/yyyy) | ☐ Lav U | ser/Patient |
| | | | | | | |
| | Serial # | Other | # | | Other: | |
| | | | | | | |
| | 6. If Implanted, Give Da | ate (mm/dd/yyyy) | 7. If Exp | lanted, Giv | e Date (mm | /dd/yyyy) |
| | | | | | | |
| | 8. Is this a Single-use | Device that was Re | eprocessed a | and Reused | on a Patie | nt? |
| | Yes No | | | | | |
| Total principle of the second | 9. If Yes to Item No. 8, | Enter Name and A | ddress of Re | processor | _ | - 164 |
| More | | | | | ĺ | 760 |
| 6. Relevant Tests/Laboratory Data, including Dates | | | | | L | 727 |
| | | | | | - | |
| 3 day hospital stay with a 48 hour EEG on | | | | | MAY | A |
| (b) (6) Follow up EEG in (b) (6) | | | | | MAT | 22 201 |
| when more episodes occured. Multiple other | | | | | | |
| seizure episodes without hospital stay | F. OTHER (CON | | | | TS | |
| because the doctors said that unless they | Product names and the | nerapy dates (exclu | ide treatment | of event) | | |
| lasted greater than 15 minutes that we | l I | | | | | |
| should just wait the episode out at home. | | | | | | |
| One | | | *. | | | |
| More | | | | | | |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, | 1 | | | | | More |
| race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) | G. REPORTER | (See confident | tiality sect | tion on b | ack) | |
| Unexplained rash brakouts during this time | 1. Name and Address | | | | | |
| as well. His whole body would break out in a | (b) (6) | | | | | |
| | | | | | | |
| hive. | | | | | | |
| | Dhan " | | E | | | |
| More | Phone ((b) (6) | | (b) (6) | | | |
| | 2. Health Professional | 12 3 Occupation | | 14 | . Also Repo | orted to: |
| C. PRODUCT AVAILABILITY | | Jos Goodparion | | Γ | | |
| Product Available for Evaluation? (Do not send product to FDA) | Yes V No | | | | Manufa | |
| Yes No Returned to Manufacturer on: | 5. If you do NOT want | your identity disc | osed | | User F | • |
| Yes No Returned to Manufacturer on:(mm/dd/yyyy) | to the manufacturer | r, place an "X" in t | nis box: | | Distrib | utor/importer |

9305621-01-00-02



5 CasetD: 9895621

Internet Submission - Page 3

B6. Relevant tests/laboratory data, including dates continued

episode happened at church where a pediatrician witnessed my son's demeanor and health directly after the episode.

D\$\$ MAY 22 2013

CDER

DLUNTARY reporting of

CaseID: 9314081

Form Approved: OMB No. 0910-0291, Expires: 10/31/08

| | See OMB statement on reve |
|------------------------|---------------------------|
| | FDA USE ONLY |
| Triage unit sequence # | 513207 |

| - rage 43 | | | | | | | |
|--|-----------------------|-------------------|----------------|-------------------------|------------------------|--|--|
| D. SUSPECT PROD | UCT(S) | | | | | | |
| 1. Name, Strength, Manufacturer (trom product label) Baby Orajel Benzocaine 7.5% CHURCH & DWIGHT | | | | | | | |
| Baby Orajel #2Nighttime | Benzoca | ine 1 | 0% CH | URCH & | OWIGHT | | |
| 2. Dose or Amount | Freq | uency | | Route | | | |
| #1 pea size | | dail | | ро | | | |
| #2 pea size | [4 × | daily | | ро | | | |
| Dates of Use(If unknown best estimate) | , give duration) from | /to (or | | bated After | | | |
| 07/10/2010 | 09/05/2 | 010 | #1 Yes | or Dose R | Doesn't Apply | | |
| #2 07/10/2010 | 09/05/2 | 010 | #2 7 Ye | s 🗆 No | Doesn't | | |
| 4. Diagnosis or Reason for teething pain | Use (Indication) | | 8. Event R | eappeared | After Apply | | |
| #2 teething pain | | | #1 Ye | | Z Doesn't | | |
| 6. Lot # | 7. Expiration Date | , | #2 Ye | s \square No | Apply Doesn't | | |
| #1 | #1 | | | r Unique ID | Apply | | |
| #2 | #2 | | 0. 1100 0 | | | | |
| E. SUSPECT MEDIC | CAL DEVICE | | | | | | |
| 1. Brand Name | | | | | | | |
| Orajel 2. Common Device Name | | | | CTU | | | |
| | | | | | | | |
| 3. Manufacturer Name, Cit | y and State | | MAY | 242 | 2013 | | |
| 4. Model # | Lot # | | 5 | . Operator | of Device | | |
| Catalog # | Expiration | Date (mn | 1/dd/vvvv) | Health | Professional | | |
| Outsidg : | | | | | er/Patient | | |
| Serial # | Other # | | | Other: | | | |
| 6. If Implanted, Give Date | /mm/dd/yyyy) | 7. If Expl | anted, Give | Date (mm/ | dd/yyyy) | | |
| 8. Is this a Single-use Dev | ce that was Repro | cessed a | nd Reused | on a Patien | t? | | |
| 9. If Yes to Item No. 8, Ent | er Name and Addre | ess of Re | processor | DS | S | | |
| | | | | | 4 0040 | | |
| | | | ľ | MAY 2 | 4 2013 | | |
| F. OTHER (CONCO | MITANT) MED | ICAL P | RODUCT | s | | | |
| Product names and thera | py dates (exclude tr | eatment o | of event) | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | 041000000000 | | |
| C DEPORTED (Co | a canfidantiali | tucaat | ion on he | nak) | More | | |
| G. REPORTER (Se 1. Name and Address | e comidentiam | ly Seci | on on ba | ich) | | | |
| (b) (6) | | | | | | | |
| | | | | | | | |
| Phone (b) (6) | | E-mail (b) (6) | | | | | |
| 2. Health Professional? | . Occupation | | 4. | Also Repo | ted to: | | |
| ☐ Yes 🗹 No | Consumer/Non | -Healt | ь] | Manufa | cturer | | |
| 5. If you do NOT want you to the manufacturer, pla | | | | 💋 User Fa 🗹 Distribu | cility tor/Importer | | |

| | | vents n | roduct problems and |
|---|-----------------------------|-------------------|---------------------------------------|
| 9314081-01-00 | -01 | | use errors |
| | | • | on - Page 1/2 |
| Adverse Event Reporting Program | | | /5 |
| A. PATIENT INFORMATION | | | D. SUSPECT PR |
| 1. Patient Identifier 2. Age at Time of Even | | 4. Weight | 1. Name, Strength, Mai Baby Orajel |
| (b) (6) Date of Birth: (b) (6) | Female | 23.6 lb | #1 |
| In confidence 16 Months | ∐ Male | kg | Baby Orajel #2Nighttime |
| B. ADVERSE EVENT, PRODUCT | PROBLEM OR ER | ROR | 2. Dose or Amount |
| Check all that apply: | | | #1 pea size |
| | em (e.g., defects/malfunct | | |
| Product Use Error Problem with | Different Manufacturer of | Same Medicine | #2 pea size |
| Outcomes Attributed to Adverse Event (Check all that apply) | | | 3. Dates of Use(if unkn |
| Death: | Disability or Permane | nt Damage | best estimate) |
| (mm/dd/yyyy) | | | #1 07/10/2010 |
| Life-threatening | Congenital Anomaly/ | | #2 07/10/2010 |
| Hospitalization - initial or prolonged | ✓ Other Serious (Impor | _ | 4. Diagnosis or Reason |
| Required Intervention to Prevent Perma | nent Impairment/Damage (| Devices) | teething pa |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (n | nm/dd/yyyy) | |
| 07/26/2010 | 05/23/2013 | | #2 teething pa |
| 5. Describe Event, Problem or Product Use | | | 6. Lot # |
| We have video of sever | al episodes p | osted on | #1 |
| Incy are priv | | | #2 |
| to contact me for acce | | | E. SUSPECT ME |
| orajel and night time ended up in the hospit | | | 1. Brand Name |
| my daughters eyes roll | | | Orajel |
| her head and turning b | | | 2. Common Device Na |
| They couldn't figure o | | | 3. Manufacturer Name |
| and determined that sh | | | |
| and thought that the b | | | 4 11 - 11 11 |
| may have been being ca binkie. They sent us h | | ng on her | 4. Model # |
| anti-seizure drug but | | ure out | Catalog # |
| what could have caused | | | |
| month old to start hav | | | Serial # |
| | | | |
| | | | 6. If Implanted, Give D |
| • | | | 8. Is this a Single-use |
| | | | Yes No |
| | | | 9. If Yes to Item No. 8, |
| | | More | |
| 6. Relevant Tests/Laboratory Data, Including | Dates | | |
| (b) (6) low bun 7 (b) (6) | high c | hloride | |
| | |) (6) | |
| high reactive lymphocy | te 4 | | |
| | | | F. OTHER (CON |
| | | | Product names and th |
| | | | |
| | | | |
| | | More | |
| 7. Other Relevant History, Including Preexis | ting Medical Conditions | (e.g., allergies, | |
| race, pregnancy, smoking and alcohol use, l | iver/kidney problems, etc.) | | G. REPORTER |
| allergy to penicillin, | | | 1. Name and Address (b) (6) |
| n/a she is only 4, no | | | |
| | ne drinks, sh | e doesn't | |
| have liver, | | | Phone * |
| | | More | Phone (b) (6) |
| C. PRODUCT AVAILABILITY | | | 2. Health Professional |
| Product Available for Evaluation? (Do not se | nd product to FDA) | | ☐ Yes 🗹 No |
| | | | 5. If you do NOT want |
| Yes V No Returned to Ma | anufacturer on:(m | m/dd/yyyy) | to the manufacturer |

9314081-01-00-02



.... professionals of adverse events and product problems Internet Submission - Page 2

B5. Describe event or problem continued

having. She was on the anti-seizure meds for about 2-3 weeks as we were seeking a second opinion as the meds were not working. We met with nuro at $^{(b)(6)}$ $^{(b)(6)}$ and she said pull be and she said pull her off all meds I want a new eeg a week after all meds are out of her system. We took her off the meds and by day 3 she was having less eye rolling and by the day of the eeg it happened once that day. We NEVER put her back on the anti-seizure drug because her eeg was normal and the doc said we didn't need to. We also NEVER gave her orajel again. with in a month no more eye rolling and no more blue around her lips. She is an amazing health little girl and this stuff needs to be labeled and dispensed responsibly. We had no idea that this was the cause of her issue we just stopped everything and here years later I find an article that describes exactly what we were going through with our own baby.

MAY 24 2013

3510

Steen ..



CaseID: 9314081 5 / 3 20 7

.h professionals of adverse events and product problems Internet Submission - Page 4

B7. Other relevant history, including preexisting medical conditions continued

kidney or other issues.

dss MAY 24 2013



OLUNTARY reporting of vents, product problems and product use errors

CaseID: 9316714
Fo A proved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Triage unit sequence # 5/3 409

| The FDA Safety Information and Adverse Event Reporting Program | Internet Subma | issio | | | | |
|---|---|--------|--|--|--|--|
| A. PATIENT INFORMATION | | | | | | |
| 1. Patient Identifier Unspecified Date of Birth: | Female 23 | lb | | | | |
| In confidence 20 Months | ✓ Male or | kg | | | | |
| B. ADVERSE EVENT, PRODUCT | PROBLEM OR ERROR | | | | | |
| Check all that apply: | | ı | | | | |
| | em (e.g., defects/maifunctions) Different Manufacturer of Same Medici | ne | | | | |
| Outcomes Attributed to Adverse Event (Check all that apply) | | | | | | |
| Death: | Disability or Permanent Damage | | | | | |
| Life-threatening | Congenital Anomaly/Birth Defect | | | | | |
| Hospitalization - initial or prolonged | ✓ Other Serious (Important Medical Events) | rents) | | | | |
| Required Intervention to Prevent Perma | ent Impairment/Damage (Devices) | | | | | |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (mm/dd/yyyy) | | | | | |
| 04/30/2013 | 05/26/2013 | | | | | |
| 5. Describe Event, Problem or Product Use | rror | | | | | |
| I have been giving my son hylands teething tablets since he was 6 months old. I have noticed some things that I did not like after giving my son hylands teething tablets. My son would seem aggitated, he would start shaking his body every once in a while, and also, my son does not talk real good, he is delayed in motor skills, and speech, and at times, cannot keep his balance. These problems are still ongoing and reacuring with my son At 19 1/2 months of age, My son was teething so I gave him hylands teething tablets. Later, my son's body started shaking and then he fell to teh floor with his body still shaking. His eyes were open but I | | | | | | |
| 6. Relevant Tests/Laboratory Data, Including | | ore | | | | |
| - Different events hav after taking hylands t he was 6 months old -t not being able to slee delayed motor skills, his balance, seizures, *ALL EVENTS HAPPENED A | e happened with my sething tablets sind remors, aggitation, p, delayed speech, not being able to ke shortness of breath FTER I GAVE | eep | | | | |
| Other Relevant History, Including Preexistance, pregnancy, smoking and alcohol use, I | ting Medical Conditions (e.g., allergies, | ore | | | | |
| *On-going appointments seizures, and speech/m to hylands teething ta this product is still | otor skills delays d blets. * Because | | | | | |
| C. PRODUCT AVAILABILITY | м | ore | | | | |
| Product Available for Evaluation? (Do not se | nd product to FDA) | | | | | |
| Yes No Returned to M | nulacturer on:(mm/dd/vvvv) | —[| | | | |

| - Page 1 CDEK | | | | |
|--|-----------------|----------------------------|--------------|---------------------------------------|
| D. SUSPECT PRODU | | roduct.label) | | |
| Hylands Teethin #1Tablets | g Not | Availabl | e Not | Available |
| #2 | | | | |
| 2. Dose or Amount | | Frequency when nee | ded | Route |
| #1 2 teething tab | lets | when hee | ueu | po |
| #2 | | | | |
| Dates of Use(If unknown, best estimate) | give duration |) from/to (or | | bated After Use or Dose Reduced? |
| #1 05/01/2011 | | 25/2013 | #1 Yes | C Decent |
| #2 | | | #2 Yes | s No Doesn't |
| Diagnosis or Reason for Teething | Use (Indication | on) | 8. Event R | eappeared After |
| #1 | | | Reintroc | |
| #2 | | | #1 10 10 | Apply |
| 6. Lot# "1 Not Available | 7. Expiration | Date | #2 Ye | Apply Apply |
| #1 #2 | #1 | | | r Unique ID vailable |
| #2 E. SUSPECT MEDIC | | E | HOE A | |
| 1. Brand Name | | | | |
| Hylands Teething 2. Common Device Name | Tablets | | | CIII |
| Not Available | | | | |
| Manufacturer Name, City Purchased teethir | | s in (b) (6) | М | AY 2 8 2013 |
| 4. Model # | Lot # | | 5 | . Operator of Device |
| Catalog # | | vailable ation Date (mr | n/dd/yyyy) | Health Professional Lay User/Patient |
| Serial # | Other | * | | Other: |
| 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. If Exp | lanted, Give | Date (mm/dd/yyyy) |
| 8. Is this a Single-use Devi | ce that was F | Reprocessed a | nd Reused | on a Patient? |
| Yes No 9. If Yes to Item No. 8, Ente | v Nome and | Address of Da | proceent | |
| 9. II 165 to item No. 6, Ente | r Name and | Address of Ne | processor | DSS |
| | | | v | AY 28 2013 |
| | | | 141/ | 41 20 2013 |
| F. OTHER (CONCOL Product names and therap | | | | S |
| My son will have | | | | |
| speech and motor neurologist on F | | | | |
| conta | - | | | More |
| G. REPORTER (See | e confiden | tiality sect | ion on ba | ick) |
| 1. Name and Address (b) (6) | | | | |
| | | | | |
| Phone # (b) (6) | | E-mail (b) (6) | | |
| 2. Health Professional? 3. | Occupation | | 4. | Also Reported to: |
| Yes No | | | | Manufacturer User Facility |
| If you do NOT want your to the manufacturer, pla | | | Z | Distributor/Importer |

9316714-01-00-02

WATCH

4th professionals of adverse events and product problems Internet Submission - Page 2

B5. Describe event or problem continued

couldn't seem to get my son to snap out of what looked like a seizure. I picked up my phone and when I was about to dial 911, my son stopped shaking and was able to be responsive. He had peed himself. He was crying and very freaked out. I took him to the ER and found out that my son infact, had a seizure. Two days later, I followed up with his pediatrician. His pediatrician refered us to a neurologist. We see the neurologost Friday May 31, 2013.

DSSMAY 28 2013

9316714-01-00-03

FCase10-19316914

.h professionals of adverse events and product problems Internet Submission - Page 3

B6. Relevant tests/laboratory data, including dates continued

(b) (6) -19 1/2 months old-, my son had a MY SON HYLANDS TEETHING TABLETS* - May 1st, 2013 -19 1/2 months old-, my seizure. Took him to the ER and they confirmed it. son had to see a development coordinator due to delayed motor skills and delayed speech May 2nd, 2013 - 19 1/2 months old-, follow up with pediatrician due to seizure and ER visit. - May 23rd, 2013 - 20 1/2 months old-, My son started seeing his speech/motor skills therapist due to delays. He has to see this therapist once a week now. - May 31, 2013 -20 1/2 months old-, My son will be seeing a neurologist for tremors and seizures.

MAY 28 2013

9316714-01-00-04



...th professionals of adverse events and product problems Internet Submission - Page 4

B7. Other relevant history, including preexisting medical conditions continued

the shelves and because hylands teething tablets have cause delays and seizures with my son, I am seeking legal action and will be talking with a lawyer/attorney and will be seezing further actions.

MAY 28 2013



9316714-01-00-05

an professionals of adverse events and product problems Internet Submission - Page 5

F. Other (Concomitant) medical products continued

cting his pediatrician and a lawyer/attorney on Friday May 31, 2013 about the hylands teething tablets and what it has done to my son and to take further action.

> DSS MAY 28 2013

5Case(D:193)6714



OLUNTARY reporting of product use errors

events, product problems and (Internet/Submission - Page 1/)

| - | | | N. | |
|------|--------|--------|------|----|
| | | | 2 | |
| 8 11 | Form A | oprove | d: O | ME |

Triage unit sequence #

CaseID: 9325460

| preved: | омв | No. | 0910-0 | 291, | Expire | s: | 10/31 | /08 |
|---------|-----|-----|--------|------|--------|----|-------|-----|
| | | Se | е ОМВ | stat | ement | on | reve | se |
| | | | | | | | | |

| THE FDA Salety Information and | (Inter | net/Submission | - Page 1// | | | , , , | |
|--|------------------------|---------------------|---|-----------------|---------------------------|----------------------------------|----------------------------------|
| Adverse Event Reporting Program | | | | | | | |
| A. PATIENT INFORMATION | | | D. SUSPECT PRO | | | | |
| 1. Patient identifier (b) (6) (2. Age at Time of Event, or Date of Right (b) (6) | 3. Sex | 4. Weight 17 Ib | 1. Name, Strength, Manual Hylan's Teethi # ¹ Gel | | 000003* 1adonna | Hyland' | s Baby |
| In confidence 9 Months | ✓ Male | кд | #2 | | | | |
| B. ADVERSE EVENT, PRODUCT PRO | BLEM OR ERR | OR | 2. Dose or Amount | | Frequency | Ro | oute |
| Check all that apply: | | | #1 % ribbon on f | inger | prn | • | |
| 1. Adverse Event Product Problem (e. | | | #2 | | | pc | , |
| 2. Outcomes Attributed to Adverse Event | ., | , | | | | | |
| (Check all that apply) Death:(mm/dd/yyyy) | Disability or Permaner | t Damage | 3. Dates of Use(If unknow best estimate) #1 04/28/2013 | | n) from/to (or 19/2013 | 5. Event Abated A Stopped or Dos | se Reduced? |
| | Congenital Anomaly/B | irth Defect | #1 01/20/2013 | | | | Apply |
| Hospitalization - initial or prolonged | Other Serious (Importa | ant Medical Events) | #2 | | | #2 Yes 1 | No Doesn't Apply |
| Required Intervention to Prevent Permanent In | npairment/Damage (D | Pevices) | 4. Diagnosis or Reason for Teething | or Use (Indicat | ion) | 8. Event Reappea | |
| 74 3 | ite of this Report (mi | | #1 | | | Reintroduction | 1? |
| 05/11/2013 | 05/30/2013 | ,,,,,,,, | #2 | | | #1 Yes I | No Doesn't |
| 5. Describe Event, Problem or Product Use Error | | | 6. Lot # | 7. Expiratio | n Date | | — Decemb |
| | | . 1 | ndc 54973-752 | | II Duit | #2 Yes 1 | No Apply |
| After using teething gel, | child had | seizures | #1 #1 | #1 | | 9. NDC # or Uniqu | ue ID |
| and twitching | | | #2 | #2 | | 54973-7521 | 2 |
| | | | E. SUSPECT MEDI | CAL DEVI | CE | | |
| | | | 1. Brand Name | | | A | EER D |
| | | | Hyland's Baby 2. Common Device Name | | | <u>C</u> | 10 |
| | | i | Teething Gel | , | | - | |
| 1 | | | 3. Manufacturer Name, C | ity and State | | MAY 3 | 1 2013 |
| | | | Hyland's Inc., I | Los Angel | es CA 900 | | |
| | | | 4. Model # | Lot # | | | rator of Device |
| | | | Catalog # | Expi | ration Date (m | Lay | y User/Patient |
| | | | Serial # | Othe | r# | Ott | her: |
| | | | 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Exp | olanted, Give Date (r | mm/dd/yyyy) |
| | | | 8. Is this a Single-use De | vice that was | Reprocessed a | and Reused on a Pa | atient? |
| | | More | 9. If Yes to Item No. 8, En | iter Name and | Address of Re | eprocessor | |
| 6. Relevant Tests/Laboratory Data, Including Date | | | | | | | |
| Child taken by ambulance follow-up wit | h primary | care | | | | | |
| provider on 05/13/2013, p | | ₀₁₃ | E OTHER (CONC. | DAUT A NIT | MEDICAL | DRODUCTO | |
| neurologist 05/14/2013, E hospital admit (b)(6) | | labs not | F. OTHER (CONC) Product names and then | | | | 0 |
| directly pertaining to po | | | Product names and then | apy dates (exc | aude aeaanen | US US | 2 |
| belladonna poisoning but | | | | | | | • |
| consequence of using the | | | | | | MAY 31 | 2019 |
| | | More | | | | MAIOI | More |
| 7. Other Relevant History, Including Preexisting N | fedical Conditions (| e.g., allergies, | O DEDODEED (O | | -11-111 | | MOLE |
| race, pregnancy, smoking and alcohol use, liver/kid | | | G. REPORTER (S | ee confidei | mailty seci | lion on back) | |
| No health concerns prior occur, box needed to be c | | h did not proceed* | 1 Name and Address (b) (6) | | | | |
| | | \$472 Sept. 18 | Phon _{(b) (6)} | | E-mail (b) (6) | | |
| | | More | 2. Health Professional? | 3 Occupation | | 4 Alec B | eported to: |
| C. PRODUCT AVAILABILITY | | | | Other He | | l <u> </u> | • |
| Product Available for Evaluation? (Do not send pro | oduct to FDA) | | Yes No | | | | nufacturer er Facility |
| Yes No Returned to Manufac | cturer on: | | 5. If you do NOT want yo | ur identity dis | closed | | er Facility tributor/Importer |

to the manufacturer, place an "X" in this box:

...ch professionals of adverse events and product problems Internet Submission - Page 3

B6. Relevant tests/laboratory data, including dates continued

teething gel, 72HR EEG starting on (b) (6) MRI with contrast/ under anesthesia (b) (6)
After countless hours in the doctor, on the phone with the doctor/ neurology, hospital and research online, data suggests the teething gel proves to fit symptoms of belladonna poisoning

> DSS MAY 31 2013

Mail to: MEDWATCH

or FAX to:

5600 Fishers Lane Rockville, MD 20852-9787

1-800-FDA-0178



THE FUK Salety Information and

red: OMB No. 0910-0291, Expires: 10/31/08 See OMB statement on reverse.

CaseID: 9325466

OLUNTARY reporting of vents, product problems and product use errors

/Internet Submission - Page 1

| FDA USE ONLY | | | | |
|---------------------------|----|------|--|--|
| Triage unit sequence # | 51 | 3863 | | |
| | | | | |

| . PATIENT INFORMATION | D. SUSPECT PRO | | | | | |
|---|---|----------------------------|--------------------|--------------|----------------------------|------------------|
| Patient Identifier 2. Age at Time of Event, or 3. Sex 4. Weight Date of Birth: | 1. Name, Strength, Manu Hyland teethi: | ufacturer (from pr Regu | duct label) 1ar | ну | land | |
| 8 months | #1tablets | | | | | |
| In confidence 18 Months V Malekg | #2 | | | | | |
| . ADVERSE EVENT, PRODUCT PROBLEM OR ERROR | 2. Dose or Amount | | requency | | Route | |
| eck all that apply: | #1 1-2 tablets | | As neede | d- | ро | |
| Adverse Event Product Problem (e.g., defects/malfunctions) | | | | | | |
| Product Use Error Problem with Different Manufacturer of Same Medicine | #2 | | | | | |
| Outcomes Attributed to Adverse Event (Check all that apply) | 3. Dates of Use(If unkno | wo give duration) | from/to (or | 5 Event A | bated After Us | e . |
| Death: Disability or Permanent Damage | best estimate) | ,,, gare caracier, | ireirate (er | | d or Dose Red | uced? |
| (mm/dd/yyyy) | #1 06/24/2011 | 10/0 | 1/2012 | #1 Ye | s No 🖠 | Doesn Apply |
| Life-threatening Congenital Anomaly/Birth Defect | #2 | | | #2 Ye | - D. | Doesn |
| Hospitalization - initial or prolonged Other Serious (Important Medical Events) | 4. Diagnosis or Reason | for Use (Indicatio | n) | #2 Ye | is No | → Apply |
| Required Intervention to Prevent Permanent Impairment/Damage (Devices) | Teething paid | | * | | leappeared Aft duction? | er |
| Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) | #1 | | | | s 🛮 No | Does |
| 10/18/2012 05/30/2013 | #2 | | | | | Apply |
| Describe Event, Problem or Product Use Error | 6. Lot# | 7. Expiration | Date | #2 🗌 Ye | s 🗌 No 🛭 | ☐ Doesn Apply |
| Mave used Hyland teething tablets as needed | #1 | #1 | | 9. NDC # c | or Unique ID | , |
| and per instructions since my son started | #2 | #2 | | | • | |
| teething in June of 2011. He was completely | E. SUSPECT MED | ICAL DEVIC | Ξ | | | |
| nnconscious on (D) (6) and taken by ambulance to the ER. He was unconscious and | 1. Brand Name | | | 1.0 | | |
| not moving or responding for four hours | Hylands Baby | | | | | |
| straight. The dr said he'd had a seizure. | 2. Common Device Nam | | | | | |
| | Teething tables 3. Manufacturer Name, 6 | | | | | |
| | | , | | | | |
| | | | | | | |
| | 4. Model # | Lot# | | | 5. Operator of | |
| | Catalog # | Evniro | tion Date (mi | m/dd/www) | Health Pro | ofession |
| | Catalog # | Expira | aon Date (IIII | | Lay User/ | Patient |
| CTU | Serial # | Other | # | | Other: | |
| | | | | | Momme | |
| 44N/ 0.1 2012 | 6. If Implanted, Give Dat | te (mm/dd/yyyy) | 7. If Exp | lanted, Give | Date (mm/dd/ | уууу) |
| MAY 3 1 2013 | 8. Is this a Single-use D | evice that was D | enrocessed : | and Reused | on a Patient? | |
| | Yes V No | ovice uidt was n | Piocessed (| u neustu | on a rausit! | |
| | 9. If Yes to Item No. 8, E | nter Name and A | ddress of Re | processor | | |
| More | | | | | | |
| MOTE | | | | | | |
| Relevant Tests/Laboratory Data, Including Dates | | | | | | |
| Relevant Tests/Laboratory Data, Including Dates | | | | | | |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) | | | | | | |
| Relevant Tests/Laboratory Data, Including Dates In er in (b)(6) at (b)(6) medical center CT scan, MRI, EKG, etc. on | | | | | | |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) at (c) | F. OTHER (CONC | | | | гs | |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) at (c) | F. OTHER (CONC | | | | гѕ | |
| Relevant Tests/Laboratory Data, Including Dates In er in (b)(6) at (b)(6) nedical center CT scan, MRI, EKG, etc. on | | | | | гѕ | |
| Relevant Tests/Laboratory Data, Including Dates | | | | | гѕ | |
| Relevant Tests/Laboratory Data, Including Dates In er in (b)(6) at (b)(6) medical center CT scan, MRI, EKG, etc. on | | | | | rs | ×2,41134 |
| Relevant Tests/Laboratory Data, Including Dates In er in (b)(6) nedical center CT scan, MRI, EKG, etc. on (b)(6) More | Product names and the | rapy dates (exclu | de treatment | of event) | · na | More |
| Relevant Tests/Laboratory Data, Including Dates In er in (b)(6) medical center CT scan, MRI, EKG, etc. on (b)(6) | Product names and the | rapy dates (exclu | de treatment | of event) | · na | More |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) medical center CT scan, MRI, EKG, etc. on (d) (6) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and akcohol use, liver/kidney problems, etc.) No previous health problems or medical | Product names and the | rapy dates (exclu | de treatment | of event) | · na | More |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) nedical center CT scan, MRI, EKG, etc. on () (6) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) | Product names and the | rapy dates (exclu | de treatment | of event) | · na | More DS |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) nedical center CT scan, MRI, EKG, etc. on (b) (6) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) No previous health problems or medical | Product names and the | rapy dates (exclu | de treatment | of event) | · na | More D |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) nedical center CT scan, MRI, EKG, etc. on (b) (6) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) No previous health problems or medical | G. REPORTER (S | rapy dates (exclu | ide treatment | of event) | · na | More 05 |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) nedical center CT scan, MRI, EKG, etc. on (b) (6) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) No previous health problems or medical | Product names and the | rapy dates (exclu | de treatment | of event) | · na | DS 31 |
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) nedical center CT scan, MRI, EKG, etc. on (16) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) To previous health problems or medical history. Very healthy toddler. | G. REPORTER (S | rapy dates (exclu | iality sect | of event) | · na | D(|
| Relevant Tests/Laboratory Data, Including Dates In er in (b) (6) at (b) (6) nedical center CT scan, MRI, EKG, etc. on (b) (6) More Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) No previous health problems or medical history. Very healthy toddler. | G. REPORTER (S 1. Name and Address (b) (6) | rapy dates (exclu | iality sect | of event) | ack) | DS |

ise facilities, ps and manufacturers ORY reporting

| CaseID. 9341721 | |
|---|-----|
| Form Approved: OMB No. 09 10-029 1, Expires 12/31 | /11 |

| | See OMB statement on rever |
|---------------------|----------------------------|
| Afr Report # | |
| 3/9/3 | |
| F/Importer Report # | |
| | |

| of <u>5</u> | | | | |
|---|---------------------|--|-------------------------------------|-----------------|
| C. SUSPECT PF 1. Name (Give labeled #1 HYLAND'S TH | RODUCT(S) | | | FDA Use Or |
| Name (Give labeled | d strength & mfr of | 80. | | |
| #1 HYLAND'S TI | EETHING TABI | FC61A | NA. | |
| #2 | 11 | 114. | | |
| 2. Dose, Frequency 8 | Route Used | JN 0 5 201 | Pates (If unknown best estimate) | , give duration |
| #1 UNKNOWN DOS | SAGE | #1 | J best estimate) | |
| #2 | | CDB | | - |
| 4. Diagnosis for Use | (Indication) | 5. | Event Abated Af | ter Use |
| #1 TEETHING PA | \IN | 1,,, | Stopped or Dose | - Door |
| #2 | | | 1 L Yes V N | Apply |
| 6. Lot# | 7. Exp. Date | , # | 2 Yes No | Doesn Apply |
| #1 | #1 | 8. | Event Reappeare | ed After |
| #2 | #2 | # | Reintroduction? | Doesn |
| 9. NDC# or Unique ID | | | | Apply |
| 54973-7504-1 | | l l | 2 Yes No | L Apply |
| 10. Concomitant Medi | ical Products and | Therapy Dates (E | xclude treatment o | f event) |
| : | | | | |
| | | | | |
| | | | | |
| D. SUSPECT ME | DICAL DEVIC | 3 | | |
| 1. Brand Name | | | | |
| 2. Common Device Na | ıme | | | |
| | | | | |
| 3. Manufacturer Name | , City and State | | | |
| | | | | |
| 4. Model # | Lot# | | 5. Operato | or of Device |
| Catalog # | Expira | tion Date (mm/dd | //www | h Professional |
| | | | | ser/Patient |
| Serial # | Other | # | Other | : |
| 6. If Implanted, Give Da | ate (mm/dd/yyyy) | 7. If Explants | ed, Give Date (mm | /dd/www |
| | | | | , |
| B. Is this a Single-use I | Device that was R | eprocessed and F | Reused on a Patie | nt? |
| 9. If Yes to Item No. 8, | Enter Name and A | ddress of Repro | TARE OF | |
| , | | war and or respire | 263301 | |
| | | | | |
| O Device Available for | E 1 4 6 6 | | | |
| Device Available for Yes No | | not send to FDA) Manufacturer on: | | |
| | | | (mm/dd/y) | yyy) |
| Concomitant Medica | al Products and T | herapy Dates <i>(Ex</i> | clude treatment of | event) |
| | | | | |
| | | | | |
| E. INITIAL REPOR | RTER | | | |
| Name and Address | Pho | ne # (b) (6) | | |
| 0) (6) | <u> </u> | | Do. | $\overline{}$ |
| , (-) | akin . | | | 5 |
| | | | DSO JUN 0 72 | . |
| | U. | | - 12 | U13 |
| Health Professional? | 12 04 | | | |
| Yes No | 3. Occupation | , and the second | 4. Initial Reports Report to FD/ | Α [|
| ∞ [⊻] ™ | 1 | | | باطل 🛋 ما |

| In confidence 3. ADVERSE EVENT Adverse Event Outcomes Attribut (Check all that apply Death: Life-threatenin Hospitalization | 2. Age at Time of Event: or | roduct Problem (σ | | 4. Weig |
|---|--|--|---|---|
| In confidence 3. ADVERSE EV. Adverse Event Outcomes Attribut (Check all that appl) Death: Life-threatening Hospitalization Required Inten | of Event: or Date of Birth: /ENT OR PRODI t and/or Pred to Adverse Event // (mm/dd/yjyy) g | JCT PROBLE roduct Problem (a | ✓ Female | or |
| Adverse Event Outcomes Attribut (Check all that appl) Death: Life-threatening Hospitalization Required Intent | or6 Date of Birth: /ENT OR PRODU t and/or Product ed to Adverse Event // // // // // // // // // / | JCT PROBLE roduct Problem (a | Male | |
| Adverse Event Outcomes Attribut (Check all that appl) Death: Life-threatening Hospitalization Required Intent | Date of Birth: /ENT OR PRODU t and/or Product Produc | roduct Problem (σ | Male | |
| Adverse Event Outcomes Attribut (Check all that appl) Death: Life-threatening Hospitalization Required Intent | /ENT OR PRODU t and/or Produced to Adverse Event y) (mm/dd/yyyy) | roduct Problem (σ | M | unctions) |
| Adverse Event Outcomes Attribut (Check all that appl) Death: V Life-threatenin Hospitalization Required Interv | t and/or Product to Adverse Event (mm/dd/yyyy) | roduct Problem (σ | | unctions) |
| Outcomes Attribut (Check all that appl) Death: Life-threatenin Hospitalization Required Intent | ed to Adverse Event /) (mm/dd/yyyy) | | n.g., defects/malfi | unctions) |
| Check all that apply Death: Life-threatening Hospitalization Required Interv | y) (<i>mm/dd/yÿyy</i>) 9 | Disability o | | |
| Death: Life-threatening Hospitalization Required Interv | (<i>mm/dd/yÿyy</i>) 9 | Disability o | | |
| Hospitalization | 9 | | r Permanent Dar | mane |
| Hospitalization | - | Congenital | Anomaly/Birth D | |
| Required Interv | | _ | ous (Important M | |
| | vention to Prevent Perr | | | |
| Date of Lyellt (min | | | Report (mm/dd/ | |
| 00/0 | 0/2009 | 1 | 05/22/2013 | |
| Describe Event or | Problem | | | |
| RANDDAUGHTER | HAD A BLOOD C | LOT ON HER I | DATE WITTH | |
| EIZURES. TOO | K HER TO BE T | ESTED. DOCT | CORS NOT SI | JRE WH |
| I WAS DUE TO. | LEFT SCAR TI | SSUE ON HER | BRAIN. W | AS USI |
| OW OFTEN. WA | NTS TO KNOW I | E BUI NOT SU F TEETHING T | JRE HOW MAN CABLETS CAL | NY OR ISED T |
| NJURY. | | | THE LETTER OF THE | 7000 1 |
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| Relevant Tests/Labo | ratory Data, Includin | g Dates | | |
| | | • | | |
| KNOWN TESTS (| CONDUCTED. | | | |
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| ther Relevant Histo | ry. Including Pressie | ting Medical Cond | distance (a.e. alla | |
| ace, pregnancy, smol | king and alcohol use, t | epatic/renal dysfur | iction, etc.) | gies, |
| | | | | |
| | | OTHER MEDIC | ONS. NO I | NJURY |
| Æ. | ING PILE. NO | OTHER MEDIC | ATTONS AT | THE |
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| | | | | |
| | Relevant Tests/Labo KNOWN TESTS (ONOWN. NO FE HEAD. NOT A ME. | EIZURES. TOOK HER TO BE TO TWAS DUE TO. LEFT SCAR TI EETHING TABLETS AT THE TIME OW OFTEN. WANTS TO KNOW I NUURY. Relevant Tests/Laboratory Data, Including KNOWN TESTS CONDUCTED. Wher Relevant History, Including Preexistance, pregnancy, smoking and alcohol use, for the conduction of the conduction | EIZURES. TOOK HER TO BE TESTED. DOC'T WAS DUE TO. LEFT SCAR TISSUE ON HER EETHING TABLETS AT THE TIME BUT NOT SI DW OFTEN. WANTS TO KNOW IF TEETHING TO NUURY. Relevant Tests/Laboratory Data, Including Dates KNOWN TESTS CONDUCTED. Wher Relevant History, Including Preexisting Medical Conduct, pregnancy, smoking and alcohol use, hepatic/renal dysture. CNOWN. NO FEVER. NO RECENT VACCINATI HEAD. NOT A PRE-MIE. NO OTHER MEDICALE. | Relevant Tests/Laboratory Data, Including Dates KNOWN TESTS CONDUCTED. Relevant History, Including Preexisting Medical Conditions (e.g., allerace, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) GNOWN. NO FEVER. NO RECENT VACCINATIONS. NO I HEAD. NOT A PRE-MIE. NO OTHER MEDICATIONS AT ME. |

 Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Company Representative

Distributor

Other:

Foreign

Study
Literature
Consumer
Health Professional
User Facility

3. Report Source (Check all that apply)

2. UF/Importer Report Numbe

5. Phone Number

9341721-01-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

9. Approximate Age of Device

Yes _

☐ No

Yes

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

> Patient Code Device

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

EDYTA FRACKIEWICZ

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

10-day 📝 Initial

√ 15-day Follow-up # ____

9. Manufacturer Report Number

54973 RAE052213EF002

5-day

7-day

05/22/2013

30-day

Periodic

HYLAND'S, INC. 154 W. 131ST STREET

1. Contact Office - Name/Address (and Manufacturing Site

T. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

10. Event Problem Codes (Refer to coding manual)

☐ Hospital

Nursing Home

Facility

Other: _

Outpatient Treatment

Home

12. Location Where Event Occurred

☐ Initial ☐ Follow-up #

Page 2 of 5

| 5 | |
|--|--|
| H. DEVICE MANUFACTURERS ONL | Y |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious trijury | Additional Information |
| Malfunction | Response to FDA Reques |
| Other: | Device Evaluation |
| | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | ☐ Yes ☐ No |
| | ☐ res ☐ No |
| 6. Evaluation Codes (Refer to coding manual) | |
| | |
| Method | |
| Results | |
| | |
| Conclusions | |
| If Remedial Action Initiated, Check Type | 8 Usage of Davice |
| _ | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | removal reporting number: |
| Other: | |
| | |
| 0. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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| | DSS |
| | 11141 |
| | JUN 0 7 2013 |
| | |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

STN#

510(k) # ___ Combination Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)
BLOOD CLOT, SEIZURES

Yes Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

Please DO NOT RETURN this form to this address

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9341721

FDA USE ONLY



MIEDVVAICE

FORM FDA 3500A (6/10) (continued)

(CONTINUATION PAGE)

For use by user-facilities, s, distributors, and manufacturers tor MANDATORY reporting

Page 3 of 5

| B.5. Describe Event or Problem (continued) | | | | |
|--|-----------------------------|--|---|-------------------------------------|
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| B.6. Relevant Tests/Laboratory Data, Includi | ing Dates (continued) | | | |
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| B.7. Other Relevant History, Including Preex | isting Medical Conditions (| e.g., allergies, race, pregnan | cy, smoking and alcohol use, hepatic/re | enal dysfunction, etc.) (continued) |
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| | | | | |
| Concomitant Medical Products and Therapy | Dates (Exclude treatment of | event) (For continuation of C | .10 and/or D.11; please distinguish) | |
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| Other Remarks | | | | |
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| | | A Company of the Comp | | |
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| | | | | JUN 0 6 2013 |
| | | | | 2013 |
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CUSTOMER COMPLAINT RECORD



| TAKEN BY: | | | | COMPLAI | NT #: _RVD052213 | EF002 |
|--|---|--|--|---|---------------------------------------|--|
| INCENDIA | EDYTA F | FRACKIEWICZ | | DATE OF COMPL | AINT: 05/22/13 | Applied Million of mighting many as approximate integration many as again. |
| PRODUCT: | TEETHIN | NG TABLETS | | ITEM C | ODE: TEET | |
| SIZE: | | | | LОТ | NO.: DOESN'T HA | AVE ANYMORE |
| REPORTER: | (b) (6) | | | | | |
| ADDRESS: | | | | | | |
| CITY: | | | | (b) (6) | 7 | |
| COUNTRY: | USA | | | ZIP CODE: | | |
| PHONE #: | (b) (6) | | | ZIP CODE: | | |
| E-MAIL: | | | | | | |
| NATURE OF COMPL | LAINT: GF | RANDAUGHTER HAD A B | BLOOD CLOT ON HER B | RAIN WITH SEIZURES | TOOK HER TO BE T | ESTED DOCTORS |
| NOT SURE WHAT IT HOW OFTEN. WAN HAVE VERY DETAIL | T WAS DUE TO. LEF ITS TO KNOW IF TEE LED INFORMATION 1 | T SCAR TISSUE ON HER | R BRAIN. WAS USING T ED THE INJURY. PATIE | EETHING TABLETS AT NT CONTINUES TO HAV | THE TIME BUT NOT /E SEIZURES. GRAI | SURE HOW MANY OR |
| PRODUCT RECEIVE INSPECTION: Idual Case | | Y N N (CIRCLE ONE) | PROD | JCT BEING RETURNED | FOR INSPECTION: | Y N (CIRCLE ONE) |
| | | B I I A 1 I A I | DAT | E REQUESTED PRODU | CT BE RETURNED: | |
| | | | | | | Y (N) |
| 9341721 | -01-00-04 | | | UPS | CALL TAG ISSUED: | (CIRCLE ONE) |
| 5341727 | -01-00-04 | | | DATE PR | ODUCT RECEIVED: | |
| OF OT 1 C | | SNI | | | | |
| SECTION II: | INVESTIGATIO | <u> </u> | | | | |
| | | | | | | |
| INVESTIGATION: | THIS COMP | PLAINT WAS TAKEN DUR | | | CONCERN AND FOR | WARDED DIRECTLY |
| INVESTIGATION: | THIS COMP | | | | CONCERN AND FOR | WARDED DIRECTLY |
| INVESTIGATION: | THIS COMP | PLAINT WAS TAKEN DUR | | | CONCERN AND FOR | WARDED DIRECTLY |
| INVESTIGATION: | THIS COMP | PLAINT WAS TAKEN DUR | | | CONCERN AND FOR | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FO | _THIS COMP ST AND MEDICAL DI ORWARDED TO PHA | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A | E DATA CAPTURE AND | EVALUATION. | CONCERN AND FOR | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FO | _THIS COMP ST AND MEDICAL DI ORWARDED TO PHA | PLAINT WAS TAKEN DUR | E DATA CAPTURE AND | EVALUATION05/2 | | WARDED DIRECTLY |
| ADVERSE EVENT FO | _THIS COMP ST AND MEDICAL DI ORWARDED TO PHA | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR | E DATA CAPTURE AND | EVALUATION05/2 | 2/13 | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FOR | _THIS COMP ST AND MEDICAL DI ORWARDED TO PHA ORWARDED TO PHA | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR | E DATA CAPTURE AND | EVALUATION05/2 | 2/13 | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FOR | _THIS COMP ST AND MEDICAL DI ORWARDED TO PHA ORWARDED TO PHA | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR | E DATA CAPTURE AND | EVALUATION05/2 | 2/13 | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FOR | _THIS COMP ST AND MEDICAL DI ORWARDED TO PHA ORWARDED TO PHA | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR | E DATA CAPTURE AND | EVALUATION05/2 | 2/13 | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FOR SECTION III: | THIS COMP ST AND MEDICAL DI ORWARDED TO PHA CORRECTIV | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR ARMACIST / NURSE FOR VE ACTION: | E DATA CAPTURE AND | EVALUATION. 05/2 EDY | 2/13 TA FRACKIEWICZ | WARDED DIRECTLY |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FO SECTION III: | THIS COMP ST AND MEDICAL DI ORWARDED TO PHA CORRECTIV | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR ARMACIST / NURSE FOR VE ACTION: | E DATA CAPTURE AND | EVALUATION. 05/2 EDY | 2/13 TA FRACKIEWICZ | |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FO SECTION III: CORRECTIVE ACTION SECTION IV: | THIS COMP ST AND MEDICAL DI ORWARDED TO PHA CORRECTIV DN(S) COMPLETED E | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR ARMACIST / NURSE FOR VE ACTION: | E DATA CAPTURE AND | EVALUATION. 05/2 EDY | 12/13 TA FRACKIEWICZ | |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FO | THIS COMP ST AND MEDICAL DI ORWARDED TO PHA CORRECTIV DN(S) COMPLETED B ADVERSE EVEN | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR ARMACIST / NURSE FOR VE ACTION: BY: NT REPORTS | E DATA CAPTURE AND | EVALUATION. 05/2 EDY | 12/13 TA FRACKIEWICZ | F002 |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTIONS SECTION IV: | THIS COMP ST AND MEDICAL DI ORWARDED TO PHA CORRECTIV DN(S) COMPLETED B ADVERSE EVEN | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR ARMACIST / NURSE FOR VE ACTION: BY: THE PORTS YE ACTION NOTE OF THE PORTS | E DATA CAPTURE AND | EVALUATION. 05/2 EDY | TA FRACKIEWICZ ATE: RAE052213E | F002 |
| INVESTIGATION: TO THE PHARMACIS ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTIONS SECTION IV: ADVERSE EVENT RESERVENT RESE | THIS COMP ST AND MEDICAL DI ORWARDED TO PHA ORWARDED TO PHA CORRECTIV DN(S) COMPLETED B ADVERSE EVEN ERIOUS: EPORTED ON: | PLAINT WAS TAKEN DUR IRECTOR FOR TIMELY A ARMACIST / NURSE FOR ARMACIST / NURSE FOR VE ACTION: BY: THE PORTS YE ACTION NOTE OF THE PORTS | E DATA CAPTURE AND | EVALUATION. 05/2 EDY A BY: EDYTA FF | TA FRACKIEWICZ ATE: RAE052213E | |

cc: QA / QC Packaging Production Shipping / Receiving

JUN 0 6 2013





SERIOUS ADVERSE EVENT DATA FORM

| ·Al | E#: | RAE052213EF002 | | COMPLAINT #: | RVD052213EF001 | |
|-----------|--------------|--|--|---|------------------------------|-------------|
| SI | ECTION I: | PATIENT INFORMATIO | N (IF DIFFERENT FROM | REPORTER ON FORM | <u>VD1)</u> | |
| N | AME: | (b) (6) - | | | | |
| Al | DDRESS: | | | | | |
| CI | ITY; | | | STATE: (b) |) (6) | |
| C | OUNTRY: | USA | | ZIP CODE: | | |
| Pi | HONE #: | | | | | |
| E- | MAIL: | | | | | |
| SI | ECTION II: | PACKAGING INFORMA | TION: | | | |
| | | AFFIX PACKAGING LABEL HERE | | AFFIX COPY OF OUT NCLUDE DRUG FACTS A PANE | ND PRINCIPAL DISPLAY | |
| | | being shown of an employment of the second o | The control of the co | Teething Ta Tabletas para la D - Symptomatic Relief for Techning in Children - Symptomatic Relief for Techning in Children - Symptomatic Tabletas perm la D - Symptomatic Relief for Techning in Children | | |
| Individua | al Cas | e Safety Report | | N. S. Land and Street Co. | Teething Tablets | |
| | | | • | | IR . | |
| (1) | 934172 | *1-01-00-05 | | Manage | | |
| | | | | | | |
| <u>5E</u> | CTION III | CORRECTIVE ACTION | <u>:</u> | | | |
| | | | | - | | · |
| co | PRRECTIV | E ACTION(S) COMPLETED BY: | | DA | NTE: | |
| SE | CTION IV | | 1 | | | _ |
| RE | VIEWED I | BY MANAGEMENT BY: | Walt | | date: <i>05-28-1</i> ate: | DSS |
| ВҮ | : <u>N/A</u> | QA / QC DIRECT | \ OR | _ D/ | ATE: | |

9341729-02-00-01

distributors and manufacturers
MANDATORY reporting

| CaseID: 9341729 | |
|-----------------|--|
| | |

| Form Approve | d: OMB No | 09 10-029 1 | Expires 12/31/11 |
|--------------|-----------|-------------|------------------|

| Mfr Report# 54 | 3 600 | 0 . 7 |
|--------------------|-------------|--------|
| . رحون | <u> 346</u> | page s |
| JF/Importer Report | # | 1 |

| A. PATIENT INF | | | | |
|--|--|---|-------------------------|-----------------|
| Patient Identifier b) (6) | 2. Age at Time of Event: | Vuora | 3. Sex | 4. Weight |
| | or1 | Years | Female | or lbs |
| In confidence | Date of Birth: | | ✓ Male | kgs |
| | VENT OR PRODU | CT PROBLE | M | |
| 1. 🕢 Adverse Even | t and/or Pro | duct Problem (e | .g., defects/malf | unctions) |
| 2. Outcomes Attribu (Check all that app | ted to Adverse Event | | | |
| Death: | | Disability o | r Permanent Da | mage |
| Life-threatenin | (mm/dd/yyyy) ng | Congenital | Anomaly/Birth [| Defect |
| Hospitalization | n - initial or prolonged | Other Serie | ous (Important N | ledical Events |
| Required Inter | rvention to Prevent Perm | anent Impairment | /Damage (Devi | ces) |
| 3. Date of Event (mr | n/dd/yyyy) | 4. Date of This | Report (mm/do | √ <i>yyyy</i>) |
| 00/0 | 00/2009 | | 05/23/2013 | 3 |
| 5. Describe Event or | Problem | | | |
| | TH FEBRILE CONVICTIME OF SEIZUR | | HILD DID F HAS NOT F | |
| | | ar Date. | | |
| 6. Relevant Tests/Le | aboratory Data, Includi | ng Dates | | |
| 6. Relevant Tests/Le UNKNOWN TESTS | | ng Dates | | |
| | | ng Dates | | |
| UNKNOWN TESTS | S CONDUCTED | isting Medical Co | onditions (e.g. | allergies. |
| UNKNOWN TESTS | | isting Medical Co | onditions (e.g., | allergies, |
| 7. Other Relevant H | S CONDUCTED | isting Medical Co hepatic/renal dys | function, etc.) | allergies, |
| 7. Other Relevant H race, pregnancy, s | istory, Including Preex | isting Medical Co hepatic/renal dys NG FROM HEA | function, etc.) | allergies, |
| 7. Other Relevant H race, pregnancy, s | istory, Including Preex moking and alcohol use, | isting Medical Co hepatic/renal dys NG FROM HEA | function, etc.) | allergies, |
| 7. Other Relevant H race, pregnancy, s | istory, Including Preex moking and alcohol use, | isting Medical Co hepatic/renal dys NG FROM HEA | function, etc.) | allergies, |
| 7. Other Relevant H race, pregnancy, s | istory, Including Preex moking and alcohol use, | isting Medical Co hepatic/renal dys NG FROM HEA | function, etc.) | allergies, |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| Y reporting | UF/Importer Rep | port# | , | | ĺ |
|---|------------------|---------------|------------------|---------------|-----------------------------|
| 10 A | | | | | |
| C. SUSPECT PRODU | CT/S) | | | F | DA Use Only |
| Name (Give labeled streng | | | | | |
| #1 HYLAND'S TEETHI | | | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Route | Used | | | | ive duration) |
| #1 1 TABLET AS NEE | DED | from/to #1 | (or best es | timate) | |
| | | | | | |
| #2 4. Diagnosis for Use (Indicat | tion) | #2 | 5. Event A | Abated After | Use |
| #1 FEETHING PAIN | | | Stoppe | d or Dose R | |
| #2 | | | #1 \(\text{Y}\) | es No | Apply |
| | 7. Exp. Date | | #2 \ \ Ye | es No | Doesn't Apply |
| ! | #1 | | | Reappeared | |
| | #2 | | _ | duction? | ☐ Doesn't |
| #2 9. NDC# or Unique ID | #4 | - | #1 Ye | es No | Apply |
| 54973-7504-1 | | | #2 🗌 Ye | es No | Doesn't Apply |
| 10. Concomitant Medical Pr | oducts and The | apy Dates | (Exclude to | realment of e | event) |
| Brand Name Common Device Name | | | | | |
| 3. Manufacturer Name, City | and State | | | | |
| 4. Model # | Lot # | | | 5. Operator | |
| Catalog # | Expiratio | n Date (mn | n/dd/yyyy) | | Professional ser/Patient |
| | | | | Other: | |
| Serial # | Other # | | | Other. | |
| 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. If Expl | anted, Giv | e Date (mm | (dd/yyyy) |
| 8. Is this a Single-use Devi | ce that was Repr | ocessed a | nd Reuse | d on a Patie | nt? |
| 9. If Yes to Item No. 8, Ente | r Name and Add | ress of Re | processor | | |
| | | | | | |
| 10. Device Available for Ev | | | - | | |
| Yes No [| Returned to N | lanufacture | r on: | (mm/dd/y | <i>yyy</i>) |
| 11. Concomitant Medical P | roducts and The | rapy Dates | (Exclude | treatment of | event) |
| E. INITIAL REPORTS 1. Name and Address | | # (b) (6) | | | 180 |
| Hallo silla radi 655 | | | | | ~00. |
| (b) (6) | | | | SEF | 0 9 2013 |
| 2. Health Professional? 3 | Occupation | | 4. 1 | nitial Repor | ter Also Sent |

Yes V No

9341729-02-08-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

∏ No

Yes

☐ No

Date User Facility or Importer Became

11. Report Sent to FDA?

Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ HYLAND'S, INC.

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

7. Type of Report (Check all that apply)

10-day 📝 Initial

5-day

7-day

05/22/2013

30-day

Periodic

√ 15-day Follow-up # 1

9. Manufacturer Report Number

54973 RAE052213EF001

154 W. 131ST STREET LOS ANGELES, CA 90061

1. Contact Office - Name/Address (and Manufacturing Site

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

Initial
Follow-up # _____

10. Event Problem Codes (Refer to coding manual)

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

8. Date of This Report

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

2. Phone Number 310-768-0700 3. Report Source (Check all that apply)

Foreign

Study
Literature
Consumer
Health Professional
User Facility

Company Representative

Distributor

Other:

(Specify)

(mm/dd/yyyy)

Page 2 of 10

| | FDA USE UNLY |
|---|---|
| : 10 | |
| | |
| H. DEVICE MANUFACTURERS ON | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death was speed to destruct a speed of the control | Correction |
| Serious Injury | Additional Information |
| Malfunction Other: | Response to FDA Request Device Evaluation |
| | - Land |
| 3. Device Evaluated by Manufacturer? | Device Manufacture Date (mm/yyyy) |
| Not Returned to Manufacturer | |
| Yes Evaluation Summary Attach | 5. Labeled for Single Use? |
| No (Attach page to explain why not) or provide code: | |
| | Yes No |
| 6. Evaluation Codes (Refer to coding manual) | |
| Mathod | |
| Method | |
| Results - | [-] |
| | |
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | ☐ Initial Use of Device ☐ Reuse |
| Repair Inspection | Unknown |
| Replace Patient Monitoring | 9. If action reported to FDA under |
| Relabeling Modification/ Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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| | DSS SEP 0 9 2013 |
| | - 65013 |

CaseID: 9341729

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA #

IND#

STN#

510(k) # ___ Combination

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

SEIZURES / FEBRAL CONVULSIONS

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."





Case 1341329 Ml. 214 (de # 7008) 00048128 987

May 23, 2013

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 5.69 per bottle. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach President

Enc: Refund Check - \$ 6.22

DSS SEP 0 9 2013



ER COMPLAINT RECORD



| 93417 | 29-02- | 00-04 | | | . COV | MPLAINT#: | RVD052213EF | :001 | |
|---------------------------|------------|--|--|---|---|--|--|--------------|-------------------|
| IAKEN BY: | | EDYTA FRACKIEWICZ | | | DATE OF CO | | 05/22/13 | | |
| PRODUCT: | | TEETHING TABLETS | | | • | EM CODE: | TEET | | ~ |
| SIZE: | | 77 10 10 10 | , | | · weeks a second of | LOT NO.: | DOESN'T HAV | /E | • |
| REPORTER: | (b) (6) | | | | | | | | |
| ADDRESS: | | ***** | | | | | | | |
| | | | | , | | | | | |
| CITY: | (b) (6) | | | | STATE: | (b) (6) | | | |
| COUNTRY: | USA | | | | ZIP CODE: | | | | |
| PHONE #: | (b) (6) | | | | | | | | |
| E-MAIL: | | | | | | | | | |
| | EVERS AT | GAVE 1 TABLET AS BETWEEN GIVING 1 THE TIME OF SEIZURES. (ANTS A REFUND FOR ONE | TEETHING TABLET CHILD HAS NOT HA BOTTLE. ALSO TO | S AND SEIZURE AD A SEIZURE I OOK REPORT F | ES. CHILD WA N QUITE A WH OR CHILD'S BI | S DIAGNOSE IILE. MOTHE ROTHER WH | ED WITH FEBRI ER HAS SEIZURI O HAS SEIZURI | LE CONVUL | SIONS. SULT OF |
| | | FOR ADDITIONAL SPA | ICE PLEASE USE F | REVERSE OR A | TTACH A SEP | ARATE SHE | ΕT | | |
| PRODUCT RECEIVINSPECTION: | /ED FOR | (CIRCLE O | RECE | | T BEING RETU | | | Y (CIRCLE | NE |
| | | | SEP 06 | | | | FAG ISSUED: | Y (CIRCLE | NE |
| | | | 00 | <u> </u> | DAT | TE PRODUCT | RECEIVED: _ | | |
| SECTION II: | INV | ESTIGATION | CD | M | | | | | |
| INIVERTIGATION. | - | THE COMPLAINT WAS TAKE | EN DUDINO TEET E | NEO411 40 4 0 | FD\#05 DE(A | | NI AND EQUITE | | OT 1 V |
| INVESTIGATION: | | HIS COMPLAINT WAS TAKE MEDICAL DIRECTOR FOR TI | | | | ED CONCER | KN AND FORWA | IKDED DIKE | CILY |
| TO OUR PHARMAC | JIST AND I | MEDICAL DIRECTOR FOR TI | IMELT AE DATA CA | IFTORE AND E | VALUATION. | | | | - |
| | | | | | | | | | |
| | | | | | | | | | |
| ADVERSE EVENT | FORWARD | ED TO PHARMACIST / NUR | SE FOR EVALUATE | ON O N : | | 05/22/13 | | | |
| ADVERSE EVENT I | FORWARD | ED TO PHARMACIST / NUR | SE FOR EVALUATION | ON BY: | | EDYTA FR | RACKIEWICZ | | |
| SECTION III: | <u>C</u> | CORRECTIVE ACTION: | | | | | | | |
| 05/22/13: PREPAR | ED REFUN | ID REQUEST TOTALING \$ 6. | .22. 06/12/13: MAII | ED REFUND C | HECK # 50937 | 5 TOTALING | \$ 16 26 ON ART | ICLE # 7008 | 31830 |
| 000486289877. | | | | | | o romano | ¥ 10.20 0117111 | 1000 | 71000 |
| | | | | | | | *** | | |
| CORRECTIVE ACT | ION(S) CO | MPLETED BY: | (b) (6) | | | DATE: | 05/23/13 & 06/ | 11/13 | |
| SECTION IV: | ADVI | ERSE EVENT REPORTS | - 1 | | | AE #: _ | RAE052213EF | 001 | · . |
| ADVERSE EVENT S | SERIOUS: | $(_{Y})_{I}$ | N | | | | | | |
| ADVERSE EVENT | REPORTED | O ON: 05/22 | /13 | | BY: EDY | TA FRACKIE | EWICZ | | |
| SECTION V: | | | _ 1 | , | | | | | 220 |
| REVIEWED BY MAI | NAGEMEN | T BY: _ | RNU | A | | DATE: C | 98-27 | -13 | SEP 0 9 2 |
| BY: N/A | | QA / QC DIRECTOR | | | | DATE: | w | | |

cc: QA/QC Packaging Production Shipping / Receiving

SEP 0 6 2013

| | CaseID: 9341740 | |
|---|-----------------|--|
| F | A | |

| | See OMB statement on reverse |
|---------------------|------------------------------|
| Ifr Report # 54973 | |
| F/Importer Report # | |

| 1 (. | See OMB statement of |
|---|----------------------|
| user facilities, utors and manufacturers | Mfr Report # 54972 |
| ATORY reporting | UF/Importer Report # |
| | |

| Date Or Male | FORM FDA 3500 | 0A (6/10) | | | Page |
|--|--|--|--|---------------------------------------|-----------|
| or confidence of Birth: B. ADVERSE EVENT OR PRODUCT PROBLEM 1. Adverse Event and/or Product Problem (e.g., defects/meltunctions) 2. Outcomes Attributed to Adverse Event (Check attributed to Check Event (Check attributed to Check Event (Check attributed to Check Event (Check | A. PATIENT INF | ORMATION | | | |
| or | | | | 3. Sex | 4. Weight |
| In confidence of Birth: Male | (2) (3) | 6 | Months | Female | Ibs |
| B. ADVERSE EVENT OR PRODUCT PROBLEM 1. Adverse Event and/or Product Problem (e.g., defects/melfunctions) 2. Outcomes Attributed to Adverse Event (Check all that apply) | In confidence | | | | |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: (Imm/ad/yyyy) Life-threatening Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/ad/yyyy) O0/00/2003 4. Date of This Report (mm/ad/yyyy) O0/00/2003 5. Describe Event or Problem BACK IN 2003 FOR 6 MONTH CHECK-UP CHILD WAS AT THE DOCTOR'S OFFICE AND WHILE SHE WAS IN THE ROOM AFTER BEING WEIGHED THE CHILD TURNED BLUE AND HAD A SEIZURE. WAS ONLY USING TEETHING TABLETS AT THE TIME. WAS IN OFFICE FOR VACCINATIONS BUT DID NOT RECEIVE THEM YET. DOCTORS NOT ABLE TO DETERMINE CAUSE OF SEIZURES. CONTINUED TO HAVE SEIZURES - DROP SEIZURES DAILY AND GRAND MAL ONCE A MONTH. TAKES KEPRA FOR SEIZURES. SPINAL TAP AND OTHER TESTS WITH INCONCLUSIVE RESULTS. NO FEVER AT THE TIME. | | | T DDODLE | | kgs |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: (mm/dd/yyyy) Life-threatening Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) O0/00/2003 4. Date of This Report (mm/dd/yyyy) O5/22/2013 5. Describe Event or Problem BACK IN 2003 FOR 6 MONTH CHECK-UP CHILD WAS AT THE DOCTOR'S OFFICE AND WHILE SHE WAS IN THE ROOM AFTER BEING WEIGHED THE CHILD TURNED BLUE AND HAD A SEIZURE. WAS ONLY USING TEETHING TABLETS AT THE TIME. WAS IN OFFICE FOR VACCINATIONS BUT DID NOT RECEIVE THEM YET. DOCTORS NOT ABLE TO DETERMINE CAUSE OF SEIZURES. CONTINUED TO HAVE SEIZURES - DROP SEIZURES DAILY AND GRAND MAL ONCE A MONTH. TAKES KEPRA FOR SEIZURES. 3. Relevant Tests/Laboratory Data, Including Dates SPINAL TAP AND OTHER TESTS WITH INCONCLUSIVE RESULTS. NO FEVER AT THE TIME. | B. ADVERSE EV | ZENT OR PRODUC | JI PROBLE | Vi | |
| Check all that apply Death: | | | duct Problem (e. | g., defects/malfu | ınctions) |
| Congenital Anomaly/Birth Defect Congenital Anomaly/Birth Defect Other Serious (Important Medical Event Prospect (Important Medical Event Prospect (Important Medical Event Proposed Other Serious (Important Medical Event Ono/00/2003 Ono/ | | | | | |
| ☐ Congenital Anomaly/Birth Defect ☐ Hospitalization - initial or prolonged ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mn/dd/yyyy) | Death: | | Disability o | r Permanent Dar | mage |
| Hospitalization - initial or prolonged Other Serious (Important Medical Event Required Intervention to Prevent Permanent Impairment/Damage (Devices) A. Date of Event (mm/dd/yyyy) | Life-threatening | | Congenital | Anomaly/Birth D | efect |
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| S. Describe Event or Problem BACK IN 2003 FOR 6 MONTH CHECK-UP CHILD WAS AT THE DOCTOR'S OFFICE AND WHILE SHE WAS IN THE ROOM AFTER BEING WEIGHED THE CHILD TURNED BLUE AND HAD A SEIZURE. WAS ONLY USING TEETHING TABLETS AT THE TIME. WAS IN OFFICE FOR VACCINATIONS BUT DID NOT RECEIVE THEM YET. DOCTORS NOT ABLE TO DETERMINE CAUSE OF SEIZURES. CONTINUED TO HAVE SEIZURES - DROP SEIZURES DAILY AND GRAND MAL ONCE A MONTH. TAKES KEPRA FOR SEIZURES. S. Relevant Tests/Laboratory Data, Including Dates SPINAL TAP AND OTHER TESTS WITH INCONCLUSIVE RESULTS. NO FEVER AT THE TIME. | 3. Date of Event (mm | /dd/yyyy) | 4. Date of This | Report (mm/dd | (yyyy) |
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| NO FEVER AT THE TIME. | OFFICE FOR VAC DOCTORS NOT AE CONTINUED TO H GRAND MAL ONCE | CCINATIONS BUT I BLE TO DETERMINI HAVE SEIZURES - C A MONTH. TAKI | DID NOT REC E CAUSE OF DROP SEIZU ES KEPRA FO | CEIVE THEM SEIZURES. JRES DAILY | YET. |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) | SPINAL TAP AND | OTHER TESTS WI | | USIVE RESU | LTS. |
| | ⁷ . Other Relevant Hist race, pregnancy, smo | ory, including Preexist oking and alcohol use, he | ing Medical Con patic/renal dysfu | ditions (e.g., alle nction, etc.) | ergies, |

PLEASE TYPE OR USE BLACK INK

| Submission of a report | does not constitute a | n admission that | medical |
|--------------------------|------------------------|------------------|----------|
| personnel, user facility | importer, distributor, | manufacturer or | product |
| caused or contributed t | o the event. | | p. oaao. |

| of <u>5</u> | | | | | | EDA U O.: |
|----------------------------|--------------|-----------|---|--------------|---------------|---------------------------------------|
| C. SUSPECT PRO | DUCT(S |) | | | | FDA Use On |
| 1. Name (Give labeled s | - | , | | | | |
| | ZINING I | WDPE12 | | | | |
| #2 | | | | | | |
| 2. Dose, Frequency & F | | | Therapy D from/to (or | | | give duration) |
| #1 DOESN'T REME | MBER CCC | ive | ď | | | |
| #2 | | | #2 | | | |
| 4. Diagnosis for Use (In | ndication) | 5 201 | 5. 8 | | Abated Afte | |
| #1 TEETHING PAI | MOIN A | 9 201 | #1 | Y | | ☐ Doesn |
| #2 | OF | \D. | | | | ☐ Apply ☐ Doesn |
| 6. Lot# | 7 E L | 144 | #2 | | | L Apply |
| #1 | #1 | | | | Reappeared | After |
| #2 | #2 | | #1 | _ | - | Doesn Apply |
| 9. NDC# or Unique ID | | | | | | Doesn |
| 54973-7504-1 | | | #2 | | | L Apply |
| 10. Concomitant Medic | al Products | and Thera | apy Dates (Ex | clude tr | reatment of | event) |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| D. SUSPECT MED | ICAL DE | VICE | | | | |
| 1. Brand Name | | VIO. | | | | |
| 2. Common Device Nan | | | | | | |
| 2. Common Device Nan | 1e | | | | | |
| 3. Manufacturer Name, | City and Sta | ate | | | | |
| | | | | | | |
| 4. Model# | L | ot# | | - [| 5. Operator | of Device |
| | | | | | Health | Professional |
| Catalog # | [| xpiration | Date (mm/dd/) | (מממ | | er/Patient |
| Serial# | | Other # | | \dashv | Other: | |
| | | | | | | |
| 6. If Implanted, Give Da | te (mm/dd/yy | (YY) | 7. If Explante | d, Give | Date (mm/ | dd/yyyy) |
| 8. Is this a Single-use D | evice that w | as Repro | cessed and R | eused | on a Patier | nt? |
| Yes No | | | | | on a ratio | |
| 9. If Yes to Item No. 8, E | nter Name a | and Addre | ss of Reproc | essor | | · · · · · · · · · · · · · · · · · · · |
| | | | | | | |
| | | | | | | |
| 10. Device Available for | Evaluation? | (Do not s | end to FDA) | | | |
| Yes No | | • | ufacturer on: | | | |
| | | | | | (mm/dd/yy | |
| 11. Concomitant Medica | Products a | ind Thera | py Dates (Exc | clude tr | reatment of o | event) |
| | | | | | | |
| | | | | | | |
| E. INITIAL REPOR | TER | | | | | |
| 1. Name and Address | | Phone # | (b) (6) | | D - | |
| (F) (C) | | | | | $-\nu_{S}$ | 'S - |
| (b) (6) | M a c | | | | | |
| J | N 0 6 | 2012 | 4 | • / | | 2013 |
| | | -417 | (7 | (| \' 4 | J 10 |
| | | | | L | 10 | F |
| 2. Health Professional? | 3. Occupat | ion | | 4. Ini Re | tial Reporte | er Also Sent |
| Yes No | | | | | | io 📵 Unk. |
| | | | | | | |

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700 3. Report Source (Check all that apply)

Company
Representative

Distributor

Other:

Foreign

Study
Literature
Consumer
Health Professional
User Facility

(mm/dd/yyyy)

9341740-01-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

No

11. Report Sent to FDA?

 Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

> Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

EDYTA FRACKIEWICZ HYLAND'S, INC. 154 W. 131ST STREET

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

7-day Periodic

✓ 15-day Follow-up #___ 9. Manufacturer Report Number

54973 RAE052213EF003

10-day / Initial

5-day

30-day

Contact Office - Name/Address (and Manufacturing Site for Devices)

DOLK FACILITY INVIPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial
Follow-up #

2. UF/Importer Report Number

5. Phone Number

Page 2 of 5

| of <u>5</u> | |
|---|--|
| H. DEVICE MANUFACTURERS ONL 1. Type of Reportable Event | -Y 2. If Follow-up, What Type? |
| Death Serious Injury Malfunction | Correction Additional Information Response to FDA Request |
| Other: | Device Evaluation |
| Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached | Device Manufacture Date (mm/yyyy) |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| Evaluation Codes (Refer to coding manual) | |
| Method | |
| Results - | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification Repair Inspection Replace Patient Monitoring | Reuse Unknown |
| Relabeling Modification/ Adjustment Other: | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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| | DSS |
| | JUN 0 7 2013 |
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA #

IND#

STN# PMA/

510(k) # __ Combination Product

Pre-1938

SEIZURES

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9341740

FDA USE ONLY



9341740-01-00-03

INITIO STATE OF

FORM FDA 3500A (6/10) (continued)

(CONTINUATION PAGE)

For use by user-facilities,
s, distributors, and manufacturers
for MANDATORY reporting

Page 3 of 5

| Describe Event or Problem (continued) Relevant Tests/Laboratory Data, Including Dates (continued) Other Relevant History, Including Preexisting Medical Conditions (e.g., altergies, race, pregnancy, anoxing and alcohol use, hepatic-ternal dysfunction, etc.) (continued) necembrat Medical Products and Therapy Dates (Exclude restined of event) (For continuation of C. 10 and or D.11; please distinguish) ser Remarks JUN 0 7 2013 JUN 0 6 2013 | ORM FDA 3500A (6/10) (Continued) | 1 age 5 01 | |
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STANDARD HOMEOPATHIC

CUSTOMER COMPLAINT RECORD



| SECTION I: | | | COMPLAINT | #: _RVD052213E | F003 |
|--|--|---|---|---|--|
| TAKEN BY: | EDYTA FRA | ACKIEWICZ | DATE OF COMPLAIN | NT: 05/22/2013 | |
| PRODUCT: | TEETHING | TABLETS | ITEM COL | DE: TEET | |
| SIZE: | | | | O.: DOESN'T HA | VE ANYMORE |
| REPORTER: | (b) (6) | | | | |
| ADDRESS: | | | | | |
| CITY: | | | STATE: (b) (6) | | |
| COUNTRY: | USA | | ZIP CODE: | | |
| PHONE #: | (b) (6) | | | | |
| E-MAIL: | | | | | |
| MONTH. TAKES H | PLAINT: OFFIC PLAINT: OFFIC PLAINT | CE AND WHILE SHE WAS IN NG TABLETS AT THE TIME. USE OF SEIZURES. CONTIN NO FEVER AT THE TIME. W ER THAT SIDE EFFECTS DU | BACK IN 2003 FOR THE 6 MONTH CHECK THE ROOM AFTER BEING WEIGHED THE WAS IN OFFICE FOR VACCINATIONS BUT IUED TO HAVE SEIZURES – DROP SEIZUR ENT TO THE DOCTOR WHO CONDUCTED E TO HOMEOPATHICS TEND TO BE TRANS USE REVERSE OR ATTACH A SEPARATE OF | CHILD TURNED BL DID NOT RECEIVE ES DAILY AND GRA A SPINAL TAP AND SIENT IN NATURE | UE AND HAD A THEM YET. AND MALONCE A |
| PRODUCT RECEIVE | VED FOR e Safety Repo | Y (CIRCLE ONE) | PRODUCT BEING RETURNED F | OR INSPECTION: | Y (CIRCLE ONE) |
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| | | | UPS CA | ALL TAG ISSUED: | Y (CIRCLE ONE) |
| | | | | | |
| 934174 | 10-01-00-04 | | | OUCT RECEIVED: | |
| SECTION II: | INVESTIGATION THIS COMPLA | | DATE PROD | OUCT RECEIVED: | ARDED DIRECTLY |
| SECTION II: INVESTIGATION: TO THE PHARMAC | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE | CTOR FOR TIMELY AE DAT | DATE PROD | ICERN AND FORW | ARDED DIRECTLY |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE | CTOR FOR TIMELY AE DAT | DATE PROD EET RECALL AS A SERVICE RELATED CON A CAPTURE AND EVALUATION. UATION ON: 05/22/ | ICERN AND FORW | ARDED DIRECTLY |
| SECTION II: INVESTIGATION: TO THE PHARMAC | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE | MACIST / NURSE FOR EVAL | DATE PROD EET RECALL AS A SERVICE RELATED CON A CAPTURE AND EVALUATION. UATION ON: 05/22/ | ICERN AND FORW | ARDED DIRECTLY |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT ADVERSE EVENT SECTION III: | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM FORWARDED TO PHARM | MACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACION: | DATE PROD EET RECALL AS A SERVICE RELATED CON A CAPTURE AND EVALUATION. UATION ON: 05/22/ | ICERN AND FORWA | ARDED DIRECTLY |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT ADVERSE EVENT SECTION III: | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM CORRECTIVE | MACIST / NURSE FOR EVALUACTION: | DATE PROD EET RECALL AS A SERVICE RELATED COM A CAPTURE AND EVALUATION. UATION ON: UATION BY: EDYTA DAT | ICERN AND FORWA | |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT ADVERSE EVENT SECTION III: CORRECTIVE ACT | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM CORRECTIVE CORRECTIVE ION(S) COMPLETED BY: | MACIST / NURSE FOR EVALUACTION: | DATE PROD EET RECALL AS A SERVICE RELATED COM A CAPTURE AND EVALUATION. UATION ON: UATION BY: EDYTA DAT | ICERN AND FORWA | |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT ADVERSE EVENT SECTION III: CORRECTIVE ACT SECTION IV: | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM CORRECTIVE TION(S) COMPLETED BY: ADVERSE EVENT | MACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACION: | DATE PROD EET RECALL AS A SERVICE RELATED COM A CAPTURE AND EVALUATION. UATION ON: UATION BY: EDYTA DAT AE | ICERN AND FORWA | |
| SECTION II: INVESTIGATION: TO THE PHARMACE ADVERSE EVENT ADVERSE EVENT SECTION III: CORRECTIVE ACT SECTION IV: ADVERSE EVENT S | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM CORRECTIVE TION(S) COMPLETED BY: ADVERSE EVENT | MACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACION: REPORTS Y / N | DATE PROD EET RECALL AS A SERVICE RELATED COM A CAPTURE AND EVALUATION. UATION ON: UATION BY: EDYTA DAT | ICERN AND FORWA | |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT ADVERSE EVENT SECTION III: CORRECTIVE ACT SECTION IV: ADVERSE EVENT I | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM CORRECTIVE CORRECTIVE MADVERSE EVENT SERIOUS: REPORTED ON: | MACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACION: REPORTS Y / N | DATE PROD EET RECALL AS A SERVICE RELATED COM A CAPTURE AND EVALUATION. UATION ON: UATION BY: EDYTA DAT AE | ICERN AND FORWA | |
| SECTION II: INVESTIGATION: TO THE PHARMAC ADVERSE EVENT ADVERSE EVENT SECTION III: CORRECTIVE ACT SECTION IV: ADVERSE EVENT II SECTION V: | INVESTIGATION THIS COMPLAI CIST AND MEDICAL DIRE FORWARDED TO PHARM CORRECTIVE CORRECTIVE ADVERSE EVENT SERIOUS: REPORTED ON: | MACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACIST / NURSE FOR EVALUACION: REPORTS Y / N | DATE PROD EET RECALL AS A SERVICE RELATED CON A CAPTURE AND EVALUATION. UATION ON: UATION BY: EDYT DAT AE BY: EDYTA FRAN | A FRACKIEWICZ E: RAE052213EF | |

JUN 0 6 2013



CaseID: 9341740

SERIOUS ADVERSE EVENT DATA FORM

| AE#: RA | E052213EF003 | co | DMPLAINT #: RVD05 | 52213EF003 | |
|--------------------------------------|--|--|---|---|----------------------------------|
| SECTION I: | PATIENT INFORMATION | (IF DIFFERENT FROM REPORTE | R ON FORM VD1) | | |
| NAME: | (b) (6) | | | | - |
| ADDRESS: | | | | | - |
| CITY: | | | STATE: (b) (6) | | - |
| COUNTRY: | USA (b) (6) | | ZIP CODE: | | - |
| PHONE #: E-MAIL: | | | | | - |
| | - | | | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | |
| SECTION II: | PACKAGING INFORMATION | ON: | | | |
| . A | FFIX PACKAGING LABEL HERE | | OPY OF OUTER CARTO OUG FACTS AND PRINC PANELS) | | |
| Individual Case 9341740 SECTION III: | The state of the s | Tee Table Supposed to Technology Supposed to Technol | thing Tablets thing Tablets tas para la Dentición tk Relei ta berra la Dentición Redei ke Techniga tablets Tabletas para la Dentición Redei ke Techniga t. Calden | Teething Tablets | |
| SECTION IV: | CTION(S) COMPLETED BY: | Wulf | | 15-28-12 | DSS JN 0 7 2013 |
| BY: <u>N/A</u> | QA / QC DIRECTOR | ₹ | DATE: | UN 0 6 2013 | · - |

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11

4. Weight

9341747-02-00-01

2. Age at Time

1. Patient Identifier

FORM FDA 3500A (6/10) A. PATIENT INFORMATION

For use by user-facilities, ters, distributors and manufacturers for MANDATORY reporting

| ∆ See OMD statement on rouse |
|------------------------------|
| e rage h |
| |
| FDA Use On |
| |

| (IDITIO | 1. 2 | - | | | | | |
|----------|---------------------------------------|----------------|--------------|---|----------------|--------------------------|----------------|
| age 1 o | if 1/205 | | | | | F | DA Use Only |
| | C. SUSPECT PR | | | | | | |
| ight | 1. Name (Give labeled | | | | | | - 1 |
| lbs | #1 HYLAND'S T | EETHING | TABLETS | | | | |
| or | #2 | | | | | | j |
| kgs | 2. Dose, Frequency 8 | & Route Use | d | 3. Thera | py Dates (If | unknown, gi | ive duration) |
| | #1 UNKNOWN | | | #1 | U (Ur Desi esi | inate) | - 1 |
| s) | #1 0344.03 | | | | | | |
| | #2 | // | | #2 | 5 Event A | bated After | Use |
| - 1 | 4. Diagnosis for Use #1 TEMP RELIE | | NC DATN | | | or Dose R | |
| | #1 TEMP RELIE | E TEETHT | TATE ON | | #1 [] Ye | s No | Apply |
| ents) | #2 | | | | #2 Ye | s No | Doesn't Apply |
| | 6. Lot # | 7. Ex | p. Date | | | Reappeared | |
| \dashv | #1 | #1 | | | | duction? | l |
| | #2 | #2 | | | #1 🗌 Ye | s No | Doesn't Apply |
| \dashv | 9. NDC# or Unique I | D | | | #2 TY6 | s TNo | Doesn't |
| - | 54973-7504- | | | | | | Apply |
| 1 | 10. Concomitant Me | dical Produc | cts and The | rapy Date | es (Exclude ti | reatment of | event) |
| | 1 | | | | | | |
| - | 1 | | | | | | |
| s | | | | | | | |
| s | D. SUSPECT N | EDICAL | DEVICE | | | | |
| ١ | 1. Brand Name | IEDICAL | DEVICE | | | | |
| | | | | | | | |
| - 1 | 2. Common Device | Name | | | | | |
| - 1 | 3. Manufacturer Na | me, City and | State | | | | |
| | | | | | | | |
| - 1 | 4. Model # | | Lot# | | | 5. Operato | r of Device |
| 1 | | | | | | Healt | n Professional |
| ١ | Catalog # | | Expiration | on Date (| mm/dd/yyyy) | Lay | lser/Patient |
| ١ | Serial # | | Other # | | | Other | : |
| ١ | Jenai # | | | | | | |
| ١ | 6. If Implanted, Giv | e Date (mm/ | (dd/yyyy) | 7. If E | xplanted, Gi | ve Date (mn | √dd/yyyy) |
| ┨ | 8. Is this a Single-u | Douber 4 | hat was Bo | 27000000 | d and Rouse | d on a Patie | ent? |
| - 1 | | No | nat was Ne | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | a and House | | |
| - 1 | 9. If Yes to Item No | o. 8, Enter Na | ame and Ad | dress of | Reprocesso | г | |
| ١ | | | | | | | |
| - 1 | | | | | | | |
| ļ | 10. Device Availab | le for Evalue | ation? (Do r | ot send to | o FDA) | | |
| ١ | Yes | | Returned to | | | | |
| 1 | | | | | | (mm/dd/ | |
| | 11. Concomitant N | ledical Prod | ucts and Ti | erapy Da | ates (Exclude | e treatment | of event) |
| | | | | | | | |
| | | | | | | | |
| Ε | E. INITIAL RE | PORTER | | | | | |
| | 1. Name and Addr | | | ne #(b) (6 | | | |
| | | | <u> </u> | | | - Ne | |
| | (b) (6) | | | | | DS SEP 0 S | 1 5 |
| | | | | | | SEP A | |
| | | | | | | -, 01 | 2013 |
| | | | | | | | |
| 1 | 2. Health Profess | ional? 3. O | ccupation | | 4. | Initial Rep Report to | orter Also Sen |
| t | ☐ Yes [7] | - 1 | | | | | No lunk |

Individual Case Safety Report

9341747-02-00-02

User Facility Importer

3. User Facility or Importer Name/Address

4. Contact Person

Approximate Age of Device

Yes _

☐ No

Yes

☐ No

11. Report Sent to FDA?

 Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

Event Problem Codes (Refer to coding manual)

Hospital

Home

Other:

Nursing Home

Outpatient Treatment

12. Location Where Event Occurred

Initial
Follow-up #

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ HYLAND'S, INC.

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

7. Type of Report (Check all that apply)

5-day

7-day

10-day

05/24/2013

30-day

Periodic

Initial

15-day Follow-up#_1

9. Manufacturer Report Number

54973 RAE052413EF001

154 W. 131ST STREET LOS ANGELES, CA 90061

for Devices)

1. Contact Office - Name/Address (and Manufacturing Site

2. UF/Importer Report Number

5. Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

2. Phone Number

310-768-0700

3. Report Source (Check all that apply)

Company Representative

Distributor

Other:

Foreign

Study
Literature
Consumer
Health Professional
User Facility

Page 2 of

| | PDA 03L ONET |
|---|---|
| - DEVICE MANUEACTURERS ONLY | |
| H. DEVICE MANUFACTURERS ONLY Type of Reportable Event | 2. If Follow-up, What Type? |
| Death Serious Injury Malfunction Other: | Correction Additional Information Response to FDA Request Device Evaluation |
| Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| 6. Evaluation Codes (Refer to coding manual) | |
| Method - |]-[|
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type Recall Notification Repair Inspection | 8. Usage of Device Initial Use of Device Reuse Unknown |
| Replace Patient Monitoring Relabeling Modification/ Adjustment Other: | 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
| | DSS ISEP 0 9 2013 |

CaseID: 9341747

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

STN#

510(k) # ___ Combination

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)

FEBRILE SEIZURES

Yes

☐ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."





CaseP09321737MH WATCL#701 1830 QQQ4862 9853

May 28, 2013

(b) (6)

Dear

Pursuant to your letter regarding our Hyland's Teething tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 5.69. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach

President

Enc: Refund Check - \$ 6.22

DSS Sep **0 9** 2013

Standard Homeopathic Company • Setting the Standard in Homeopathy, Since 1903
210 West 131st Street • Box 61067 • Los Angeles, CA 90061 • (213) 321-4284 • fax (310) 516-8579
P.O. Box 87 • Bryn Mawr, PA 19010 • (215) 520-0580 • fax (215) 520-0582



FOMER COMPLAINT RECORD



Contract of the State

| 93417475025005 | 93 | COMPLAINT #: | RVD052413EF001 |
|----------------------------------|--|--|-------------------------------------|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 05/24/13 |
| PRODUCT: | HYLAND'S TEETHING TABLETS | ITEM CODE: | TEET DOESN'T HAVE |
| SIZE: | | LOT NO.: | PURCHASED IN 2010 |
| REPORTER: _(b) (6) | | | |
| ADDRESS: | | | RECEIVED |
| (b) (6) | | 41.40 | |
| CITY: | | STATE: _(b) (6) | SEP 0 6 2013 |
| COUNTRY: USA (b) (6) | | ZIP CODE: | |
| PHONE #: | | | CDR |
| E-MAIL: | SEIZURE ON (b) (6) CHILD HAD JU | ST TURNED 2 YEARS OLD. [| DOES NOT KNOW HOW MUCH OR |
| (b) (6) BUT DOES NOT KNOW | HOW OFTEN SHE WAS GIVING TEETHING TABLET LIZED OVERNIGHT. X-RAYS AND MRI A FEW WEEKS LATE I F USING TEETHING TABLETS. DOCTOR DIAGNOSED AS 101°F AFTER THE SEIZURE AT THE HOSPITAL. NO ALLER | R. TESTS WERE NORMAL. FEBRILE SEIZURES. NO OT | HAD ANOTHER SEIZURE IN (b) (6) |
| | FOR ADDITIONAL SPACE PLEASE USE REVERSE OF | RATTACH A SEPARATE SHE | ET |
| | | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y N PRODI | UCT BEING RETURNED FOR | INSPECTION: Y N (CIRCLE ONE) |
| mor conon. | ,, | E REQUESTED PRODUCT BE | , |
| | | IIPS CALL | TAG ISSUED: (CIRCLE ONE) |
| | | UF3 CALL | TAG 1330ED. (CINCLE ONE) |
| | | DATE PRODUC | T RECEIVED: |
| SECTION II: INV | /ESTIGATION | | |
| INVESTIGATION: | THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS | SERVICE RELATED CONCE | RN AND FORWARDED DIRECTLY |
| TO THE PHARMACIST AND I | MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND | EVALUATION. | |
| | | | |
| | | | |
| ABUEDAE EVELE EODWADA | DED TO BUILDING OF CALLES FOR EVALUATION ON | 05/04/40 | |
| | DED TO PHARMACIST / NURSE FOR EVALUATION DY: | 05/24/13 EDVTA E | DACKIDAIIC7 |
| | DED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDITAL | RACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| 05/28/13: PREPARED REFU | ND REQUEST TOTALING \$ 6.22. 06/12/13; MAILED REFUN | CHECK # 509377 TOTALING | S \$ 6.22 ON ARTICLE # 700818300004 |
| 86289853. | | | |
| | 4-44-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4-4 | | |
| CORRECTIVE ACTION(S) CO | OMPLETED BY: | DATE: | 05/28/13 & 06/12/13 |
| SECTION IV: ADV | VERSE EVENT REPORTS | AE #: | RAE052413EF001 |
| ADVERSE EVENT SERIOUS: | · · · · · · · · · · · · · · · · · · · | | DSS SEP 0 9 2013 |
| ADVERSE EVENT REPORTE | ED ON: 05/24/13 | BY: EDYTA FRACK | SEP 0 9 2013 |
| SECTION V: | | | 0 4 5013 |
| REVIEWED BY MANAGEMEN | NT BY: MW | DATE: | 08-27-13 |
| BY: N/A | · · | DATE: | |
| | | _ | |

cc: QA / QC Packaging

Production Shipping / Receiving

OTC m

#2

CaseID: 9342328

Form Approved: OMB No. 09 10-029 1, Expires 12/31/1: See OMB statement on reverse

Therapy Dates (If unknown, give duration) from/to (or best estimate)

FDA Use Only

by user-facilities, lutors and manufacturers ATORY reporting

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

#1 2TABS 3 TIMES; 2 TABS PM

| 441 | / | See Own statement on rev |
|-----|----------------------|--------------------------|
| , | Mfr Report # 54973 | |
| , , | UF/Importer Report # | |
| | | |

#2

| | • | | | A |
|------------------------|---|--------------------|--------------------|---------------------------------------|
| FORM FDA 3500 | A (6/10) | | | Page |
| A. PATIENT INF | ORMATION | | | |
| I | 2. Age at Time | | 3. Sex | 4. Weight |
| b) (6) | of Event: 3 1/2 | Months | Female | Ibs |
| | Date | | | or |
| In confidence | of Birth: | | ✓ Male | kgs |
| B. ADVERSE EV | ENT OR PRODU | CT PROBLE | VI | |
| . Adverse Event | and/or Pro | duct Problem (e | .g., defects/malfo | unctions) |
| Check all that apply | ed to Adverse Event | | | |
| Death: | , | ☐ Disability o | r Permanent Dar | mage |
| Life-threatening | (mm/dd/yyyy) | · | Anomaly/Birth D | |
| = | - initial or prolonged | | ous (Important M | |
| | ention to Prevent Perm | | | , |
| Date of Event (mm | | | Report (mm/dd | · · · · · · · · · · · · · · · · · · · |
| | - 05/10/2013 | 1 | 05/29/2013 | |
| Describe Event or I | | | 00/23/2010 | |
| PISODE. DOCT | TS AND 30 MINU ORS DIAGNOSED EPIȘODES SINCE | SHAKING EP | | SHAKING |
| | | Hec | olver | j |
| | | AUG | 2 2 2013 | |
| | | C | DR | |
| | | | | |
| . Relevant Tests/Lab | oratory Data, Including | g Dates | | |
| MEDICAL TESTS | WERE NORMAL. | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| en Ver | | | | i |
| | | | | |
| Other Relevant History | ory, Including Preexis | ting Medical Cor | ditions (e.g. all | ernies |
| race, pregnancy, smo | king and alcohol use, h | epatic/renal dysfo | inction, etc.) | g. c c, |
| | | | | |
| | | | | |
| | | | | |
| | | ь | | |
| | 2 | | | |
| | | | | |
| | | | | |

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| Diagnosis for Use (Indication) | | | vent Abated After Use |
|---|-------------------|---------------------------------------|--|
| #1 TEMP RELIEF TEETHING PAIN | | | topped or Dose Reduced? Yes No Doesn't |
| #2 | | "' | Apply |
| 6. Lot # | 7. Exp. Date | #2 | Yes No Doesn't |
| #1112723 | #1 | | vent Reappeared After eintroduction? |
| #2 | #2 | | Yes No Doesn't |
| 9. NDC# or Unique ID | | | Apply Doesn't |
| 54973-3127-1 10. Concomitant Medical P | | #2 | ☐ res ☐ No ☐ Apply |
| D. SUSPECT MEDIC | | | |
| Common Device Name | | | |
| 2 Manufacture Name Of | | · · · · · · · · · · · · · · · · · · · | |
| 3. Manufacturer Name, City | and State | | |
| 4.10.4.4.0 | | | |
| 4. Model# | Lot# | | 5. Operator of Device |
| Catalog # | Expiration | Date (mm/dd/y | Health Professional |
| Serial # | Other # | | Lay User/Patient Other: |
| Serial # | Other# | | Other. |
| 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/dd/yyyy) |
| 8. Is this a Single-use Device Yes No | ce that was Repr | ocessed and Re | oused on a Patient? |
| 9. If Yes to Item No. 8, Ente | r Name and Add | ess of Reproce | ssor |
| | | • | |
| 10. Device Available for Eva | aluation? (Do not | send to FDA) | |
| Yes No | Returned to Ma | anufacturer on: _ | (mm/dd/yyyy) |
| 11. Concomitant Medical Pr | oducts and Ther | apy Dates (Exc | |
| | | | · . |
| E. INITIAL REPORTE 1. Name and Address | | # (b) (6) | |
| i. Name and Address | Prione | (2) (3) | D _ |
| b) (6) | | | DSS |
| | | | AUG 2 3 2013 |
| 2. Health Professional? 3. | AUG . | 2 2 2013 | 4. Initial Reporter Also Sent Report to FDA Yes No Unk. |
| | | | |

CaseID: 9342328

FDA USE ONLY

9342328-02-00-02

age 2 of 18

| Check One | | 2. UF/Importer Report Number | |
|--|---|--|-------|
| User Facility | ા 🗀 Imp | porter in less, in a tress the last residence of the substitution | |
| User Facility or Imp | porter Name | e/Address | |
| | | | |
| | | | |
| | | | |
| Contact Person | | 5. Phone Number | |
| | | | |
| Date User Facility of Importer Became | | 7. Type of Report 8. Date of This Report (mm/dd/yyyy) | ort |
| Aware of Event (mi | m/aa/yyyy) | Initial | |
| | Ian E | Follow-up# | |
| Approximate Age of Device | 1 _ | Problem Codes (Refer to coding manual) | |
| | Patient Code | | |
| | Device Code | | |
| 1. Report Sent to FD | | 12. Location Where Event Occurred | |
| Yes | | Hospital Outpatient Diagnostic Fac | ilie |
| No (mm/de | d/yyyy) | Home Ambulatory | IIIŧy |
| 3. Report Sent to Ma | nufacturer | ─ I Nursing Usess | У |
| Yes(mm/do | d/www | Facility | |
| ☐ No | ~ 1717) | Other:(Specify) | |
| | | | |
| 5. ALL MANUFA | ACTURE | RS | |
| Contact Office - Na | | RS s (and Manufacturing Site 2. Phone Number | |
| Contact Office - Na for Devices) | me/Addres | s (and Manufacturing Site 2. Phone Number 310-768-0700 | |
| Contact Office - Na for Devices) EDYTA FRACKII | me/Address | s (and Manufacturing Site 2. Phone Number | oly) |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST | me/Address EWICZ C. STREET | 2. Phone Number 310-768-0700 3. Report Source (Check all that app | oly) |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC. | me/Address EWICZ C. STREET | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study | oly) |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST | me/Address EWICZ C. STREET | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature | oly) |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST | me/Address EWICZ C. STREET | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study | |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, | ewicz C. STREET CA 900 | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature Consumer | |
| Contact Office - Na for Devices) EDYTA FRACKING HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm/m | EWICZ C. STREET CA 900 | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature Consumer Health Profession | |
| Contact Office - Na for Devices) EDYTA FRACKING HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm/state) | EWICZ C. STREET CA 900 | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature Consumer Health Profession User Facility Company Representative Distributor | |
| Contact Office - Na for Devices) EDYTA FRACKING HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm/m | EWICZ C. STREET CA 900 | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature Consumer Health Profession User Facility Company Representative | |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm/s 25/29/2) If IND, Give Protocol | EWICZ C. STREET CA 900 | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature Consumer Health Profession User Facility Company Representative Distributor STN # PMA/ | |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm/s 25/29/2) If IND, Give Protocol Type of Report (Check all that apply) | EWICZ C. STREET CA 900 Odd/yyyy) 2013 ol# | 2. Phone Number 310-768-0700 3. Report Source (Check all that app | |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm// 25/29/2 If IND, Give Protocol Type of Report (Check all that apply 5-day 30-d | EWICZ C. STREET CA 900 Odd/yyyy) 2013 ol# | 2. Phone Number 310-768-0700 3. Report Source (Check all that app Foreign Study Literature Consumer Health Profession Representative Distributor STN # Distributor Other: PMAV 510(k) # Combination Product Yes | |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm// 25/29/2 If IND, Give Protocol Type of Report (Check all that apply 5-day 9-day 9-day 9-day 10-day 10 | EWICZ C. STREET CA 900 2013 col# | 2. Phone Number 310-768-0700 3. Report Source (Check all that app. Foreign Study Literature Consumer Health Profession User Facility Company Representative Distributor Distributor Other: PMA/ 510(k) # Combination Yes Pre-1938 Yes Yes | |
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| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm// 25/29/2 If IND, Give Protocol Type of Report (Check all that apply 5-day 9-day 9-day 9-day 10-day 10 | EWICZ C. STREET CA 900 (dd/yyyy) 2013 ol# day odic al ow-up# 1 | 2. Phone Number 310-768-0700 3. Report Source (Check all that application of the company of the | |
| Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, Date Received by Manufacturer (mm// 35/29/2 if IND, Give Protocol Check all that apply 5-day 30-d 7-day Perk 15-day Folio 15 | EWICZ C. STREET CA 900 (dd/yyyy) 2013 ool# | 2. Phone Number 310-768-0700 3. Report Source (Check all that application of the consumer of t | |

| O | f <u>// 8</u> | |
|---|---|---|
| | H. DEVICE MANUFACTURERS ONLY | A 1 4 6 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 |
| | 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| | Death | Correction |
| | Serious Injury | Additional Information |
| | Malfunction | Response to FDA Request |
| | Other: | Device Evaluation |
| | 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| | ` | (mm/yyyy) |
| | Not Returned to Manufacturer Yes Evaluation Summary Attached | |
| | | 5. Labeled for Single Use? |
| | No (Attach page to explain why not) or provide code: | |
| | | Yes No |
| | 6. Evaluation Codes (Refer to coding manual) | |
| | | 7 [|
| | Method | |
| | Results - | 7- |
| | | |
| | Conclusions | |
| | 7. If Remedial Action Initiated, Check Type | 3. Usage of Device |
| | Recall Notification | Initial Use of Device |
| | Repair Inspection | Reuse |
| | Replace Patient Monitoring | Unknown |
| | | If action reported to FDA under |
| | Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| | Other: | |
| | | |
| | 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850
Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9342328

AUG 2 2 2013



9342328-02-00-03

TINUATION PAGE) by user-facilities, butors, and manufacturers DATORY reporting

| FORM FDA 3500A (6/10) (continued) | Page 3 of 1/2 8 | . १ अनु र त्युप्त के मुश्लाविष्ट्रमा १००० ३ व ४१० है। |
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| B.5. Describe Event or Problem (continued) | | |
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| B.6. Relevant Tests/Laboratory Data, Including Dates (conti | nued) | |
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| B.7. Other Relevant History, Including Preexisting Medical | Conditions (e.g., allergies, race, pregnancy, smoking and a | Icohol use, hepatic/renal dysfunction, etc.) (continued) |
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| Concomitant Medical Products and Therapy Dates (Exclude | etreatment of event) (For continuation of C.10 and/or D.11; p | olease distinguish) |
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| Other Remarks | | Doo |
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Case 1069122328 mld While # 700 18300048628 9846

May 29, 2013

| (b) (6) | | |
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Dear

Pursuant to your phone call regarding our Hyland's Baby Teething tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 9.19. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely.

Dan Krombach President

Enc: Refund Check - \$ 10.04

DSS ^{AUG} **23** 2013

Standard Homeopathic Company · Setting the Standard in Homeopathy, Since 1903
210 West 131st Street · Box 61067 · Los Angeles, CA 90061 · (213) 321-4284 · fax (310) 516-8579
P.O. Box 87 · Bryn Mawr, PA 19010 · (215) 520-0580 · fax (215) 520-0582

Individual Case Safety Report

cc: QA/QC

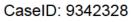
Production

COMPLAINT RECORD

| , | _CaseID: 9342328 |
|---|------------------|
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| | 102Cal8 |

| 93423 | 28-02-00-06 | | 0.00.78 |
|--------------------------------------|--|--|--|
| 55.24 | | COMPLAINT #: | 2333 |
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 05/23/13 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 |
| SIZE: | 135 TABLETS | LOT NO.: | 112723 |
| REPORTER: | (b) (4) | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE; (b) (4) | |
| COUNTRY: | USA | ZIP CODE: | |
| PHONE #: | (b) (4) | | |
| E-MAIL: | ON MAY 5, 2013, GAVE 2 TABLETS OF BAI | OV TESTUNO TARI ETO IN AM MOON | AFTERNOON ALOTONIA |
| MINUTES LATER O SINCE 05/10/13. N | PLAINT: CALLED ON 05/24/13. MAY 5, 2013 CHILD ECONDS. FROM 05/05 – 05/07 HAD 3 MORE EPISODES. TOO HO SAID CHILD WAS FINE. DID TEST MEASUREMENTS AND CHILD HAD A SHAKING EPISODE. DOCTORS CALLED SHAKING SHAKING EPISODES / SEIZURES SINCE 05/10/13. WANTS ER TO DISCUSS CAUSES FOR SYMPTOMS WITH DOCTORS. | STARTED SHAKING AT APPROXIMATION THE DOCTOR AND SAID HE ALL WAS FINE. 05/10/13 PM MOTHER NG EPISODES "SEIZURES". HAS NOT A REFLIND FOR ONE BOTTLE OF BALLIND FOR DOLE BOTTLE OF BALLIND FOR B | ELY 6:45 PM. CHILD WAS ALERT, ELOOKED FINE. 05/10/13: SAW A R GAVE 2 TABLETS AND 30 USED BABY TEETHING TABLETS |
| - | FOR ADDITIONAL SPACE PLEASE USE REV | ERSE OR ATTACH A SEPARATE SHE | ET |
| PRODUCT RECEIVINSPECTION: | /ED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR I | (CIRCLE ONE) |
| | | UPS CALL 1 | Y N (CIRCLE ONE) |
| | | DATE PRODUCT | RECEIVED: |
| SECTION II; | INVESTIGATION | | |
| INVESTIGATION: | REVIEWED BATCH RECORD. MANUFACTURING A | ND PACKAGING WERE DONE ACCOR | DING TO FOTARI IGUED BROOF |
| | E PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND | | DING TO ESTABLISHED PROCE- |
| | THE PARTY OF THE P | EVERTIMING LOOKS OK. | |
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| | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION O | | |
| | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION E | BY: EDYTA FR | ACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | • | |
| 05/29/13: PREPARE | ED REFUND REQUEST TOTALING \$ 10.04. | | |
| | | | |
| | | | |
| CORRECTIVE ACTI | ON(S) COMPLETED BY: | DATE: _ | 05/29/13 |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: _ | AUG 2 3 2013 |
| ADVERSE EVENT S | SERIOUS: (Y)/ N | | AUG 2 3 201 |
| ADVERSE EVENT R | REPORTED ON: 05/23/13 | BY: EDYTA FRACKIE | wicz - 0 2013 |
| SECTION V: REVIEWED BY MAN | IAGEMENT BY: | DATE: | 66-01-13 |
| ву: | Dyman Jack | DATE: | 06-04-13 |
| cc: QA/QC | Production | | AUG 22 2013 |







SERIOUS ADVERSE EVENT DATA FORM

| AE #:1383 | · | COMPLAINT #: 2333 |
|--|--|--|
| SECTION I: | PATIENT INFORMATION (IF DI | IFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| | | (b) (6) |
| CITY: COUNTRY: | USA | STATE: |
| PHONE #: | (b) (6) | ZIP CODE: |
| E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | |
| AFFI | X PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| Indifferentiates: Improving indigency in continuous and proper individuals and additional and account with the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the first control of the control of the control of the control of the control of the control of the contro | HOMEOPATHIC Teething Tablets September and a control of the cont | Teething Tablets No grant With the state The state |
| | | |
| SECTION III: | CORRECTIVE ACTION: | |
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| CORRECTIVE ACT | ION(S) COMPLETED BY: | DATE: |
| SECTION IV: | 10- | AUG 2 |
| REVIEWED BY MA | VAGEMENT BY: | DATE: 06-0413 |
| BY: | | DATE: |
| | QA / QC DIRECTOR | |

AUG 22 2013



DMPLAINT RECORD



9342328-02-00-08

| 00,2020 | | COMPLAINT #: 2333 | |
|--|--|--|---------------------------------------|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: 05/23/13 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: BTETT1 | 35 |
| SIZE: | 135 TABLETS | LOT NO.: 112723 | |
| REPORTER: (b) (6) | | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE: | |
| COUNTRY: USA (b) (6) | | ZIP CODE: | |
| PHONE #: | | | - |
| E-MAIL: | ON MAY 5 2012 CAVE 2 TABLETO OF 5 | | |
| NEUROLOGIST WHO SAID (| CALLED ON 05/24/13. MAY 5, 2013 CHIL FROM 05/05 - 05/07 HAD 3 MORE EPISODES. TO CHILD WAS FINE. DID TEST MEASUREMENTS AN | BABY TEETHING TABLETS IN AM, NOON, AFTERNOO D STARTED SHAKING AT APPROXIMATELY 6:45 PM DOK HIM TO THE DOCTOR AND SAID HE LOOKED FI ND ALL WAS FINE. 05/10/13 PM MOTHER GAVE 2 TAI | NE. 05/10/13: SAW A |
| SINCE 05/10/13, NO SHAKIN | NG EPISODES / SEIZURES SINCE 05/10/13 WAN | KING EPISODES "SEIZURES". HAS NOT USED BABY TS A REFUND FOR ONE BOTTLE OF BABY TEETHING | TARLETC /125 |
| BABY. NO NEW FOODS. | CUSS CAUSES FOR SYMPTOMS WITH DOCTOR | S. NO FEVER ON MAY 5. NOT ILL ON MAY 5, CHILD |) WAS FULL-TERM |
| | FOR ADDITIONAL SPACE PLEASE USE RE | VERSE OR ATTACH A SEPARATE SHEET | |
| PRODUCT RECEIVED FOR INSPECTION: | Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR INSPECTION: | Y (CIRCLE ONE) |
| | Pacely | DATE REQUESTED PRODUCT BE RETURNED: | |
| | W 77 29% upp 41 | UPS CALL TAG ISSUED: | Y (N) (CIRCLE ONE) |
| | AUG 2 2 2 | | |
| | | DATE PRODUCT RECEIVED: | |
| SECTION II: INV | VESTIGATION CO | DATE PRODUCT RECEIVED: | |
| | CDH | | |
| INVESTIGATION: | CDM REVIEWED BATCH RECORD. MANUFACTURING | AND PACKAGING WERE DONE ACCORDING TO EST | |
| INVESTIGATION: | CDH | AND PACKAGING WERE DONE ACCORDING TO EST | |
| INVESTIGATION: | CDM REVIEWED BATCH RECORD. MANUFACTURING | AND PACKAGING WERE DONE ACCORDING TO EST | |
| INVESTIGATION: | CDM REVIEWED BATCH RECORD. MANUFACTURING | AND PACKAGING WERE DONE ACCORDING TO EST | |
| INVESTIGATION: I | CDM REVIEWED BATCH RECORD. MANUFACTURING | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. | |
| INVESTIGATION: FOURES TO ENSURE PRODUCE ADVERSE EVENT FORWARD | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 | |
| DURES TO ENSURE PRODUCE ADVERSE EVENT FORWARD ADVERSE EVENT FORWARD | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A DED TO PHARMACIST / NURSE FOR EVALUATION | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 | |
| ADVERSE EVENT FORWARD SECTION III: | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 EDYTA FRACKIEWICZ | TABLISHED PROCE- |
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| ADVERSE EVENT FORWARD SECTION III: 0 05/29/13: PREPARED REFUN | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 EDYTA FRACKIEWICZ | TABLISHED PROCE- |
| ADVERSE EVENT FORWARD ADVERSE EVENT FORWARD ADVERSE EVENT FORWARD SECTION III: 05/29/13: PREPARED REFUN 00486289846. | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: ND REQUEST TOTALING \$ 10.04. 06/12/13; MAIL | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 NBY: EDYTA FRACKIEWICZ ED REFUND CHECK # 509378 TOTALING \$ 10.04 ON | ARTICLE # 70081830 |
| ADVERSE EVENT FORWARD SECTION III: 0 05/29/13: PREPARED REFUN | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: ND REQUEST TOTALING \$ 10.04. 06/12/13; MAIL | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 EDYTA FRACKIEWICZ | ARTICLE # 70081830 |
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| ADVERSE EVENT FORWARD ADVERSE EVENT FORWARD ADVERSE EVENT FORWARD SECTION III: CORRECTIVE ACTION(S) COMMERCE ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED SECTION V: | REVIEWED BATCH RECORD. MANUFACTURING CT QUALITY. INSPECTED RETAINED SAMPLE A DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: ND REQUEST TOTALING \$ 10.04. 06/12/13; MAIL! MPLETED BY: (b) (4) ERSE EVENT REPORTS O ON: 05/23/13 | AND PACKAGING WERE DONE ACCORDING TO EST ND EVERYTHING LOOKS OK. NON: 05/23/13 EDYTA FRACKIEWICZ DATE: 05/29/13 & 0 AE #: 1383 BY: EDYTA FRACKIEWICZ | ARTICLE # 70081830 DSS AUG 2 3 2013 |

cc: QA / QC Packaging Production Shipping / Receiving AUG 22 2013_{VD1}

user-facilities,

CDER

CaseID: 9342345

| Form Approved: | OMB No. | 09 10-029 1 | Expires 12/31/11 |
|----------------|---------|-------------|------------------|

| | See OMB statem ent on rever |
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| Mfr Report # 549/3 | |
| LIE/monorter Report # | |

| Page | 1 | of XX | |
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| A. PATIENT IN | FORMATION | an degeneration of the | alar 16 yı ve fathalı ve kirili fillik il ga raşılı saklırlı a | Appropriate and the |
|--------------------------------|---------------------------------|-----------------------------|---|---------------------|
| Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight |
| b) (6) | | /2 Years | 0 | ib. |
| | or | | _ Female | or |
| In confidence | of Birth: | | ✓ Male | kg |
| B. ADVERSE E | VENT OR PRO | DUCT PROBL | EM | |
| Adverse Eve | nt and/or | Product Problem | (e.g., defects/malf | unctions) |
| | ited to Adverse Eve | | (-3, | |
| (Check all that app | yy) | | | |
| Death: | (mm/dd/yyyy) | Disability | or Permanent Da | mage |
| √ Life-threateni | ng | Congeni | tal Anomaly/Birth [|)efect |
| Hospitalizatio | n - initial or prolonged | d 📝 Other So | erious (Important M | ledical Events |
| Required Inte | ervention to Prevent P | ermanent Impairme | ent/Damage (Devic | es) |
| Date of Event (m | m/dd/yyyy) | 4. Date of Th | is Report (mm/da | (yyyy) |
| 01/ | 00/2012 | | 05/23/2013 | 3 |
| Describe Event o | Problem | | | |
| AND 1 manted | 1 1 /A VENDA | | | _ |
| | 1 1/2 YEARS | | | |
| EIZURE INJAN | JUARY 2012. H | HAD SEVERAL | SEIZURES SI | NCE |
| HEN. HAD AN | EEG AND MRI; | ; ALL ARE NO | RMAL. NOT | DUE TO |
| EVERS. HAD | A COUPLE THAT | THEY THOUG | HT WERE FEV | ER |
| NDUCED BUT S | OME WERE NOT. | . CHILD HAS | NOT HAD A | SEIZURE |
| N 3 - 4 MONT | | OULD SHAKE, | | |
| | HE WHILE SEIZ | | INDE ONGOINE | 01000, |
| and not broken | TID WILLDS ODIS | 31110. | | |
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| Dalawa t Tasta II a | | | | |
| nelevalit Tests/La | boratory Data, Inclu | ding Dates | | |
| EG AND MRI. | RESULTS WERE | E NORMAL. | | |
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| | | | | |
| Other Relevant His | story, Including Pres | existing Medical C | onditions (e.g., all | lergies, |
| race, pregnancy, sr | noking and alcohol us | se, riepatic/renal dy | siunction, etc.) | |
| | | | | |
| THER HAS HIS | STORY OF SEIZE | URES DUE TO | HEAD TRAUMA | ١. |
| OTHER HAS HIS ROTHER HAS HI | STORY OF SEIZE ISTORY OF FEB | URES DUE TO RILE CONVULS | HEAD TRAUMA | ١. |

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

MEDICATIONS FOR SEIZURES.

| v: v ! | | | | |
|---|--|--|---------------|------------------------|
| XX | | | | FDAL |
| C. SUSPECT PRODUC Name (Give labeled strengti | | | | |
| #1 HYLAND'S BABY TE | | | | |
| #2 | | | | |
| Dose, Frequency & Route | Used | 3. Therapy | Dates (If unk | nown, g ř ve du |
| #11 TABLET AS NEED | | | r best estima | |
| | | | | |
| #2 Diagnosis for Use (Indication | on) | #2 | Event Ahate | ed After Use |
| #1 RELIEVE TEETHING | * | | Stopped or | Dose Reduc |
| #2 | | # | 1 Yes | √ No _ |
| | Exp. Date | #. | 2 Yes [| No |
| #1113207 # | 1 | . 8. | | peared After |
| 12 #2 | 2 | | Reintroduct | tion? |
| NDC# or Unique ID | | | | |
| 54973-31271-5 | | #. | 2 Yes [| No |
|). Concomitant Medical Prod | ducts and The | rapy Dates (E | xclude treatm | nent of event) |
| | | | | |
| | | | | |
| | | | | |
| D. SUSPECT MEDICAL | L DEVICE | | | |
| Brand Name | | | | |
| Common Device Name | | | | |
| | | | | |
| Manufacturer Name, City a | nd State | | | |
| | | | | |
| Model # | Lot# | | 5. Op | perator of De |
| Catalog # | Expiration | n Date (mm/de | //yyyy) | Health Profes |
| | | | | Lay User/Pat |
| Serial # | Other # | | | Other: |
| If Implanted, Give Date (mn | n/dd/yyyy) | 7. if Explant | ed, Give Dat | e (mm/dd/yyy |
| la Abia a Cinala ana Dania | (h-1 | L | | |
| | tnat was Kepr | ocessed and | Reused on a | Patient? |
| Is this a Single-use Device Yes No | | | | |
| | lame and Add | ress of Repro | cessor | |
| Yes No | lame and Add | ress of Repro | cessor | |
| Yes No | lame and Add | ress of Repro | cessor | |
| Yes No | | _ | cessor | |
| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalu | | send to FDA) | | |
| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalue Yes No. No. 1 | ation? (Do not Returned to M | send to FDA) anufacturer or | i:(mr. | n/dd/yyyy) |
| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalu | ation? (Do not Returned to M | send to FDA) anufacturer or | i:(mr. | |
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| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evaluting Yes No | ation? (Do not Returned to M lucts and Ther | send to FDA) anufacturer or | i:(mr. | |
| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalue Yes No. No. 1 | ation? (Do not Returned to M lucts and Ther | send to FDA) anufacturer or | i:(mr. | nent of event) |
| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalu Yes No Concomitant Medical Production. | ation? (Do not Returned to M lucts and Ther | send to FDA) anufacturer or apy Dates (E | i:(mr. | nent of event) |
| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalu Yes No Concomitant Medical Production. | ation? (Do not Returned to M lucts and Ther | send to FDA) anufacturer or apy Dates (E | i:(mr. | nent of event) |
| Yes No If Yes to Item No. 8, Enter No. 9 Device Available for Evalu Yes No Concomitant Medical Production INITIAL REPORTER Name and Address | ation? (Do not Returned to M lucts and Ther | send to FDA) anufacturer or apy Dates (E | i:(mr. | nent of event) |
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| Yes No If Yes to Item No. 8, Enter No. 9 Device Available for Evalu Yes No Concomitant Medical Production INITIAL REPORTER Name and Address | ation? (Do not Returned to M lucts and Ther | send to FDA) anufacturer or apy Dates (E | i:(mr. | nent of event) |
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| Yes No If Yes to Item No. 8, Enter No. 9. Device Available for Evalu Yes No Concomitant Medical Prod INITIAL REPORTER Name and Address (6) | ation? (Do not Returned to M lucts and Ther Phone | send to FDA) anufacturer or apy Dates (E | :(mr. | AU |

Individual Case Safety Report

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

2. Phone Number 310-768-0700

Foreign

Company

Distributor

Other:

Representative

☐ Study Literature ✓ Consumer Health Professional User Facility

Report Source (Check all that apply)

(Specify)

(mm/dd/vvvv)

9342345-02-00-02

Importer

3. User Facility or Importer Name/Address

Check One

User Facility

4. Contact Person

9. Approximate

Yes

☐ No

Yes

No

Age of Device

11. Report Sent to FDA?

6. Date User Facility or

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

05/22/2013

EDYTA FRACKIEWICZ

HYLAND'S, INC. 154 W. 131ST STREET

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

5-day 30-day

7-day Periodic

15-day Follow-up # 1

9. Manufacturer Report Number

10-day Initial

54973 AE # 1378

1. Contact Office - Name/Address (and Manufacturing Site

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Home

Other:

12. Location Where Event Occurred

Outpatient Treatment

Initial Follow-up # Page 2 o

| of XX | |
|---|--|
| H. DEVICE MANUFACTURERS ONLY | Mariana da Andrewalda da d |
| Type of Reportable Event Death Serious Injury Malfunction | 2. If Follow-up, What Type? Correction Additional Information Response to FDA Request |
| Other: | Device Evaluation |
| 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: | 4. Device Manufacture Date (mm/yyyy) 5. Labeled for Single Use? |
| provide dode. | Yes No |
| 6. Evaluation Codes (Refer to coding manual) | |
| Recall Notification Repair Inspection Replace Patient Monitoring | Usage of Device Initial Use of Device Reuse Unknown |
| Relabeling Modification/ Adjustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| | DSS AUG 2 3 2013 |

CaseID: 9342345

FDA USE ONLY

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

PMA

510(k) # Combination Product

Pre-1938

OTC Product

SEIZURES

8. Adverse Event Term(s)

Yes

Yes

✓ Yes

IND#

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

NTINUATION PAGE)

se by user-facilities,

CaseID: 9342345

for MANDATORY reporting

Page 3 of

MEDWAICH FORM FDA 3500A (6/10) (continued)

| B.5. Describe Event or Problem (c | continued) | | | | | - |
|---|----------------------------------|---------------------------------------|--------------------------|-----------------------|-------------------------------|---|
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| B.6. Relevant Tests/Laboratory Da | sta Including Dates (continued | | | | | |
| D.O. Nelevant Tests/Laboratory Da | ica, including bates (continued) | | | | | |
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| B.7. Other Relevant History, Include | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | rsfunction, etc.) (continued) | _ |
| B.7. Other Relevant History, Include | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | vsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Includ | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | rsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Includ | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | rsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Includ | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | rsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Includ | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal dy | rsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Includ | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | rsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Includ | ling Preexisting Medical Cond | itions (e.g., allergies, race, pregna | ncy, smoking and alcohol | use, hepatic/renal d | rsfunction, etc.) (continued) | |
| | | | | | vsfunction, etc.) (continued) | |
| B.7. Other Relevant History, Include B.7. Other | | | | | rsfunction, etc.) (continued) | |
| | | | | | rsfunction, etc.) (continued) | |
| | d Therapy Dates (Exclude treat | | | | rsfunction, etc.) (continued) | |
| | d Therapy Dates (Exclude treat | | | | rsfunction, etc.) (continued) | |
| | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | | rsfunction, etc.) (continued) | |
| | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | | rsfunction, etc.) (continued) | |
| | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | rsfunction, etc.) (continued) | |
| Concomitant Medical Products and | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | | |
| | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | | |
| Concomitant Medical Products and | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | | |
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| Concomitant Medical Products and | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | DSS AUG 2 3 2013 | |
| Concomitant Medical Products and | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | | |
| Concomitant Medical Products and | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | | |
| Concomitant Medical Products and | d Therapy Dates (Exclude treat | | C.10 and/or D.11; please | distinguish) | | |



OMPLAINT RECORD

| 4/5/10as | base # |
|----------|----------|
| Hylands | 7008K |
| | 00048128 |

| 9342345- | 02-00-04 | COMPLAINT # | 2227 | 75 P |
|-------------------------------------|--|---|--|--|
| TAKEN BY: | EDYTA FRACKIEWICZ | COMPLAINT #: DATE OF COMPLAINT: | 05/22/13 | 770' |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 | Market and an arrange and arrange arrange and arrange arrange arrange and arrange ar |
| SIZE: | 135 TABLETS | LOT NO.: | | |
| REPORTER: (b) (6 |) | | | W. C. |
| ADDRESS: | | | | |
| | | | | |
| CITY: | | STATE: (b) (6) | | - |
| COUNTRY: USA | The state of the s | ZIP CODE: | | |
| PHONE #: (b) (6 | | | | |
| E-MAIL: | GAVE 1 TABLET 1 ½ YEARS AGO WHEN | NEEDED, HAD A CEIZUDE IN IANUAR | V 2040 HAD OF W | |
| AND NOT BREATHE WHILE | SINCE THEN. HAD AN EEG, MRI. ALL AI NDUCED BUT SOME WERE NOT. CHILD HAS NOT E SEIZING. SEND A REFUND FOR 1 BOTTLE. MOT JRE. CHILD HAS NO HISTORY OF HEAD TRAUMA. | RE NORMAL. NOT DUE TO FEVERS. H HAD A SEIZURE IN 3 – 4 MONTHS. CH HER HAS SEIZURES DUE TO HEAD TR BROTHER HAS HISTORY OF FEBRILE | IAD A COUPLE TH LD WOULD SHAK AUMA. NO MEDIC CONVULSIONS. | AT THEY E UNCONSCIOUS |
| | FOR ADDITIONAL SPACE PLEASE USE RE | VERSE OR ATTACH A SEPARATE SHE | ET | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | | Y N (CIRCLE ONE) |
| | | UPS CALL | TAG ISSUED: | Y (CIRCLE ONE) |
| | | DATE PRODUC | T RECEIVED: | |
| SECTION II: IN | VESTIGATION | | | |
| INVESTIGATION: | DEVICATED DATOUR DECORDS ANALYSIS OF TRUE | | | |
| - | REVIEWED BATCH RECORD. MANUFACTURING | | DING TO ESTABL | SHED PROCE- |
| DORES TO ENSURE PROD | UCT QUALITY. INSPECTED RETAINED SAMPLE AN | ND EVERYTHING LOOKS OK. | | |
| | | | | |
| | | | | |
| ADVERSE EVENT FORWAR | RDED TO PHARMACIST / NURSE FOR EVALUATION | ON: 05/22/13 | | |
| ADVERSE EVENT FORWAR | RDED TO PHARMACIST / NURSE FOR EVALUATION | BY: EDYTA FF | RACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | |
| 05/23/13: PREPARED REFU | UND REQUEST TOTALING \$ 10.04. | | | |
| | | | | |
| | | | | |
| CORRECTIVE ACTION(S) C | OMPLETED BY:(b) (6) | DATE: | 05/23/13 | |
| SECTION IV: AD | VERSE EVENT REPORTS | AE #: | 1378 | |
| ADVEDEC EVENT SERIOUS | | • | | |
| ADVERSE EVENT SERIOUS | 0. | | | |
| ADVERSE EVENT REPORTE SECTION V: | ED ON: 05/22/13 | BY: EDYTA FRACKIE | WICZ | Dec |
| X-V11VII T. | | AAA I. | | DSS AUG 2 3 2013 |
| REVIEWED BY MANAGEME | NT BY: | DATE: | 06-04-13 | <u> </u> |
| BY: Oym | an Sal | DATE:(| 06-04-13 06-04- | -/3 |
| V | arr as sinceron | | | |

cc: QA/QC Packaging

Production Shipping / Receiving

Form # VD1

AUG 22 2013

CaseID: 9342345

E EVENT DATA FORM

| AE #: | 1378 | COMPLAINT #: 2327 | |
|--------------------------------|----------------------------|---|-------------------|
| SECTION | E PATIENT INFORMAT | ION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: ADDRESS | (b) (6) - : | | |
| CITY: COUNTRY PHONE #: E-MAIL: | : <u>USA</u> (b) (6) | STATE: (b) (6) ZIP CODE: | |
| SECTION I | I: PACKAGING INFORM | IATION: | |
| | AFFIX PACKAGING LABEL HE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Teething Tablets Teething Tablets | · |
| SECTION III | E CORRECTIVE ACTION | N: | |
| CORRECTIV | /E ACTION(S) COMPLETED BY: | DATE: | |
| SECTION IV | EY MANAGEMENT BY | DATE: 06-04-13 AU | DSS |
| BY: | QL QC DIRECT | DATE: 03-05-12 | b 2 3 201; |



COMPLAINT RECORD



9342345-02-00-06 COMPLAINT #: 2327 TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 05/22/13 PRODUCT: HYLAND'S BABY TEETHING TABLETS LOT NRECEIVED SIZE: 135 TABLETS (b) (6) REPORTER: AUG 2 2 2013 ADDRESS: (b) (6) CITY: STATE: COUNTRY ZIP CODE: (b) (6) PHONE # E-MAIL: GAVE 1 TABLET 1 ½ YEARS AGO WHEN NEEDED. HAD A SEIZURE IN JANUARY 2012. HAD SEVERAL SEIZURES NATURE OF COMPLAINT: SINCE THEN. HAD AN EEG, MRI. ALL ARE NORMAL. NOT DUE TO FEVERS. HAD A COUPLE THAT THEY THOUGHT WERE FEVER INDUCED BUT SOME WERE NOT. CHILD HAS NOT HAD A SEIZURE IN 3 - 4 MONTHS. CHILD WOULD SHAKE UNCONSCIOUS, AND NOT BREATHE WHILE SEIZING. SEND A REFUND FOR 1 BOTTLE. MOTHER HAS SEIZURES DUE TO HEAD TRAUMA. NO MEDICATIONS FOR SEIZURES. NOT PREMATURE. CHILD HAS NO HISTORY OF HEAD TRAUMA. BROTHER HAS HISTORY OF FEBRILE CONVULSIONS. FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR PRODUCT BEING RETURNED FOR INSPECTION: INSPECTION: (CIRCLE O (CIRCLE ONE DATE REQUESTED PRODUCT BE RETURNED: UPS CALL TAG ISSUED: (CIRCLE ONE DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCE-DURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ SECTION III: CORRECTIVE ACTION: 05/23/13: PREPARED REFUND REQUEST TOTALING \$ 10.04. 06/12/13: MAILED REFUND CHECK # 509375 TOTALING \$ 16.26 ON ARTICLE # 70081830 000486289877 (b) (6) CORRECTIVE ACTION(S) COMPLETED BY: DATE: 05/23/13 & 06/12/13 SECTION IV: ADVERSE EVENT REPORTS AE #: __1378 ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ DSS

DATE: 68-06-13 AUG-232013 SECTION V: REVIEWED BY MANAGEMENT BY: BY:

DATE: 08-05-13

cc: QA/QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 64 1836 000486 9877

May 23, 2013

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 9.19 per bottle. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach President

Enc: Refund Check - \$ 10.04

9342356-01-00-01

or use by user-facilities, distributors and manufacturers MANDATORY reporting

| CaseID: 9342356 |
|---|
| Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse. |

| | COO CHID CLUCOTION OF TOTAL |
|----------------------|-----------------------------|
| Mfr Report # 54973 | |
| UF/Importer Report # | |
| | |

| | FORM FD | A 3500 | OA (6/10) | | | | Page 1 |
|------------------------------|--|------------------------|---|---------------------------|--|-------------------------------------|------------|
| | A. PATIE | NT INF | ORMATI | ON | | | |
| | Patient Ide (b) (6) | entifier | Age at T of Event | | 15 # h = | 3. Sex | 4. Weight |
| | (=) (=) | | or | 4 | Months | Female | or lbs |
| | In confide | ence | Date of Birth: | | | ✓ Male | kgs |
| | B. ADVE | RSE E | ENT OR | PRODU | CT PROBLE | M | |
| | 1. 🕢 Adve | rse Even | t and/or | Pr | oduct Problem | (e.g., defects/mali | functions) |
| | 2. Outcomes (Check all | | | rse Event | | | |
| | Deat | | | | Disability | or Permanent Da | mage |
| | Life-t | hreatenin | (mm/dd/y g | yyy) | Congenit | al Anomaly/Birth I | Defect |
| | ٠ | | - initial or p | | | rious (Important N | |
| |] | | | revent Perm | | nt/Damage (Devid | |
| | 3. Date of Ev | | n vaavyyyy) .2 – PRE | SENT | 4. Date of In | is Report (mm/de 05/29/201 | |
| | 5. Describe | | | | | | |
| | 05/24/13 | 3 INFO | RMATION | OBTAIN | ED FROM CU | STOMER: (b) | (6) |
| | SON STAF | RTED H | AVING S | EIZURES | . USING B | ABY TEETHIN NO FEVER A | |
| | TABLETS TIME OF | | RE. SE | IZURE I | | SED HIM TO | |
| ¥ | OXYGEN T | | | NT TO (b) | (6) ED FOR 2 1 | /2 - 3 WEEF | (8 |
| | UNDERWEN | NT GAS | TRIC TU | BE SURG | ERY SECOND | ARY TO OXY | GEN LOSS |
| Ą | TO BRAIN | | IZURE P | RESENTE | D AS SHAKI | NG AND DROG | DLING FOR |
| B. | 1 PILNOIS | ٠. | | | | | |
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| \mathbb{F} | | | | | | | |
| | | | | | | | |
| | 6. Relevant | Tests/La | boratory Da | ata, Includi | ng Dates | | |
| | TESTS I | N HOSD | TTAL (b) (| 6) | MRI. X-RA | Y, SWALLOW | STUDY. |
| | OBSERVA: | | | | , | | |
| | (b) (6) | GAS | TRIC TU | BE SURG | ERY | | |
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| | 7. Other Re | levant Hi gnancy, s | story, inclu moking and | ding Preex alcohol use | isting Medical (, <i>hepatic/renal d</i> | Conditions (e.g., ysfunction, etc.) | anergies, |
| | CURRENT | DIAGN | OSIS: I | FAILURE | TO THRIVE | , EPILEPSY, | , APNEA, |
| | GERD. | | | | | | |
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| | | | | | FDA Use C | niy |
| C. SUSPECT PRODU | | | | | | |
| Name (Give labeled streng | | RI.ETS | | | | |
| #1 HYLAND'S BABY T | ELITING TA | DDE19 | | | | - |
| #2 | | I | | | | Ļ |
| Dose, Frequency & Route | | | y Dates (II (or best es | | give duratio | n) |
| #1 1 1/2TAB PO BID | EOD X1MO | #1 | | | | _ |
| #2 | | #2 | | | | |
| . Diagnosis for Use (Indical | tion) | - | | Abated Aft | er Use Reduced? | |
| #1 TEMP RELIEF TEE | THING PAIN | | #1 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | | ☐ Doe | sn't |
| #2 | | | | | — App — Doe | _ |
| . Lot # | 7. Exp. Date | | #2 Ye | es ∐ No | App | |
| #1 | #1 | | | Reappeare duction? | d After | |
| #2 | #2 | | _ | es No | Doe | |
| NDC# or Unique ID | | | #2 Y | es 🗀 No | Doe | sn't |
| 54973-3137-3 0. Concomitant Medical Pr | | | | | App | у |
| SUSPECT MEDIC | AL DEVICE | | | | | |
| . Brand Name | AL DEVICE | | | | | |
| . Brand Name | AL DEVICE | | | | | |
| . Brand Name . Common Device Name | | | | | | |
| Brand Name Common Device Name Manufacturer Name, City | | | | 5. Operato | or of Devic | Ð |
| . Brand Name Common Device Name Manufacturer Name, City Model # | and State | n Date (mn | Vdd/vyyy) | Heal | th Professio | nal |
| . Brand Name . Common Device Name . Manufacturer Name, City | and State | n Date (ma | n/dd/yyyy) | Heal | th Professio Jser/Patien | nal |
| Brand Name Common Device Name Manufacturer Name, City Model # | and State | n Date (mn | v/dd/yyyy) | Heal | th Professio Jser/Patien | nal |
| . Brand Name . Common Device Name . Manufacturer Name, City . Model # Catalog # | Lot # Expiration Other # | | | Heal | th Profession User/Patien r: | nal |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # | Lot # Expiration Other # | 7. If Expl | anted, Giv | Heal Lay I Othe | th Profession User/Patien r: n/dd/yyyy) | nal |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # If Implanted, Give Date (i | Lot # Expiration Other # | 7. If Expl | anted, Giv | Heal Lay I Othe | th Profession User/Patien r: n/dd/yyyy) | nal |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # If Implanted, Give Date (i) Is this a Single-use Device Yes No | Lot # Expiration Other # | 7. If Expl | anted, Giv | Heal Lay Othe | th Profession User/Patien r: m/dd/yyyy) ent? | onal t |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # If Implanted, Give Date (i) Is this a Single-use Device Yes No | Lot # Expiration Other # | 7. If Expl | anted, Giv | Heal Lay Othe | th Profession User/Patien r: m/dd/yyyy) ent? | onal t |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # If Implanted, Give Date (i) Is this a Single-use Device Yes No | Lot # Expiration Other # | 7. If Expl | anted, Giv | Heal Lay Othe | th Profession User/Patien r: m/dd/yyyy) ent? | onal t |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # Serial # Bit Implanted, Give Date (i) Yes No If Yes No If Yes to Item No. 8, Enter | Lot # Expiration Other # Control of the two services of the two se | 7. If Expl | anted, Giv | Heal Lay Othe | th Profession User/Patien r: n/dd/yyyy) | onal t |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # Serial # Bit Implanted, Give Date (i) Yes No If Yes No If Yes to Item No. 8, Enter | Lot # Expiration Other # Control of the two services of the two se | 7. If Explored a ress of Re | anted, Giv | Heal Lay U Othe | th Profession User/Patien r: n/dd/yyyy) ent? DS | onal t |
| I. Brand Name 2. Common Device Name 3. Manufacturer Name, City 4. Model # Catalog # Serial # 3. If Implanted, Give Date (iiii) 1. Yes No 1. If Yes to Item No. 8, Enter 10. Device Available for Ev. | Lot # Expiration Other # mm/dd/yyyy) ce that was Repr r Name and Add aluation? (Do not) Returned to M | 7. If Expl | anted, Giv nd Reuseo processor OA) r on: | Heal Lay U Othe Date (mr | th Profession User/Patien r: n/dd/yyyy) ent? DS | onal t |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # Serial # Si If Implanted, Give Date (iii) Yes No If Yes to Item No. 8, Enter | Lot # Expiration Other # mm/dd/yyyy) ce that was Repr r Name and Add aluation? (Do not) Returned to M | 7. If Expl | anted, Giv nd Reuseo processor OA) r on: | Heal Lay U Othe Date (mr | th Profession User/Patien r: n/dd/yyyy) ent? DS | onal t |
| Serial # 3. If Implanted, Give Date (iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii | Lot # Expiration Other # The second of the | 7. If Expl | anted, Giv nd Reuseo processor OA) r on: | Heal Lay U Othe Date (mr | th Profession User/Patien r: n/dd/yyyy) ent? DS UN 1 (yyyy) of event) | SS 0-2 |
| 1. Brand Name 2. Common Device Name 3. Manufacturer Name, City 4. Model # Catalog # Serial # 3. If Implanted, Give Date (iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii | Lot # Expiration Other # The second of the | 7. If Expl occessed a ress of Re t send to Fi lanufacture | anted, Giv nd Reuseo processor OA) r on: | Heal Lay U Othe Date (mr | th Profession User/Patien r: n/dd/yyyy) ent? DS UN 1 (yyyy) of event) | onal t |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Individual Case Safety Report CaseID: 9342356 FDA USE ONLY 9342356-01-00-02 Page 2 of 5 H. DEVICE MANUFACTURERS ONLY SERTAGILITT/IIVIPORTER (Devices Only) 2. If Follow-up, What Type? 1. Type of Reportable Event 2. UF/Importer Report Number 1. Check One Correction User Facility Death Importer Additional Information Serious Injury 3. User Facility or Importer Name/Address Malfunction Response to FDA Request Device Evaluation Other: 3. Device Evaluated by Manufacturer? 4. Device Manufacture Date (mm/yyyy) Not Returned to Manufacturer Yes Evaluation Summary Attached 4. Contact Person 5. Phone Number 5. Labeled for Single Use? No (Attach page to explain why not) or provide code: 8. Date of This Report 6. Date User Facility or Type of Report Yes No (mm/dd/yyyy) Importer Became Aware of Event (mm/dd/yyyy) Initial 6. Evaluation Codes (Refer to coding manual) Follow-up # Method Approximate
 Age of Device 10. Event Problem Codes (Refer to coding manual) Patient Results Code Device Conclusions Code 7. If Remedial Action Initiated, Check Type 8. Usage of Device 11. Report Sent to FDA? 12. Location Where Event Occurred Initial Use of Device Outpatient
Diagnostic Facility Hospital Notification Recall Yes Reuse (mm/dd/yyyy) Repair Home Inspection ☐ No Ambulatory
Surgical Facility Unknown Patient Monitoring Nursing Home Replace 13. Report Sent to Manufacturer? If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: Modification/ Adjustment Outpatient Treatment Facility Relabeling Yes (mm/dd/yyyy) Other: ☐ No Other: (Specify) 14. Manufacturer Name/Address 10. Additional Manufacturer Narrative 11. Corrected Data G. ALL MANUFACTURERS 1. Contact Office - Name/Address (and Manufacturing Site 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) MARK PHILLIPS EDYTA FRACKIEWICZ Foreign HYLAND'S, INC. 154 W. 131ST STREET Study LOS ANGELES, CA 90061 Literature √ Consumer Health Professional User Facility Date Received by Manufacturer (mm/dd/yyyy) JUN 1 0 2013 Company (A)NDA # Representative 05/22/2013 Distributor IND# 6. If IND, Give Protocol # Other: STN# DMA. 7. Type of Report (Check all that apply) 510(k) #

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Combination

OTC Product Yes

8. Adverse Event Term(s)

Product

Pre-1938

SEIZURES

Yes

Yes

30-day

Periodic

5-day

7-day

☐ 10-day
✓ Initial

54973 AE # 1384

15-day Follow-up #

9. Manufacturer Report Number

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

JUN 0 7 2013

Individual Case Safety Report

9342356-01-00-03

(CONTINUATION PAGE)

For use by user-facilities, , distributors, and manufacturers for MANDATORY reporting CaseID: 9342356

Page 3 of 5

FORM FDA 3500A (6/10) (continued)

| 3.5. Describe Event or Problem (continued) | |
|---|------------------------------------|
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| B.6. Relevant Tests/Laboratory Data, Including Dates (continued) | |
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| | |
| B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/rel | nal dysfunction, etc.) (continued) |
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| | , |
| | |
| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish) | DSS JUN 1 0 2013 |
| | JIN 1 0 204 |
| | 20N T 0 5013 |
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| Other Remarks | JUN 0 7 2013 |
| | JUN 2013 |
| | -10 |
| | |
| | JUN 0 7 2013 |



CUSTOMER COMPLAINT RECORD



| SECTION I: | COMPLAINT | | COMPLAINT #: | 2335 | |
|---|--|---|---|---|---|
| TAĶEN BY: | MARK PHILLIP | 's | DATE OF COMPLAINT: | 05/22/13 | |
| PRODUCT: | BABY TEETHI | NG TABLETS | ITEM CODE: | BTETT135 | |
| SIZE: | 135 TABLETS | | LOT NO.: | N/A | |
| REPORTER: | (b) (6) | | | | |
| ADDRESS: | | | | | |
| | | | (b) (6) | | |
| CITY: | | | STATE: | | |
| COUNTRY: | USA (b) (6) | | ZIP CODE: | | |
| PHONE #: | | | | | |
| E-MAIL: | REPORT | TED READ ON INTERNET THAT TEE TER NOTED THE PRODUCT WAS TA | THING TABLETS CAUSE SEIZURES | AND EPILEPSY I | N INFANTS. |
| USING BABY TER FEVER AT THE T HOSPITAL AND V TO BRAIN. GOE: FOR 1 MINUTE. APNEA, GERD. I | MY SON IS NOW HAVING SEI ETHING TABLETS FOR ONE IME OF SEIZURE. SEIZURE WAS HOSPITALIZED FOR 2 2 S TO OCCUPATIONAL THER TESTS IN HOSPITAL: MRI, X MEDICINES: KEPRA 2ML EV ST IN 2 WEEKS AND WILL AS O OTHER MEDICATIONS AT | IZURES AND EPILEPTIC (SIC)*. 05/2 MONTH PRIOR. GIVING 1 ½ TABLE IN 2012 CAUSED HIM TO LOSE OX' 4 - 3 WEEKS. UNDERWENT GASTR APY. DOCTOR'S NOT SURE WHY O' (-RAY, SWALLOW STUDY, OBSERV/ ERY MORNING; 2.5ML EVERY PM; O' SK ABOUT USE OF BABY TEETHING TIME OF SEIZURE. NO INJURY OR | 24/13 FOLLOW-UP (EF): 10 (0) LTS BY MOUTH TWICE A DAY EVER YGEN TO BRAIN. WAS SENT TO (0) RIC TUBE SURGERY BECAUSE OF A CHILD HAD SEIZURE. SEIZURE PRI ATION AFTER EATING. DIAGNOSIS CYPROHEPTADINE 1 TEASPOON E TABLETS. DOES NOT WANT A RE RILLNESS AT THE TIME. ALLERGIC | SON STARTED H Y OTHER DAY FO)(6) MEMORY LOSS 2º ESENTED AS SHA S: FAILURE TO TH VERY DAY, PEPCI FUND. CHILD BO S TO AMOXICILLIN | AVING SEIZURES. R 1 MONTH. NO TO OXYGEN LOSS KING AND DROOL RIVE, EPILEPSY, ID. WILL GO BACK RN 6-WEEKS |
| | FOR ADDIT | TOWAL SPACE PLEASE USE NEVEL | NOL ON ATTAON A SEL ANATE SIN | | |
| PRODUCT RECEINSPECTION: | IVED FOR | Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: | (CIRCLE ONE) |
| NOTE: PHARMA CALL AT 5:49PM | CIST RETURNED I AND 6:05 PM ON | | DATE REQUESTED PRODUCT B | E RETURNED: | |
| LEAVING DETAIL | | RECEIV | ED | - | |
| REQUEST TO CA | NUMBER. | | | TAG ISSUED: | (CIRCLE ONE) |
| AS OF COMPLET | NOT RETURN CALL TION OF THIS 23/13 AT 3:30PM. | JUN 0 7 201 | 13 | CT RECEIVED: | |
| SECTION II: | INVESTIGATION | ODD | | _ | |
| | | CDR | | | |
| INVESTIGATION | NO LOT NUMBER se Safety Repor | R. PROCEDURES ARE IN PLACE TO | D ENSURE PRODUCT QUALITY. | | |
| | | | | | |
| | 56-01-00-04 | ACIST / NURSE FOR EVALUATION O | ON: 05/22/13 | | |
| | | ACIST / NURSE FOR EVALUATION B | | | |
| SECTION III: | CORRECTIVE AC | | | | |
| | | | | | DS |
| | | | | | |
| CORRECTIVE AC | CTION(S) COMPLETED BY: | | DATE: | | |
| SECTION IV: | ADVERSE EVENT R | <u>EPORTS</u> | AE #: | 1384 | |
| ADVERSE EVEN | T SERIOUS: | √)/ N | | | DSS |
| ADVERSE EVEN | T REPORTED ON: | 05/22/13 | BY: MARK PHILLIF | rs · | - 00 |
| SECTION V: | | D | an. | | JUN 20 |
| 0=011011 | | | VALLA | | |
| | IANAGEMENT BY: | - JANA | DATE: | 06-04-13 | <u> </u> |
| | MANAGEMENT BY: | eli. | DATE: | 06-04-13 | -/3 JUN 0 7 2013 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





SERIOUS ADVERSE EVENT DATA FORM

| AE | =#: <u>13</u> | 84 | COMPLAINT | #: 2335 | |
|------------|--|--|--|---|--------------|
| SE | ECTION I: | PATIENT INFORMATION (IF | DIFFERENT FROM REPORTER ON FOR | <u>M VD1)</u> | |
| N.A | AME: | (b) (6) | | | |
| AE | DDRESS: | -10- | | | _ |
| CI | ITY: | | STATE | (b) (6) | |
| co | OUNTRY: | USA | ZIP CODE | | |
| Pl | HONE #: | (b) (6) | | | |
| E- | -MAIL: | | | | _ |
| SI | ECTION II: | PACKAGING INFORMATIO | <u>N:</u> | | |
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| | ECTION III: | CORRECTIVE ACTION: | | | Doo |
| Individual | Case S | afety Report | | | DSS |
| | | | | | JUN 1 0 2013 |
| 93 93 | 342356-0 | 1-00-05 | | | |
| | | | | DATE: | |
| 6 | ECTION IV | | | | Dse |
| <u>5</u> | ECTION IV: | - K | DAAAn. | DATE: | |
| R | EVIEWED BY | MANAGEMENT BY | ATMULLIN | DATE: 06-04-13 | 2013 |
| В | Y: | 0.4./00 DIDEOTOR | | DATE: | <u></u> - |
| | | QA / QC DIRECTOR | • | ***** | |
| | | | | .111N | D 7 0040 |

JUN D 7 2013

9342360-01-00-01

PLEASE TYPE OR USE BLACK INK

or use by user-facilities, distributors and manufacturers MANDATORY reporting

| Form Approved: OMB No. 09 10-029 1, Expires 12/31 | /11 |
|---|-----|
| See OMB statement on reve | rse |
| | |

CaseID: 9342360

Mfr Report # 54973 UF/Importer Report #

| Page 1 of 5 |
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|-------------|

| FORM FDA 3500 | 0A (6/10) | | | Page 1 | of <u>3</u> | | | FDA Use Only |
|------------------------------|--|----------------------|-------------------|-------------|-------------------------------|--------------------|--|--|
| A. PATIENT INF | ORMATION | | | | C. SUSPECT PRO | DUCT(S) | | |
| 1. Patient Identifier | 2. Age at Time of Event: | | 3. Sex | 4. Weight | Name (Give labeled strength | • | | |
| b) (6) | or11 | Months | ✓ Female | lbs | #1 HYLAND'S BAB | Y TEETHING TA | ABLETS | |
| | Date | | Male | or | #2 | | | |
| In confidence | of Birth: VENT OR PRODUC | CT PROBLE | Λ | kgs | 2. Dose, Frequency & R | oute Used | 3. Therapy Dates (from/to (or best e | If unknown, give duration) stimate) |
| | | | | (unadia na) | #1 2-3TABS//2-32 | X/DAY//1-2DY | #1 | , |
| . Adverse Even | t and/or Pro | duct Problem (e. | .g., derects/mail | uncuonsi | #2 | | #2 | |
| (Check all that appl) | | | | | 4. Diagnosis for Use (Inc | dication) | | Abated After Use |
| Death: | (mm/dd/yyyy) | _ Disability or | r Permanent Da | mage | #1 TEMP RELIEF (| OF TEETHING F | PAIN | ed or Dose Reduced? |
| Life-threatenin | • | _ | Anomaly/Birth I | | #2 | | | — — Арріу |
| | - initial or prolonged | | ous (Important A | 1 | 6. Lot# | 7. Exp. Date | #2 🗆 Y | es No Doesn't |
| | vention to Prevent Perma | | | | #1113995 | #1 | | Reappeared After oduction? |
| 3. Date of Event (mn 12/0 | 00/2012 | 4. Date of This | 05/24/2013 | | #2 | #2 | | es No Doesn't |
| . Describe Event or | - A | | -3, -1, 201 | - | 9. NDC# or Unique ID | | | Apply |
| | | A COURT TAKE A COMMI | DD MUM CI | | 54973-3127-1 | | #2 ∐ Y | es No Apply |
| | TABLETS AND SO ONVULSIONS WITH | | | | 10. Concomitant Medica | I Products and The | rapy Dates (Exclude | treatment of event) |
| COLECTION OF THE | MUEN CHE CAME | TO CHE MOI | IID CDV AN | ים שאצב | | | | |
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| , DO | CTOR THOUGHT TH IONS OCCURED IN | AT ELECTRO | LITES COUL | 10 BE | | | | |
| | N AND SHE NEVER | | | | D CHOPECT MED | JOAL DEVICE | | |
| | | | | | D. SUSPECT MED 1. Brand Name | ICAL DEVICE | | |
| | | | | | | | | |
| | | | | | 2. Common Device Nam | 10 | | |
| | | | | | 3. Manufacturer Name, | City and State | | |
| | | | | | | | | |
| | | | | | 4. Model # | Lot# | | 5. Operator of Device |
| | | | | | |] | | Health Professional |
| | | | | | Catalog # | Expiratio | n Date (mm/dd/yyyy) | Lay User/Patient |
| | | | | | Serial # | Other # | | Other: |
| | | | | | | | | |
| | | | | | 6. If Implanted, Give Dat | te (mm/dd/yyyy) | 7. If Explanted, Giv | re Date (mm/dd/yyyy) |
| 3. Relevant Tests/Lai | boratory Data, Including | g Dates | | | 8. Is this a Single-use D | evice that was Ren | rocessed and Reuse | d on a Patient? |
| | EG GE GGEV W | n noamo: | o courpui | .m. cpp | Yes No | | | |
| SPINAL TAP, E ANYTHING. | EG, CAT SCAN, M | RI. DOCTO | KS COULDN | T SEE | 9. If Yes to Item No. 8, E | nter Name and Add | fress of Reprocessor | |
| | | | | | | | | DSS |
| | | | | | | | | IIIN T O OO |
| | | | | | 10. Device Available for | Evaluation? (Do no | t send to FDA) | JUN 1 020 |
| | | | | | Yes No | Returned to M | Manufacturer on: | |
| | | | | | 11. Concomitant Medica | I Products and The | rany Dates /Fyclude | (mm/dd/yyyy) |
| Other Polyant His | story, Including Preexis | ting Madical Co. | nditions (e.g. | ellernies | - Consoning medica | rowwood and the | | |
| race, pregnancy, sn | noking and alcohol use, I | hepatic/renal dysf | unction, etc.) | ner gies, | | | | JUN 🍎 2 |
| NO KNOWN ALLER | RGIES. FULL TE | RM PREGNANC | CY. NO OT | HER | E INITIAL DEDGE | TCD | | 4 |
| MEDICATIONS AT | | FEVER. | 110 01 | | E. INITIAL REPOR | | # (b) (6) | |
| | | | | | . Name and Address | Prione | | to: |
| | | | | | (b) (6) | <u>-</u> | ttrae - | r |
| | | | | | | • | JUN D ZOD | 12 _ |
| | | | | | | | TI | |
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| ubmissis- of s | | etitute en ed | minolon that | modical | 2. Health Professional? | 13 Occupation | | nitial Reporter Also Sent |
| ersonnel, user fa | eport does not con scility, importer, dis | | | | l | 5. Occupation | [*] | Report to FDA |
| caused or contrib | uted to the event. | | | | ☐ Yes 🗸 No | | 1.1 | Yes No 📵 Unk. |

Individual Case Safety Report

9342360-01-00-02

Importer

3. User Facility or Importer Name/Address

Check One
 User Facility

4. Contact Person

9. Approximate Age of Device

Yes

☐ No

Yes

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

> Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ HYLAND'S, INC.

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

10-day 📝 initial

54973 AE # 1380

| 15-day | Follow-up # ___
| 9. Manufacturer Report Number

7-day

05/23/2013

30-day

Periodic

154 W. 131ST STREET LOS ANGELES, CA 90061

 Contact Office - Name/Address (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

☐ Initial ☐ Follow-up #

2. UF/Importer Report Number

5. Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

2. Phone Number 310-768-0700 3. Report Source (Check all that apply)

Foreign

Study
Literature
Consumer
Health Professional
User Facility

Company Representative

Distributor

Other:

(Specify)

Page 2 of 5

| | | FDA USE ONLY |
|----------------------------|----------------------------------|---|
| 5 | | |
| | | |
| I. DEVICE MANUF | | |
| Type of Reportable Ev | ent | 2. If Follow-up, What Type? |
| Death | | Correction |
| Serious Injury Malfunction | | Additional Information Response to FDA Request |
| Other: | | Device Evaluation |
| | | |
| Device Evaluated by N | | Device Manufacture Date (mm/yyyy) |
| Not Returned to N | | . |
| | ation Summary Attached | 5. Labeled for Single Use? |
| provide code: | o explain why not) or | |
| | | Yes No |
| Evaluation Codes (Rel | er to coding manual) | |
| Method | | |
| Micuroa | | |
| Results | | |
| Conclusions | | |
| | | |
| If Remedial Action Init | lated, Check Type | 8. Usage of Device |
| Recall | Notification | Reuse |
| Repair | Inspection | Unknown |
| Replace Relabeling | Patient Monitoring Modification/ | 9. If action reported to FDA under |
| Relabeling | Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | |
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| . Additional Manus | facturer Narrative | and / or 11. Corrected Data |
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CaseID: 9342360

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA #

IND#

STN#

510(k) # __ Combination

Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s) CONVULSIONS

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report CaseID: 9342360 (CONTINUATION PAGE) 9342360-01-00-03 For use by user-facilities, .ers, distributors, and manufacturers for MANDATORY reporting **MEDWATCH** Page 3 of 5 FORM FDA 3500A (6/10) (continued) B.5. Describe Event or Problem (continued) B.6. Relevant Tests/Laboratory Data, Including Dates (continued) B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish) JUN 1 0 2013

JUN 0 7 2013

Other Remarks



CUSTOMER COMPLAINT RECORD



| | <u> </u> | - | | | | | | COMPLAINT #: | 2329 | | |
|-------|--|---|--|--|--|---|---|--|---|--|-------------------------------------|
| ij | TAKEN BY: PRODUCT: | | EDYTA FRACKI | EWICZ | | | DATE C | F COMPLAINT: | 05/23/13 | | |
| ďή | PRODUCT: | BABY TEETHIN | IG TABLETS | | | ITEM CODE: | | BTETT135 ' | | | |
| /idi | SIZE: | | 135 TABLETS | | | | | LOT NO.; | 113995 | | _ . |
| idual | REPORTER: | (b) (6) - | | <u> </u> | | | | | | | |
| င္ထ | ADDRESS: | - | | | | | | | | | |
| ase | | - | | | | | | (b) (6) | | | |
| Sa | | | | <u> </u> | | | STA | TE: | | | |
| fet | COUNTRY: | USA (b) (6) | | | | | ZIP CO | DDE: | | | |
| Υ | PHONE #: | _ | | | | | | | | | |
| п | NATURE OF COMPL TAKE DEEP BREATH MRI AND DOCTORS | HS LIKE S COULD G 2 - 3 TA SHE WAS | CONVULS SHE COULDN'T BR NOT SEE ANYTHII ABLETS UNDER TO IN THE HOSPITAL ING TABLETS (135 | REATHE. WEN NG. DOCTORS ONGUE 2 - 3 T . IT HAPPENED COUNT). NO H | OLLING BACK T TO THE HOS S THOUGHT EI IMES A DAY F D. NEVER HAP KNOWN ALLER | OF HEAD, S' PITAL, DID A LECTROLYTE OR 1 OR 2 D PENED AGAI RGIES. FULL | TIFFENING I A SPINAL TAI ES COULD B AYS WHEN IN. NEVER I TERM PREC | JP. WHEN SHE (PE. NO RESULTS E OFF. HOSPITA THIS HAPPENED. JSED THE TEETH BNANCY. NO OT | CAME TO SHE W S. HAD AN EEG LIZED FOR ONE SEVERAL TIM HING TABLETS A HER MEDICATIO | EWEEKEND IN ES OVER THE AGAIN. WANTS A | |
| | | | FOR ADDITIO | ONAL SPACE F | PLEASE USE F | REVERSE OR | ATTACH A | SEPARATE SHE | ET | | |
| | PRODUCT RECEIVE INSPECTION: | D FOR | (0 | CIRCLE ONE) |) | | | ETURNED FOR I | | Y N (CIRCLE ONE) | |
| | | | | DE(| CEIVI | | REQUESTE | D PRODUCT BE | KETOKNED: | | _ |
| | | | | 8 16-7 | >CIA! | | | UPS CALL | TAG ISSUED: | Y (N) (CIRCLE ONE) | |
| | | | | JUN | 0 7 2013 | 3 | | DATE PRODUC | T RECEIVED: _ | | <u> </u> |
| - | SECTION II: INVESTIGATION COR INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY. | | | | | | | | | | |
| - | ADVEDCE EVENT EC | ODWARD. | ED TO BUADANA | ICT / NIJDOE E | OD EVALUATION | ON ON | | 05/00/40 | | | _ |
| | ADVERSE EVENT FO | | | | | | | 05/23/13 EDVTA ER | RACKIEWICZ | | _ |
| | SECTION III: | | ORRECTIVE ACT | | UN EVALUATION | J.1 51. | | EDITATE | VACINEWIUZ | | DSs |
| | | 2 | | | | | | | | | - DSS _JUN 1 0 2013 |
| - | 05/24/13; PREPAREI | D REFUN | D REQUEST TOTA | ALING \$ 9.19. | | | | | | | _JUN 1 0 2013 |
| _ | | | | | | | - | | | | |
| | CORRECTIVE ACTIO | N(S) CO | MPLETED BY: | (b) (6) | | | | DATE: | 05/24/13 | | |
| | SECTION IV: | ADV | ERSE EVENT REP | ORTS | | | | AE #; _ | 1380 | | _ **DSS JUN ★ 2013 |
| | ADVERSE EVENT SE | RIOUS: | | (_Y), N | | | | | | | JUN |
| | ADVERSE EVENT RE | PORTE | ON: | 05/23/13 | | | BY: _ | EDYTA FRACKIE | EWICZ | | ZU]3 |
| | SECTION V: | | | | V. |) ahr | ١ | | | | |
| | REVIEWED BY MANA | AGEMEN | T BY: | \sim | M | 1000 | <u></u> | DATE: | 06-04-13 | JUN 0 | 7 2013 |
| | ву: | ezma | QA/QC DIR | ECTOR | | | | DATE: | 06-04. | -13 | _ |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 9342360



SERIOUS ADVERSE EVENT DATA FORM

| | AE #: | 1380 | | | COMPLAINT | #: _2329 | | _ |
|----------|--------------------------------|------------|---|----------------------|--|---------------------|-------------------------|--|
| | SECTION I: PATIENT INFORMATION | | | DIFFERENT FRO | OM REPORTER ON FORI | <u>M VD1)</u> | | |
| | NAME: | | (b) (6) | | | | | |
| | ADDRESS | S: | | | | | | |
| | | | | | OTATE | (b) (6) | | |
| | CITY: | <i>i</i> . | LICA | | STATE: ZIP CODE: | | | _ |
| | COUNTRY PHONE #: | | (b) (6) | | | | | _ |
| | E-MAIL: | | | | | | | Name of the second seco |
| | | | | | | | | |
| | SECTION | <u>II:</u> | PACKAGING INFORMATION | <u>N:</u> | | | | |
| | | AFF | IX PACKAGING LABEL HERE | | AFFIX COPY OF O | S AND PRINC | ON HERE IPAL DISPLAY | |
| | | lisa. | | • | PA | NELS) | | |
| | | | Touth in the statement of the statement | | | eening ablets | | |
| | | .77 | | | | Contraction of | 10.3 | |
| | | | | | | Huland Gavy | | |
| | | | | , 1 | | Teething Tablets | | |
| | | 28 | 777777777 | | The second of th | | | |
| | | | , r. 12-13-13-13-13-13-13-13-13-13-13-13-13-13- | | | | | |
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| | | | | | | | | |
| Individu | <u>SECTION</u> al Cas | | CORRECTIVE ACTION: Eety Report | | | | | DSS |
| | | | | | | - | | JUN 1 0 2013 |
| | | 80.01 | | | | | | |
| | 93423 | 00-01 | -00-00 | | | | | |
| | CORREC | TIVE AC | CTION(S) COMPLETED BY: | | | DATE: | | |
| | SECTION | ı IV- | . (| | | | | DSS |
| | | | | RICH | A. | | the mile of | DSS JUN P 2013 |
| | REVIEWE | ED BY M | IANAGEMENT BY: 10 | NOT ACK | | DATE: _ | 06-04-13 | |
| | BY: | | QA / QC DIRECTOR | 3 | | DATE: | FILAI | 0 7 2013 |
| | | | | | | | JUN | U / 2013 |

| F | | D: 9410155 No. 0910-0291, Expires: 10/31/08 See OMB statement on reverse. |
|--------------|-------|---|
| Mfr Report # | 54973 | |

| | See OMB statement on revers |
|----------------------|-----------------------------|
| Mfr Report # 54 73 | |
| UF/Importer Report # | |
| | |

| | 1 C 27 20007 (10/00) | | . ugo _ |
|------------------------------|---|----------------------|----------------|
| | A. PATIENT INFORMATION | | |
| | 1. Patient identifier 2. Age at Time (b) (6) of Event: | 3. Sex | 4. Weight |
| | or ——————— | Female | lbs |
| | Date | | or |
| | In confidence of Birth: | × Male | kgs |
| | B. ADVERSE EVENT OR PRODUCT PROBLE | EM | |
| | 1. Adverse Event and/or Product Problem | e.a., defects/malf | unctions) |
| | 2. Outcomes Attributed to Adverse Event | | |
| | (Check all that apply) | | |
| | Death: Disability | or Permanent Da | mage |
| | | al Anomaly/Birth D | efect |
| | Hospitalization - initial or prolonged Other Se | ious (Important M | edical Events) |
| | Required Intervention to Prevent Permanent Impairment | nt/Damage (Device | es) |
| | . | s Report (mm/da | |
| | 09/27/2010 | 11/02/2010 | |
| | 5. Describe Event or Problem | (b) (6) | |
| | TOOK 1/4 OF THE BOTTLE ON 9/25 AND TH ER WITH DIFFICULTY BREATHING. RASH O | EN ON N HIPS THAT | WENT TO |
| | STARTED AROUND THE SAME NIGHT AND IS | | |
| | WENT TO ER. GIVEN STEROIDS TO HELP C | | |
| | WENT TO ER. GIVEN STEROIDS TO HELP C AQUAPHOR FOR THE RASH' UNKNOWN ANTI-I | | E; |
| ž | | | |
| \mathbf{Z} | ER PHYSICIAN'S DIAGNOSIS WAS CROUP; D | OCTOR DIDN' | T SEE |
| C | THE RASH. | octon bibi | 1 552 |
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| Y | | | |
| PLEASE TYPE OR USE BLACK INK | | | |
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| 집 | | | |
| | | | |
| - | C. Delevert Testall about the Date to the Co. | | |
| | 6. Relevant Tests/Laboratory Data, Including Dates | | |
| | | | |
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| -1 | | | |
| - | | | |
| -1 | | | |
| - | | | |
| - | | | |
| - | per en el | | |
| ŀ | 7. Other Relevant History, Including Preexisting Medical Co | nditions (e.a., all | eraies. |
| | race, pregnancy, smoking and alcohol use, hepatic/renal dys | function, etc.) | g |
| | | | j |
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|---|-------------------------------|-------------------------------|
| Submission of a report does personnel, user facility, impo caused or contributed to the e | rter, distributor, manufactur | that medical er or product |

| J | | | |
|------------------------------|---------------------|----------------------|-----------------------------|
| 01_4 | | | FDA Use Only |
| C. SUSPECT PRO | DUCT(S) | | |
| 1. Name (Give labeled stre | - , | | |
| #1 HYLAND'S TEET | THING TABLETS | 3 | |
| #2 | | | |
| 2. Dose, Frequency & Ro | ute Used | 3. Therapy Dates (| (If unknown, give duration) |
| #1 1/4 BOTTLE IN | GESTION | from/to (or best e | estimate) |
| #2 | | - | |
| 4. Diagnosis for Use (Indi | ication) | #2 | Abated After Use |
| #1 TEETHING PAIN | • | | ed or Dose Reduced? |
| #2 | | #1 🔀 Y | res No Doesn't |
| 6. Lot # | 7. Exp. Date | #2 Y | es No Doesn't |
| #1 | #1 | 8. Event | Reappeared After |
| | | | oduction? |
| #2 9. NDC# or Unique ID | #2 | #1 L Y | es No Doesn't |
| | 3-7504-1 | #2 🔲 Y | es No Doesn't |
| 10. Concomitant Medical | | | Apply |
| | . roudets and rine | apy Dates (Excises) | realment of eventy |
| | | | |
| | | | |
| | | | |
| D. SUSPECT MEDI | CAL DEVICE | | |
| 1. Brand Name | | | |
| 2. Common Device Name | | | · |
| | | | |
| 3. Manufacturer Name. Ci | tv and State | | |
| | | | |
| 4. Model # | Lot# | | 5. Operator of Device |
| Catalog # | Expiration | Date (mm/dd/yyyy) | Health Professional |
| | | | Lay User/Patient |
| Serial # | Other # | | Other: |
| 6. If Implanted, Give Date | (mm/dd/ssss) | 7 If Evalented Chy | e Date (mm/dd/yyyy) |
| o. Il ampiantou, Give Date | (minuta yyyy) | 7. II Explanted, GIV | e Date (mmod/yyyy) |
| 8. Is this a Single-use Dev | vice that was Repro | cessed and Reused | on a Patient? |
| Yes No | | | |
| 9. If Yes to Item No. 8, Ent | er Name and Addr | ess of Heprocessor | |
| | | | |
| | | | |
| 10. Device Available for E | valuation? (Do not | send to FDA) | |
| Yes No | Returned to Ma | nufacturer on: | (mm/dd/yyyy) |
| 11. Concomitant Medical F | Products and There | apy Dates (Exclude | |
| | | - | , |
| | | | |
| E. INITIAL REPORT | FR | | |
| Name and Address | Phone 4 | (b) (6) | |
| (b) (6) | | | nee_ |
| (b) (b) | | | n92 |
| | | 4 | DD 0.0 |
| | 0.0 | A. | PR 22 2013 |
| | AP | R 1 9 2013 | |
| 2. Health Professional? 3 | . Occupation | 4 In | nitial Reporter Also Sent |
| Yes 🔀 No | MOTHER | APR 1 9 | eport to FDA |
| | | | |

| 941 | (01/00-01/00-02 | |
|--|---|--|
| User Facility Import | er | |
| 3. User Facility or Importer Name/A | ddress | |
| | | |
| | | |
| | | |
| 4. Contact Person | 5. Phone No | umber |
| 6. Date User Facility or 7. | Type of Report | 8. Date of This Report |
| Importer Became | Initial | (mm/dd/yyyy) |
| | Follow-up # | |
| 9. Approximate Age of Device | oblem Codes (Refer to codi | ng manual) |
| Patient Code | - |]-[|
| Device | - |]-[|
| 11. Report Sent to FDA? | 12. Location Where Event | Occurred |
| Yes | ☐ Hospital | Outpatient Diagnostic Facility |
| No (mm/dd/yyyy) | ☐ Home ☐ Nursing Home | Ambulatory |
| 13. Report Sent to Manufacturer? | Outpatient Treatmen | Surgical Facility |
| Yes(mm/dd/yyyy) | Facility Other: | |
| 14. Manufacturer Name/Address | | (Specify) |
| 14. Manufacturer Hameraduss | | |
| | | |
| | | |
| 0 11 11 11 11 11 11 11 11 11 11 11 11 11 | | |
| G. ALL MANUFACTURERS 1. Contact Office - Name/Address (| | 2. Phone Number |
| for Devices) HYLAND'S, INC. | | 310-768-0700 |
| 210 W. 131ST STREET LOS ANGELES, CA 9006 | 51 | 3. Report Source (Check all that apply) |
| | - | Foreign |
| | | Study Literature |
| | | ■ Consumer |
| | | Health Professional |
| Date Received by Manufacturer (mm/dd/yyyy) | 5. (A)NDA # | User Facility Company |
| 10/28/2010 | IND # | Representative Distributor |
| 6. If IND, Give Protocol # | STN# | Other: |
| | PMA/ | |
| 7. Type of Report (Check all that apply) | 510(k) # | |
| 5-day 30-day | Product Yes | |
| 10-day Initial | Pre-1938 Yes OTC Product Yes | |
| 15-day Follow-up # | | |
| 9. Manufacturer Report Number | 8. Adverse Event Term(s) DIFFICULTY BREAT | HING & RASH |
| 54973 RSAE 102810EF -003 | | |
| 11510 | | |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | | TOA GGE GNET | |
|---|--|---|-----------------|
| f_4_ | | | |
| H. DEVICE MANUFAC | TURERS ONLY | | |
| . Type of Reportable Event Death Serious Injury Maifunction Other: | TONENS ONET | 2. If Follow-up Correct Addition Response | • • |
| Not Returned to Manue Yes Evaluation No (Attach page to exprovide code: | facturer Summary Attached | 4. Device Man (mm/yyyy) 5. Labeled for | |
| Results Conclusions | coding manual) |]-[]-[| • |
| Repair In: | otification spection atient Monitoring | Initial Use Reuse Unknown If action reporte 21 USC 350i(f), removal reporti | ed to FDA under |
| 0. Additional Manufactu | rer Narrative | and / or 11. | Corrected Data |
| | | | ·. |
| | | | DSS |

CaseID: 9410155

Department of Health and Human Services Food and Drug Administration - MedWatch 10903 New Hampshire Avenue Building 22, Mail Stop 4447 Silver Spring, MD 20993-0002 OMB Statement:
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Individual Case Safety Report

INT RECORD



| | 941.0155-01-00-03 | CC CC | OMPLAINT#: | RVD102810EF-003 | <u>a sa wa wango yang wasan wasang</u> lan lalah sa mangan sa |
|-----------------|---------------------------------------|--|--------------|------------------|--|
| | ED TOTAL INCOMENTAL | DATE OF | COMPLAINT: | 10/28/10 | The state of the s |
| PRODUCT: | TEETHING TABLETS | | ITEM CODE: | | |
| SIZE: | 125 TABLETS (PK OF 4 THROU | | | THREW AWAY THE | BOTTLE |
| REPORTER: | (b) (6) | | | | |
| ADDRESS: | - | | | | |
| | - | | | | |
| CITY: | - | CTATE | (b) (6) | | |
| COUNTRY: | LIGA | STATE | - | | |
| | USA (b) (6) | ZIP CODI | E: | | |
| PHONE #: | | | | | e e e e e e e e e e e e e e e e e e e |
| E-MAIL: | | (h) | | | |
| NATURE OF COM | PLAINT: TOOK % OF THE BOTTLE | ON 9/25 AND THEN ON (6) WENT TO E | R WITH DIFFI | CULTY BREATHING. | RASH ON HIPS |
| THAT STARTED A | ROUND THE SAME NIGHT AND IS STILL COM | ITINUING. | | | |
| | FOR ADDITIONAL SPACE D | EASE USE REVERSE OR ATTACH A SE | DADATE CUE | | |
| | FOR ADDITIONAL SPACE FL | EASE USE REVERSE UR ATTACH A SE | PARATE SHE | :E / | |
| PRODUCT RECEIV | VED FOR | | | | \bigcirc |
| INSPECTION: | (CIRCLE ONE) | PRODUCT BEING RET | URNED FOR | | IRCLE ONE |
| | | DATE REQUESTED | PRODUCT BE | RETURNED: | |
| | | | | | |
| | | | UPS CALL | TAG ISSUED: (C | IRCLE ONE |
| | | | | | |
| | | D | ATE PRODUC | T RECEIVED: | |
| SECTION II: | INVESTIGATION | | | | |
| INVESTIGATION: | THIS COMPLAINT WAS TAKEN DU | RING THE TEET RECALL AS A SERVICE | RELATED CO | NCERN AND FORWAR | PDED. |
| DIRECTLY TO THE | E PHARMACIST AND MEDICAL DIRECTOR FO | | | NOENN AND PORWAR | NOED . |
| | | AT TIMEET AE DATA OAT TOILE AND EVA | LOATION. | | |
| | | | | | |
| | | | | | |
| ADVERSE EVENT | FORWARDED TO PHARMACIST / NURSE FO | R EVALUATION ON: | 10/28/10 | | |
| ADVERSE EVENT | FORWARDED TO PHARMACIST / NURSE FO | R EVALUATION BY: | EDYTA FR | RACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| COPPECTIVE ACT | ION(S) COMPLETED BY: | | | | |
| CONNECTIVE ACT | ION(S) COMPLETED BY: | | DATE: | | * + * F |
| SECTION IV: | ADVERSE EVENT REPORTS | | AE #; | RAE102810EF-003 | |
| | | 1 | • | | |
| ADVERSE EVENT | SERIOUS: Y / N |) | | er. | |
| ADVERSE EVENT | REPORTED ON: 10/28/10 | BY: ED | YTA FRACKIE | WICZ | |
| SECTION V: | | $\mathcal{M} = \mathcal{O}(\mathcal{M})$ | | | RAS |
| REVIEWED BY MAI | NAGEMENT RY: | MULS 4 (U.) | 2455 | مادول | azz |
| | | | DATE: _ | 116210 | 100 |
| BY: N/A | 01.100 BIF | **** | DATE: | | <u>^</u> ~K 22 281 9 |
| <u>.</u> | QA / QC DIRECTOR | | | | |
| cc: QA/QC | Production | | | | |
| Packaging | Shipping / Receiving | | | | Form # VD1 |

Form # VD1



CaseID: 9410155



ENT DATA FORM

| AE #: | RAE102810EF-003 | COMPLAINT # | RVD102810EF- | 003 |
|------------------|--|---|--|---------------------------------|
| SECTION | I: PATIENT INFORMATION (IF DIFFERE | NT FROM REPORTER ON FORM | <u> VD1)</u> | |
| NAME: | (b) (6) - | | | · |
| ADDRESS | | | | |
| CITY: | | STATE: | (b) (6) | |
| COUNTRY PHONE #: | (b) (6) | ZIP CODE: | | |
| E-MAIL: | | | | |
| SECTION | II: PACKAGING INFORMATION: | | | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OU (INCLUDE DRUG FACTS / PAN | TER CARTON HERE AND PRINCIPAL DISPL ELS) | AY |
| | manifestation of processing and of processing depth of the processing depth of | Teething T Tabletas para la la Symptomic Relief for Terbhing to Children What Called State of Terbhing to Children What Called State of Terbhing to Children Symptomic Relief for Terbhing to Children Symptomic Relief for Terbhing to Children Tabletas para la | | |
| SECTION II | II: CORRECTIVE ACTION: | | | |
| | | | | * |
| CORRECTI | VE ACTION(S) COMPLETED BY: | D. | ATE: | |
| SECTION IN | <u>e</u> | 1 /000n | | Dea |
| REVIEWED | BY MANAGEMENT BY: | EUV | DATE: 11 73/10 | DSS APR 22 2013 |
| BY: | QA / QC DIRECTOR | | DATE: | ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ |

CaseID: 9412421



9412421-01-00-01

or use by user-facilities, , distributors and manufacturers for MANDATORY reporting

| Form Approved: OM | B No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse. |
|----------------------|--|
| Mfr Report # 54973 | |
| UF/Importer Report # | |

MEDAAY ICH

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| reporting | To miliporta | sport if | |
|---|--|---|--|
| 4 | | | FDA Use On |
| C. SUSPECT PROD | UCT(S) | | PDA USE ON |
| . Name (Give labeled street | _ | | |
| #1 HYLAND'S BABY | TEETHING TA | ABLETS | |
| #2 | | | |
| 2. Dose, Frequency & Rou | ute Used | 3. Therapy Dat from/to (or be | tes (If unknown, give duration est estimate) |
| #1 2-3 TABS ONCE | DAY X 2WKS | #1 | |
| #2 | | #2 | |
| Diagnosis for Use (India | • | S+. | ent Abated After Use opped or Dose Reduced? |
| #1 TEMP RELIEF TE | SETHING PAIN | I | Yes No Doesn |
| #2 | T- a | #2 「 | Tyes Doesn |
| 5. Lot# #4114193 | 7. Exp. Date | | Арріу |
| #1114193 | #1 | | ent Reappeared After eintroduction? |
| #2 | #2 | #1 [| Yes No Doesn |
| 9. NDC# or Unique ID 54973-3127-1 | | #2 [| Yes No Doesn |
| 0. Concomitant Medical F | Products and Ther | apy Dates (Exclu | ude treatment of event) |
| . Brand Name | | | |
| . Common Device Name | y and State | | |
| . Common Device Name 3. Manufacturer Name, Cit | y and State | | 5. Operator of Device |
| . Common Device Name 3. Manufacturer Name, Cit | Lot # | Date (mm/dd/yy | Health Professional |
| Common Device Name Manufacturer Name, Cit Model # Catalog # | Lot # | Date (mm/dd/yy | Health Professional Lay User/Patient |
| . Common Device Name . Manufacturer Name, Cit . Model # | Lot # | ı Date (<i>mm/dd/yy</i> | Health Professional |
| . Common Device Name . Manufacturer Name, Cit . Model # Catalog # | Lot # Expiration Other # | | Health Professional Lay User/Patient |
| Common Device Name Manufacturer Name, Cit Model # Catalog # Serial # | Lot # Expiration Other # (mm/dd/yyyy) | 7. If Explanted, | Health Professional Lay User/Patient Other: Give Date (mm/dd/yyyy) |
| Common Device Name Manufacturer Name, Cit Model # Catalog # Serial # | Lot # Expiration Other # (mm/dd/yyyy) | 7. If Explanted, | Health Professional Lay User/Patient Other: Give Date (mm/dd/yyyy) |
| Common Device Name Manufacturer Name, Cit Model # Catalog # Serial # If Implanted, Give Date (| Lot # Expiration Other # (mm/dd/yyyy) Ice that was Repro | 7. If Explanted, | Health Professional Lay User/Patient Other: Give Date (mm/dd/yyyy) used on a Patient? DSS |
| 2. Common Device Name 3. Manufacturer Name, Cit 4. Model # Catalog # Serial # If Implanted, Give Date (Is this a Single-use Devi | Lot # Expiration Other # (mm/dd/yyyy) Ice that was Repro | 7. If Explanted, | Health Professional Lay User/Patient Other: Give Date (mm/dd/yyyy) used on a Patient? |
| 2. Common Device Name 3. Manufacturer Name, Cit 4. Model # Catalog # Serial # If Implanted, Give Date (Is this a Single-use Devi | Lot # Expiration Other # (mm/dd/yyyy) Ice that was Repro | 7. If Explanted, | Health Professional Lay User/Patient Other: Give Date (mm/dd/yyyy) used on a Patient? DSS |
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| Catalog # Serial # If Implanted, Give Date (Yes No. 8, Enter | Lot # Expiration Other # (mm/dd/yyyy) Ice that was Repro | 7. If Explanted, ocessed and Ret ess of Reproces send to FDA) | Health Professional Lay User/Patient Other: Give Date (mm/dd/yyyy) Used on a Patient? DSS JUN 1 0 6 (mm/dd/yy) (mm/dd/yy) 20 4 |
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2. Health Professional? 3. Occupation

Yes No

Initial Reporter Also Sent Report to FDA

Yes No Unk

| FORM FDA 350 | 0A (6/10) | | | Page |
|---|---|---|---|--|
| A. PATIENT INF | ORMATION | | | |
| 1. Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight |
| (b) (6) | of Event: | Months | l | |
| | or | | Female | or lb |
| In confidence | Date of Birth: | | ✓ Male | kg: |
| | VENT OR PRODUC | T PROBLE | M | |
| | | | | |
| 1. ✓ Adverse Even | | duct Problem (e | .g., defects/malf | unctions) |
| 2. Outcomes Attribut (Check all that appl | ted to Adverse Event | | | |
| Death: | ** | ☐ Disability o | r Permanent Da | mace |
| Life-threatenin | (mm/dd/yyyy) | | | - |
| 1 🖰 | • | _ • | Anomaly/Birth E ous (Important M | |
| 1 - | n - initial or prolonged vention to Prevent Perma | | | |
| | | | • ' | |
| 3. Date of Event (mn | | 4. Date of This | | |
| | 00/2013 | | 06/03/2013 | |
| 5. Describe Event or | Problem | | | |
| HAS HAD 3 DOST SINCE 1 1/2 WISHE THOUGHT IS (OATMEAL) SINCE MAY 10, 2013, DOSE OF BABY TO NOTICED IN THE HEAD PULLS AW AS THOUGH HE SHE THOUGHT MAS HER SON LOC VERY SENSITIVE SEEING DOCTORY SEEING DOCTORY SEEING TO THE SEEING DOCTORY | AND WAS GIVEN TEETHING TABLET: E LAST 2 DAYS C: AY WHILE NURSING SEES SOMETHING AYBE CAFFEINE W. OKED LIKE HE WA: E TO SOAPS AND I Y TODAY. TODAY. TODAY. TOTAL VITAM PRE-NATAL VITAM | HING TABLE ICED CONST INTRODUCT LD HAD THI 3 Q 5. MO 5 3 - 4 DA HILD AT NI G, WIDE EYI (MOTHER COI AS IN HER N S ON CAFFE HER ALLERG Dates | IS SINCE 3 IPATION, D ION OF SOL RD IMMUNIC THER GAVE YS AGO. S GHT IS "JI" ED, LOOK U NSIDERED A MILK ACCID INE. MOTH IES. SHE | RY SKIN. ID FOOD ATION ON LAST HE ITTERY", P AROUND GHOST). ENTALLY ER IS IS |
| personnel, user fac | port does not cons cility, importer, dist | titute an adm | nission that r | nedical product |

Individual Case Safety Report

9412421-01-00-02

FDA USE ONLY Page 2 of 4

CaseID: 9412421

| E FOR USE OV | | | | rage | | | | | | - | | |
|--|----------------|------------------|--------------|--|---------------|---------------------------------|-------------|------------------|----------------------------|--|--------------------------|---------------|
| F. FOR USE BY U | JSER FA | | | | _ | DEVICE MAN | | JRERS ON | | | | |
| User Facility | [] Impo | | r/importer i | Report Number | [.] | ype of Reportable | Event | | | 2. If Follow-up, | | 7 |
| 3. User Facility or Imp | | | | | 1 | Death Serious Injury | | | | Correcti | | |
| l com rading or map | | 71221000 | | | 11 | Malfunction | | | | | nal Informati | |
| | | | | Other: | | | | | ise to FDA F Evaluation | request | | |
| | | | | | | | | _ | | | | |
| | | | | | 3. 6 | Pevice Evaluated by | | | | Device Manuf (mm/yyyy) | facture Dat | e |
| 4. Contact Person | | | 5. Phone N | umber | 11 | Not Returned to | | | . | | | |
| T. Contact reson | | | o. Priorie i | umber | <u> </u> | = - | | mmary Attache | | 5. Labeled for S | ingle Hee? | |
| 6. Date User Facility or | r 7 | 7. Type of Repor | rt | 8. Date of This Report | 1 | No (Attach pag provide code: | де то ехріа | in why not) or | | _ | _ | |
| Importer Became Aware of Event (mm | vdd/yyyy) | ☐ Initial | | (mm/dd/yyyy) | | | | | | Yes | ∐ No | |
| | | Follow-up# | | | 6. E | valuation Codes (| Refer to co | ding manual) | <u> </u> | V | | |
| 9. Approximate | 10 Event P | Problem Codes (| | ng manual) | | Method | , [| | <u> </u> | | | 1 |
| Age of Device | _ | | | ng manual) | | | · | $\exists \vdash$ | | | |] |
| | Patient Code | | -[| | | Results | s [|]-[| | | | |
| | Device | | _ | 1- | | Conclusions | | | | _[| |] |
| 11. Report Sent to FDA | Code L | 12. Location W | lhara Evant | | | | | | | | | <u> </u> |
| | • • | Hospita | | Outpatient | ′." | Remedial Action I | _ | | 8. 0 | Isage of Device Initial Use o | of Daviso | |
| Yes(mm/dd/ | (уууу) | Home | - | Diagnostic Facility | Н | Recall | Notific | | | Reuse | ii Device | |
| No 13. Report Sent to Man | ufacturer? | Nursing | Home | Ambulatory Surgical Facility | | Repair Replace | ☐ Inspe | nt Monitoring | | Unknown | | |
| | idiactar er i | | ent Treatmer | | | Relabeling | _ | ication/ | 9. If | action reported | to FDA un | der |
| Yes(mm/dd/ | <i>'yyyy</i>) | Facility Other: | | | П | | | tment | l 2º | 1 USC 360i(f), lis emoval reporting | it correction number: | n/ |
| | | | | (Specify) | | Other: | | | - | | | |
| 14. Manufacturer Name | e/Address | | | | ١∟ | | | | | | | |
| | | | | | 10. | Additional Man | nufacturer | Narrative | and. | /or 11. | Correcte | d Data |
| | | | | | | | | | | | | |
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| G. ALL MANUFA | | | | | | | | | | | | |
| Contact Office - Nam for Devices) | ne/Address | (and Manufactur | ring Site | 2. Phone Number | | | | | | | | |
| DUMM COULD | | | | 310-768-0700 | | | | | | | | |
| TUTTI GOULD HYLAND'S, INC. | | | | Report Source (Check all that apply) | | | | | | | | |
| 154 W. 131ST | | | | Foreign | | | | | | | | |
| LOS ANGELES, | CA 9006 | 51 | | Study | | | | | | | Do | 0 |
| | | | | Literature | | | | | | | D3 | S |
| | | | | Consumer Health Professional | | | | | | | | |
| | | | | User Facility | | | | | | • | JUN 1 | U 2011 |
| Date Received by Manufacturer (mm/de | ∜ yyyy) | 5. | | Company | | | | | | | | |
| 05/23/20 | 13 | (A)NDA # | | Representative | | | | | | | | |
| 6. If IND, Give Protocol | # | IND# | | Distributor | | | | | | | | |
| | | STN# | | Other: | | | | | | | _ | ٠. ا |
| 7. Type of Report | | PMA/ 510(k) # | | | | | | | | | DS | 2 |
| (Check all that apply) | | 510(k) # | | | | | | | | | | |
| 5-day 30-day | | Product | Yes | | | | | | | JU | DSS N | 2012 |
| 7-day Period | JC . | Pre-1938 | Yes | | | | | | | | • | -0.13 |
| ☐ 10-day 🛣 Initial | -up # | OTC Product | ✓ Yes | | | | | | | | | |
| 9. Manufacturer Report | | 8. Adverse Eve | ent Term(s) | | | | | 7811 | ias - | | | |
| 54973 AE # 138 | | CONSTIPATI | | SKIN | | | | a (| 14 E | 7 2013 | | |
| | - | | | | | | | | | | | |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



CUSTOMER COMPLAINT RECORD



| | * | | | | OMPLAINT #: | 2338 | | |
|--|--|--|---|---|---|---|--|--------------|
| TAKEN BY: | | TUTTI GOULD | | DATE OF | COMPLAINT: | 05/23/13 | | |
| PRODUCT: | | HYLAND'S BABY TE | ETHING TABLETS | | ITEM CODE: | BTET-T135 | | |
| SIZE: | (b) (6) | 135 TABLETS | | | LOT NO.: | 114193 | | |
| REPORTER: | | | | | | | | |
| ADDRESS: | | | | | | | | |
| CITY: | | | | STATE | (b) (6) | | | |
| OUNTRY: | USA | | | ZIP COD | | | | |
| HONE #: | (b) (6) | | | | | | | |
| EAD PULLS AW HOUGHT MAYB OAPS AND HER | INTRODUCT AVE LAST DO AYWHILE N E CAFFEINE ALLERGIES | IABLETS SING ION OF SOLID FOOD DSE OF BABY TEETHI URSING, WIDE EYED, WAS IN HER MILK AC S SHE IS SEEING DO S AND .05 MG SYNTHE | CE 3 WEEKS. SINCE 1 MON (OATMEAL) SINCE 1 MON NG TABLETS 3 - 4 DAYS LOOK UP AROUND AS T CCIDENTALLY AS HER SC CTOR TODAY. CHILD HA ROID AT TIME OF INCIDE | NTED INFORMATION. CHIL WEEKS MOTHER NOTICE! ITH. CHILD HAD THIRD IM AGO. SHE NOTICED IN TH HOUGH HE SEES SOMETH IN LOOKED LIKE HE WAS I S BEEN GIVEN 2 - 3 TABLE NT. | D CONSTIPATI IMUNIZATION (HE LAST 2 DAY HING (MOTHER ON CAFFEINE. ETS, ONCE A [| ON, DRY SKIN. ON MAY 10, 201 'S CHILD AT NIC CONSIDERED MOTHER IS VI DAY FOR 2 WEE | SHE THOUGHT 3 AND WAS GIV 3HT IS "JITTERY A GHOST). SHE | EN 3 |
| | | FOR ADDITIONAL | L SPACE PLEASE USE RI | EVERSE OR ATTACH A SE | PARATE SHE | ET | | |
| RODUCT RECEINSPECTION: | VED FOR | Y (CIRC | LE ONE) | PRODUCT BEING RET | | | (CIRCLE ON | 2 |
| | | | RECEIVE | DATE REQUESTED | | - | y (1 | 1) |
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cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

CaseID: 9412421



DISTRIBUTION: FDA

ADVERSE EVENT FILE



FORM SAE01

SERIOUS ADVERSE EVENT DATA FORM

| | | | | T#: _2338 | |
|---|--|---|--|--|-----------------|
| SECTION I: | PATIENT INFO | ORMATION (IF DIFFERE | NT FROM REPORTER ON FO | RM VD1) | |
| NAME: | (b) (6) | | | | |
| ADDRESS: | | | | | |
| | | | | 11.10 | |
| CITY: | | | STATE | (b) (6) :: | |
| COUNTRY: | USA (b) (6) | | ZIP COD | E: | |
| PHONE #: E-MAIL: | | | | | |
| E-MAIL. | | | | | ***** |
| SECTION II: | PACKAGING II | NFORMATION: | | | |
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FURM FDA 3355A (3. 15)

| A. PATIENT INF | ORMATION | | | |
|-----------------------|---|------------------|--------------------|-----------------|
| Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight |
| (b) (6) | of Event: 7 | Months | | lbs |
| | or | | Female | or ibs |
| In confidence | Date of Birth: | | ✓ Male | kgs |
| 1 | VENT OR PRODUC | T PROBLE | И | |
| | | duct Problem (e | | unctions) |
| 1. Adverse Even | ted to Adverse Event | duct Problem (e | .g., uelectarilari | andions, |
| (Check all that appl | | | | |
| Death: | | Disability o | r Permanent Da | mage |
| Life-threatenin | (mm/dd/yyyy) | Congenital | Anomaly/Birth (| Defect |
| Hospitalization | n - initial or prolonged | Other Serie | ous (Important M | tedical Events) |
| Required Inter | rvention to Prevent Perma | anent Impairment | /Damage (Device | es) |
| 3. Date of Event (mr. | n/dd/yyyy) | 4. Date of This | Report (mm/de | <i>√уууу)</i> |
| | - 03/31/2013 | | 05/31/2013 | 3 |
| 5. Describe Event or | Problem | | | |
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| 6. Relevant Tests/La | aboratory Data, Includin | g Dates | | |
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| 7. Other Relevant Hi | istory, Including Preexistmoking and alcohol use, | sting Medical Co | onditions (e.g., a | allergies, |
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Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse.

CaseID: 9412536

ser-facilities, rs and manufacturers DRY reporting

| Mfr Report # 54973 | |
|----------------------|--|
| UF/Importer Report # | |
| | |

| 4 | | | | 50 4 Hora Onl |
|-----------------------------------|--------------------|------------------|---------------|---|
| C. SUSPECT P | RODUCT(S) | | | FDA Use Onl |
| 1. Name (Give labele | | beler) | | |
| #1 HYLAND'S B | BABY TEETHIN | IG TABLETS | | |
| #2 | | | | |
| 2. Dose, Frequency | & Route Used | | apy Dates (If | unknown, give duration |
| #13 TABS HS | ONCE IN WHI | | 0 (0 2031 631 | nna.e) |
| #2 | | #2 | | |
| 4. Diagnosis for Use | (Indication) | | | bated After Use |
| #1 TEMP RELIE | F TEETHING | PAIN | #1 Ve | d or Dose Reduced? |
| #2 | | | | — Apply |
| 6. Lot# | 7. Exp. Da | ate | #2 Ye | s ∐ No ∐ Apply |
| #1115412 | #1 | | | eappeared After duction? |
| #2 | #2 | | _ #1 ☐ Ye | s No Doesr |
| 9. NDC# or Unique | | | #2 Ye | s No Does |
| 54973-3127- 10. Concomitant Me | | ad Thomas Date | | - С - Доргу |
| | | | | |
| | | | | |
| | | | | |
| D. SUSPECT N | EDICAL DEV | ICE | | |
| 1. Brand Name | | | | |
| 2. Common Device | Name | | | |
| Z. Common Davido | | | | |
| 3. Manufacturer Na | me, City and State | e | | |
| | | | | |
| 4. Model# | Lo | t# | ľ | 5. Operator of Device |
| Catalog # | Ex | piration Date (n | nn/dd/yyyy) | ☐ Health Profession: ☐ Lay User/Patient |
| Coriol # | | thor # | | Other: |
| Serial # | | ther # | 1 | |
| 6. If Implanted, Give | Date (mm/dd/yyy | (y) 7. If Ex | planted, Give | Date (mm/dd/yyyy) |
| 8. Is this a Single-u | se Device that wa | s Reprocessed | and Reused | on a Patient? |
| | | | | |
| 9. If Yes to Item No. | 8, Enter Name a | nd Address of R | eprocess | 22 |
| | | | | J |
| | | | JUN | 1 0 2013 |
| 10. Device Available | o for Evaluation? | (Do not send to | FDA) | |
| Yes 1 | Jo □ Return | ed to Manufactur | rer on: | |
| 11. Concomitant Me | | led to Mandiactu | | (mm/dd/y) |
| - | _ | | | |
| | _ | | | |
| | _ | | | |
| E. INITIAL REF | edical Products a | | | |
| E. INITIAL REF | edical Products a | | es (Exclude f | |
| | edical Products a | nd Therapy Date | es (Exclude f | |
| | edical Products a | nd Therapy Date | es (Exclude f | |
| 1. Name and Addre | edical Products a | nd Therapy Date | es (Exclude f | |
| 1. Name and Addre | edical Products a | nd Therapy Date | es (Exclude f | |
| 1. Name and Addre | edical Products a | Phone # (b) (6) | es (Exclude t | JUN \$20 |
| 1. Name and Addre | edical Products a | Phone # (b) (6) | es (Exclude t | <u> </u> |

JUN 0 7 2013

FDA USE ONLY



| 97 | 412536-01-00 | 0-02 | ≥ of 4 | 1 |
|---|--|--|--|--|
| F. FOR USE BY USEF | R FACILITY/IMPOR | RTER (Devices Only) | H. DEVICE MANUFACTURERS ONLY | |
| 1. Check One | 2. UF Importer | Amporter Report Number | 1. Type of Reportable Event Death Serious Injury Malfunction Other: 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer | 2. If Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation 4. Device Manufacture Date (mm/yyyy) |
| Contact Person Date User Facility or Importer Became Aware of Event (mm/dd/y) | 7. Type of Report | 8. Date of This Report (mm/dd/yyyy) | Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: 6. Evaluation Codes (Refer to coding manual) | 5. Labeled for Single Use? Yes No |
| 9. Approximate Age of Device Patie Code Devi Cod 11. Report Sent to FDA? Yes No 13. Report Sent to Manufac Yes No 14. Manufacturer Name/Add | ent | here Event Occurred Outpatient Diagnostic Facility Home Surgical Facility | Recall Notification Repair Inspection Replace Patient Monitoring Relabeling Modification/ Adjustment Other: | 8. Usage of Device Initial Use of Device Reuse Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: and/or 11. Corrected Data |
| G. ALL MANUFACT 1. Contact Office - Name/A for Devices) EDYTA FRACKIEWICH HYLAND'S, INC. 154 W. 131ST STE LOS ANGELES, CA 4. Date Received by Manufacturer (mm/dd/yy) 35/24/2013 6. If IND, Give Protocol # | CZ REET 90061 5. (A)NDA # ND # STN # PMA/ 510(k) # Combination | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: | | DSS JUN 1 0 2013 DSS JUN 2 |
| 5-day 30-day 7-day Periodic 10-day Initial 15-day Follow-up 9. Manufacturer Report No. 54973 AE # 1388 | p # OTC Product umber 8. Adverse E SETZURES | Yes t Yes went Term(s) | | |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

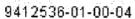
PLAINT RECORD



| 9412536-01-00-03 | COMPLAINT #: | 2340 |
|--|---|--|
| AKEN BY: EDY IA FRACKIEWICZ | DATE OF COMPLAINT: | 05/24/13 |
| PRODUCT: HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT250 |
| SIZE: 250 TABLETS | LOT NO.: | 115412 |
| (b) (6) (EPORTER: | | |
| ADDRESS: | | |
| | | |
| CITY: | STATE: (b) (6) | |
| COUNTRY: USA | ZIP CODE: | |
| (b) (6) PHONE #: | | |
| -MAIL: CHILD WAS 7 MONTHS OLD AT THE TIME. T | | |
| FEBRUARY / MARCH 2013 CHILD WAS TWITT VENT TO DOCTOR AND DOCTOR THOUGHT IT WAS A "LITTLE SEIZURE", BUT D MARCH 2013 AND REACTIONS STOPPED. REACTIONS WERE DURING THE DAY TIME. DOES NOT WANT A REFUND. WANTS TO KNOW WHY BELLADONNA IS IN EXPLAINED THE INGREDIENTS IN PRODUCT TO HER IN DETAIL, EXPLAINED THE | CHING AND JERKING IN EYES AND ID NOT FEEL A NEED TO DO TEST AND BECOMING MORE FREQUEN I THE PRODUCT. WANTS BELLADO HE HPUS AND THE FACT THAT HO | D NECK; LOOKS LIKE SPASMS. STOPPED USING PRODUCT IN IT. NO FEVER OR ILLNESS AT THE DNNA REMOVED FROM PRODUCT. MEOPATHY IS FDA REGULATED. |
| FOR ADDITIONAL SPACE PLEASE USE REVER | SE OR ATTACH A SEPARATE SHI | SET |
| PRODUCT RECEIVED FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | (CIRCLE ONE) |
| DECEIV | DATE REQUESTED PRODUCT B | |
| RECEIV | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| JUN 07 20 | 13 DATE PRODUC | CT RECEIVED: |
| SECTION II: INVESTIGATION | | |
| INVESTIGATION: REVIEWED BATCH RECORDS. MANUFACTURING A | ND PACKAGING WERE DONE ACC | ORDING TO ESTABLISHED PROCE- |
| DURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED AND EVERYTH | | |
| | · . | |
| | | |
| | | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION OF | N:05/24/13 | |
| | | FRACKIEWICZ |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B | | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B | | FRACKIEWICZ |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B | | PRACKIEWICZ DS: |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B | | FRACKIEWICZ |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B | | PRACKIEWICZ DS: |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B' SECTION III: CORRECTIVE ACTION: | Y: EDYTA I | PRACKIEWICZ DS: |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION B' SECTION III: CORRECTIVE ACTION; CORRECTIVE ACTION(S) COMPLETED BY: | Y: EDYTA I | DS: |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY SECTION III: CORRECTIVE ACTION; CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS | Y: EDYTA I | DS: JUN 1 0 |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY SECTION III: CORRECTIVE ACTION; CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS ADVERSE EVENT SERIOUS: | DATE: | DS: JUN 1 0 |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS | Y: EDYTA I | DS: JUN 1 0 |
| CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS ADVERSE EVENT SERIOUS: Y N | DATE: BY: EDYTA FRAC | DS: JUN 1 0 |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY SECTION III: CORRECTIVE ACTION; CORRECTIVE ACTION; CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED ON: 05/24/13 | DATE: BY: EDYTA FRAC | DS: JUN 1 0 |

cc: QA/QC Packaging Production Shipping / Receiving JUN 0 7 2013 Form# VD1







EVENT DATA FORM

| AE #: | 1388 | COMPLAINT #: 2340 | - |
|--|---|--|--------------------------|
| SECTION I | | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | | (b) (6) | |
| ADDRESS | : | | |
| | | OTATE. | |
| CITY: | | USA STATE: | |
| COUNTRY PHONE #: | • | (b) (6) | |
| E-MAIL: | | | |
| | | | |
| SECTION | <u>ll:</u> | PACKAGING INFORMATION: | |
| | AFF | IX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| Individual Control of the Control of | or Improviduation of the control of | Multipliance Section Section | |
| SECTION | <u>III:</u> | | DSS IN 1 0 2013 |
| | | | |
| CORRECT | TIVE AC | CTION(S) COMPLETED BY: DATE: | DSS JUN D 2013 |
| SECTION REVIEWE | | IANAGEMENT BY: DATE: 00-04-13 | |
| BY: _ | · · · · · · · · · · · · · · · · · · · | QA / QC DIRECTOR DATE: JUN 0 7 201 | 3 |

of use of use facilities, distributors and manufacturers MANDATORY reporting

| CaseID: 94 | 412646 |
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| Cascib. 34 12040 | |
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| orm Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse. | |
| | |

| | See OMB statement on rever |
|----------------------|----------------------------|
| Mfr Report# 54973 | |
| | |
| UF/Importer Report # | |
| | |

PLEASE TYPE OR USE BLACK INK

| | DA (6/10) | | | 4 | Page |
|-----------------------------------|--------------------------|-----------|----------------|-------------------------------------|---------------------------------------|
| . PATIENT INF | ORMATION | | | | |
| | 2. Age at Time of Event: | | | 3. Sex | 4. Weight |
| (6) | or | 4 M | onths. | Female | lbs |
| la confidênce | Date of Birth: | | | Male | or |
| In confidence ADVERSE EV | of Birth: /ENT OR PR(| ODUCT | PROBLEM | | kgs |
| _ | | | | | |
| ✓ Adverse Event Outcomes Attribut | | | et Problem (e. | g., defects/malf | unctions) |
| (Check all that appl) | | | _ | | |
| Death: | (mm/dd/yyyy) | [| Disability or | Permanent Da | mage |
| Life-threatenin | _ | | | Anomaly/Birth [| |
| ٠ ـ | - initial or prolong | _ | _ | es (Important M | |
| | vention to Prevent | | | | |
| Date of Event (mm 05/1 | .9/2013 | 4. | | Report (mm/dd 06/03/2013 | |
| Describe Event or | | | | , | |
| HILD SEEMS TO | O 11770E 7 EE | יים מקוע | FDV THE | CHE TAMES | |
| EETHING GEL I | | | | HER STOPPE | |
| ODAY, 05/25/ | 13. FEVER | IS LES | S BUT SHE | E IS PERSE | IRING. |
| OSPITALIZED I | FOR 3 DAYS. | FEVE | R GOES FE | ROM 98F TO | 104F. |
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| Relevant Tests/Lai | boratory Data, In | cluding D | ates | ! |) (|
| Relevant Tests/Lai | boratory Data, Ind | cluding D | ates | į | # # # # # # # # # # # # # # # # # # # |
| Relevant Tests/Lat | boratory Data, In | cluding D | ates | į. | |
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| f <u>4</u> | ' | | | FDA Use Only |
| C. SUSPECT PROD | · · · · · · · · · · · · · · · · · · · | | | |
| Name (Give labeled stren #1 HYLAND'S TEETH | - | | | |
| #2 TYLENOL | | | | |
| 2. Dose, Frequency & Rou | te Used | 3. Therapy I | Dates (If unknown, | give duration) |
| #1 SWABS GUM Q 1 | | from/to (or #1 | r best estimate) | |
| | | | | |
| #2 4. Diagnosis for Use (Indic | antion) | #2 | Event Abated Aft | or Hea |
| #1 TEMP RELIEF TE | | 3. | Stopped or Dose | Reduced? |
| | | #1 | 1 ✓ Yes ☐ No | Doesn't Apply |
| #2 6. Lot # | 7. Exp. Date | | 2 Yes No | Doesn't Apply |
| #1130135A | #1 | 8. | Event Reappeare | |
| | | | Reintroduction? | Doorn't |
| #2 9. NDC# or Unique ID | #2 | | 1 Yes No | Apply |
| 54973-7521-2 | • | #2 | 2 Yes No | Doesn't Apply |
| 10. Concomitant Medical F | Products and Ther | apy Dates (E | xclude treatment o | |
| | | | | |
| * | | | | |
| | | | | |
| D. SUSPECT MEDIC | AL DEVICE | | | |
| 1. Brand Name | AL DEVICE | • | | |
| | | | | |
| 2. Common Device Name | | | | |
| 3. Manufacturer Name, Cit | ty and State | | | |
| . (| 1 | | | |
| 4. Model# | Lot# | | 5. Operate | or of Device |
| Catalog # | Expiration | Date (mm/de | d/vvvv) | h Professional |
| | i. | | Lay | Jser/Patient |
| Serial # | Other# | | Othe | r: |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explant | ted, Give Date (mr | n/dd/yyyy) |
| | | | , | 1 |
| 8. Is this a Single-use Dev | ice that was Repr | ocessed and | Reused on a Pati | ent? |
| 9. If Yes No. 8, Ent | er Name and Add | ress of Repro | ocessor | |
| | 1 | | | |
| (株) | | | | |
| 10. Device Available for Ev | valuation? (Do col | send to EDA) | ı ' | 1 2 |
| Yes No | Returned to M | | | |
| | | | (mm/dd/ | |
| 11. Concomitant Medical F | roducts and The | apy Dates (£ | exclude treatment o | v event) |
| | | | | |
| <u> </u> | 14 PA | | | |
| E. INITIAL REPORT 1: Name and Address | | # (b) (6) | | |
| . righte and riddless | 7.1 | " (b) (6) | | DSS 19 ₂₀₁₃ |
| (b) (6) | 4/1 | \' / | . | ~0 0. |
| | Щ | | - JUN | 1020 |
| | | | | - 02013 |
| | | | | |
| 2. Health Professional? | 3. Occupation | | | rter Also Sent |
| Yes 🗸 No | | | Report to F | DA No o Unk. |
| | | | | |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

JUN 1 8 2013

[] Importer

3. User Facility or Importer Name/Address

Check One
 User Facility

4. Contact Person

Approximate Age of Device

Yes _

☐ No

Yes

No.

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

> Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

154 W. 131ST STREET LOS ANGELES, CA 90061

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

7-day

5-day 30-day

10-day Initial

54973 AE # 1387

15-day Follow-up #

9. Manufacturer Report Number

05/25/2013

Periodic

TUTTI GOULD HYLAND'S, INC.

1. Contact Office - Name/Address (and Manufacturing Site

... ON USE BY USER PACILITY INIPORTER (Devices Unly)

7. Type of Report

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700 3. Report Source (Check all that apply)

Foreign

Company Representative

Distributor

Other:

Study
Literature
Consumer
Health Professional
User Facility

(mm/dd/yyyy)

Page 2 of ⁴

| : | FDA USE ONLY |
|---|--|
| 4 | |
| LL DEVICE MANUE ACTURERS ONLY | |
| H. DEVICE MANUFACTURERS ONLY | |
| 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| 2. Device Supported by Manufacturer? | 4. Device Manufacture Date |
| 3. Device Evaluated by Manufacturer? | (mm/yyyy) |
| Not Returned to Manufacturer | |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| provide code. | Yes No |
| | |
| 6. Evaluation Codes (Refer to coding manual) | |
| Method - | 7_ |
| welloo | |
| Results | - |
| | |
| Conclusions - | - - |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| | ☐ Initial Use of Device |
| Recall Notification | |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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CaseID: 9412646

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#_

Yes

Yes

STN# PMA/

510(k) # ___ Combination Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)

SPIKES FEVER

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

Please DO NOT RETURN this form to this address.

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CUSTOMER COMPLAINT RECORD



| SECTION I: | COMPLAINT | | | COMPLAINT #: | 2339 | | |
|--|--|--|---|--|--------------------------------|------------------------|---|
| TAKEN BY: | TUTTI GOU | ILD | ; | DATE OF COMPLAINT: | 05/25/13 | egy mys temperada affa | |
| PRODUCT: | TEETHING | GEL STEE |) | ITEM CODE: | TGELU0.5Z | | _ |
| SIZE: | 0.5 OUN 35 | ECEIVER | | LOT NO.: | 130135A | | · |
| REPORTER: | 0) (6) | 2013 | | | | , | |
| ADDRESS: | | JUN 1 7 2013 | | | | | |
| _ | | cnR | | | | | |
| CITY: | | Chi | | STATE: | | | |
| | USA | | | ZIP CODE: | | | _ |
| PHONE #: | (b) (6) | | ., | | | | |
| E-MAIL: | | | | | | | |
| CARA FOR ADARES SAITS | IE IS LESS FEVERIS NT TO HOSPITAL AN ABS ON GUM EVER | D "RUNS A TEMPERATURE" SH (98°F) BUT IS PERSPIRING ND DOCTORS. THEY THINK Y 1 – 2 X 1 DAY WHEN IRRIT, DDITIONAL SPACE PLEASE (| G. STILL HAS FEVER IT'S EVERY GEL. TA ABLE. ADVISED MOT | , LAST DOSE, SHE SETT KING TYLENOL FOR FEV THER TO DISCONTINUE U | ER. MOTHER PU ISING PRODUCT | ITS A LITTLE GEL | |
| | | | | | | | ١ |
| PRODUCT RECEIVED | FOR | Y (N) (CIRCLE ONE) | PRODUCT | BEING RETURNED FOR | INSPECTION: | Y (CIRCLE ONE) |) |
| ividual Cas | e Safety Ro | | DATE R | EQUESTED PRODUCT B | E RETURNED: | | |
| | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | 10 10 10 10 10 10 10 10 | | | - | |) |
| | | | | LIDE CALL | TAG ISSUED: | (CIRCLE ONE) | , |
| | | 11 18 10 18 1 18 1 18 1 18 1 18 1 18 1 | | UPS CALL | | , | |
| 941264 | 6-01-00-03 | 10) 88 1 10 GW 1 BH | | | | | |
| | 6-01-00-03 | | | DATE PRODUC | | | |
| 941264 section II: | INVESTIGATION | <u>1</u> | | DATE PRODUC | CT RECEIVED: _ | | |
| | INVESTIGATION | | TURING AND PACKA | DATE PRODUC | CT RECEIVED: _ | BLISHED PROCE- | |
| SECTION II: | INVESTIGATION REVIEWED B | <u>1</u> | | DATE PRODUC | CT RECEIVED: _ | BLISHED PROCE- | |
| SECTION II: | INVESTIGATION REVIEWED B | NATCH RECORD. MANUFACT | | DATE PRODUC | CT RECEIVED: _ | BLISHED PROCE- | |
| SECTION II: | INVESTIGATION REVIEWED B | NATCH RECORD. MANUFACT | | DATE PRODUC | CT RECEIVED: _ | BLISHED PROCE- | |
| SECTION II: INVESTIGATION: DURES TO ENSURE I | REVIEWED B | NATCH RECORD. MANUFACT | MPLE AND EVERYTH | DATE PRODUC | ET RECEIVED: _ | BLISHED PROCE- | |
| SECTION II: INVESTIGATION: DURES TO ENSURE I | REVIEWED B PRODUCT QUALITY | NATCH RECORD. MANUFACT INSPECTED RETAINED SA | MPLE AND EVERYTH | DATE PRODUC | CT RECEIVED: _ | BLISHED PROCE- | |
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cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





SERIOUS ADVERSE EVENT DATA FORM

| Al | E#: _ | 1387 | COMPLAINT #: 2339 | |
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| <u>s</u> | ECTION I | <u>.</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| N | IAME: | - | (b) (6) | |
| А | DDRESS: | - | | |
| C | CITY: | - | STATE: | |
| С | COUNTRY | : . | USA ZIP CODE: | |
| P | PHONE #: | | (b) (6) | |
| E | -MAIL: | - | | |
| <u>s</u> | SECTION I | II: | PACKAGING INFORMATION: | |
| | | AFFI | X PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| Individ | State of the date | representation of the control of the | EXPRINED FOR POINT AND TRANSPORTED FOR POINT AN | |
| | 9412 SECTION | | 01-00-04 <u>CORRECTIVE ACTION:</u> | |
| | | | | |
| | CORREC | TIVE AC | TION(S) COMPLETED BY: DATE: | |
| : | SECTION | IV: | ANAGEMENT BY: DATE: 06-04-13 | SS |
| | REVIEWE | D BY M | ANAGEMENT BY: DATE: 06-04-13 | 9 2013 |
| | BY: _ | ھ | expression Date: 06-04-13 Date: 06-05-13 | |

JUN 1 8 2013

PLEASE TYPE OR USE BLACK

and manufacturers or MANDATORY reporting

| Casel | ID: 941 | 12659 |
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| Form Approved: Of | MB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse |
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| Mfr Report # 54 73 | |
| JF/Importer Report # | |
| | EDA lies Only |

Page 1 FORM FDA 3500A (6/10) A. PATIENT INFORMATION 1. Patient Identifier 3 Sex 2. Age at Time 4. Weight (b) (6) of Event: Months 26.8 Female or Date ✓ Male In confidence of Birth: B. ADVERSE EVENT OR PRODUCT PROBLEM Product Problem (e.g., defects/malfunctions) Adverse Event and/or 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) ✓ Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 05/24/2013 05/16/2013 5. Describe Event or Problem CHILD EXPERIENCED "JERKING EPISODE" FOR 1 MINUTE, AT THE DAYCARE 1 WEEK AGO, WHICH THE MOTHER INITIALLY DISREGARDED. HE ALSO BROKE OUT IN A RASH. HE SEEMED FINE AFTER. THEN 3 DAYS AGO, HE HAD A SEIZURE AND TREMORS WHILE ASLEEP, WITH A LOW GRADE FEVER OF 100.9. MOTHER TOOK HIM TO THE OUTPATIENT DEPARTMENT AND THEY SCHEDULED HIM FOR A FUTURE EEG AND MRI. YESTERDAY, HE WAS AGAIN GIVEN BABY TEETHING TABLETS AND 1 1/2 HOURS LATER HE BROKE OUT IN A RASH, SAME AS BEFORE. HE ALSO WAS IRRITATED AND HAD DECREASED URINE OUTPUT. 6. Relevant Tests/Laboratory Data, Including Dates SCHEDULED FOR A FUTURE EEG AND MRI. RECEIVED JUN 05 2013 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) CHILD HAS A HISTORY OF ASTHMA AND HAD AN ACUTE EPISODE AT THE END OF APRIL (APPROX. 3 WEEKS AGO). MEDICATIONS: ALBUTEROL, PULMICORT, OMNICEF, ORAPRED, AND UDEROLAL. CHILD ALSO HAD THRUSH AND WAS TAKING NYSTATIN A FEW WEEK AGO.

Submission of a report does not constitute an admission that medical

caused or contributed to the event.

| er reporting | | | |
|---|------------------|--------------------|--|
| 5 | | | F DA Use Only |
| C. SUSPECT PRODU | JCT(S) | | , pa cae only |
| Name (Give labeled stren) | , | | |
| #1 HYLAND'S BABY | TEETHING TA | BLETS | |
| #2 | | | |
| . Dose, Frequency & Rout | e Used | 3. Therapy Dat | es (If unknown, give duration) |
| #1 3TABS X 4DOSES | X 2 WEEKS | from/to (or be | est estimate) |
| #2 | • | #2 | |
| . Diagnosis for Use (Indica | etion) | | ent Abated After Use |
| #1 RELIEF OF TEET | | | opped or Dose Reduced? |
| | | #1 L | ∏ Yes ∏ No ∏ Doesn't Apply |
| #2 . Lot # | 7. Exp. Date | #2 [| Yes No Doesn't |
| #1115032 | | 8. Ev | ent Reappeared After |
| + 1113032 | #1 | | introduction? |
| 12 | #2 | #1 [| ☐ Yes ☐ No ☐ Doesn't Apply |
| NDC# or Unique ID | | #2 F | Yes No Doesn't |
| 54973-3127-2 D. Concomitant Medical P | rodusto and The | | Арргу |
| . Concomitant Medical P | TOUGUES AND THE | apy ⊃ates (⊏xc/i | uoo uoauneni ui eveni) |
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| | | | |
| D. SUSPECT MEDIC | AL DEVICE | | |
| Brand Name | | | |
| Common Device Name | | | |
| . Manufacturer Name, City | and State | | |
| . manufacturer Name, City | y and State | | |
| | | | |
| Model # | Lot # | | 5. Operator of Device |
| Catalog # | Expiration | n Date (mm/dd/y) | Health Professional |
| | | | Lay User/Patient |
| Serial # | Other # | | Other: |
| | | | |
| . If Implanted, Give Date (| 'mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/dd/yyyy) |
| . Is this a Single-use Devi | ce that was Repr | ocessed and Re | used on a Patient? |
| Yes No | oo mas mas mept | COURT WING INC | and a serial ser |
| . If Yes to Item No. 8, Ente | er Name and Add | ress of Reproce | ssor |
| | | - | |
| | | | |
| | | | |
| 0. Device Available for Ev | _ | | |
| Yes No | Returned to M | lanufacturer on: _ | (mm/dd/yyyy) |
| 1. Concomitant Medical P | roducts and The | rapy Dates (Exc | 1 77777 |
| | | | • |
| | | | |
| E INITIAL DEPOSE | | | |
| E. INITIAL REPORTE | | # (b) (6) | |
| . Name and Address | Phone | # (0) (0) | N - |
| 0) (6) | | | JUN 0 6 2013 |
| | | | 1114 |
| | | | JUN 0 6 2012 |
| | | | · 2013 |
| | | | |
| . Health Professional? 3 | Occupation | | 4. Initial Reporter Also Sent |
| √ Yes No D | ther Healthcare | Professional | Report to FDA Yes No Unk. |
| | | | |

personnel, user facility, importer, distributor, manufacturer or product

Individual Case Safety Report CaseID: 9412659

9412659-01-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

☐ No

Yes

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient

Code Device

Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

Follow-up #

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Facility

Other:

Home

12. Location Where Event Occurred

Outpatient Treatment

☐ Initial

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

(Specify)

(mm/dd/yyyy)

Page 2 of 5 H. DEVICE MANUFACTURERS ONLY 2. If Follow-up, What Type? 1. Type of Reportable Event ☐ Death ☐ Correction Serious Injury Additional Information Malfunction Response to FDA Request Other: Device Evaluation 3. Device Evaluated by Manufacturer? 4. Device Manufacture Date (mm/yyyy) Not Returned to Manufacturer Yes Evaluation Summary Attached 5. Labeled for Single Use? No (Attach page to explain why not) or provide code: ☐ No 6. Evaluation Codes (Refer to coding manual) Method Results Conclusions

8. Usage of Device

Reuse

and / or

Unknown

Initial Use of Device

If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

11. Corrected Data

| G. ALL MANUFACTURERS 1. Contact Office - Name/Address (| | 2. Phone Number |
|--|---|--|
| for Devices) | and Manuracturing Site | 310-768-0700 |
| TUTTI GOULD HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 9006 | 1 | 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional |
| I. Date Received by Manufacturer (mm/dd/yyyy) 05/23/2013 | 5. (A)NDA# | User Facility Company Representative Distributor |
| 3. If IND, Give Protocol# | STN# | Other: |
| 7. Type of Report (Check all that apply) | PMA/ 510(k) # | |
| ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up# | Product Yes Pre-1938 Yes OTC Product Yes | ·. |
| 9. Manufacturer Report Number 54973 AE # 1382 | 8. Adverse Event Term(s) SEIZURE, TREMORS, | RASH |

The public reporting burden for this collection of information has been estimated to average 66

minutes per response, including the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing the

collection of information. Send comments regarding this burden estimate or an this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

JUN 0 6 2013

Department of Health and Human Services

7. If Remedial Action Initiated, Check Type

10. Additional Manufacturer Narrative

Notification

Inspection

Modification/ Adjustment

Patient Monitoring

Recall

Repair

Replace

Other:

Relabeling

Individual Case Safety Report

9412659-01-00-03

(CONTINUATION PAGE)

For use by user-facilities, .s, distributors, and manufacturers for MANDATORY reporting

CaseID: 9412659

JUN 0 5 2013

Page 3 of 5

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| ORM FDA 3500A (6/10) (continued) | |
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| B.5. Describe Event or Problem (continued) | |
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| B.6. Relevant Tests/Laboratory Data, Including Dates (continued) | |
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| B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol | use, hepatic/renal dysfunction, etc.) (continued) |
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| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please | distinguish) |
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| | |
| Other Remarks | |
| | DSS |
| | DSS JUN 0 6 2013 |
| | JUN 0 6 2013 |
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CUSTOMER COMPLAINT RECORD



| SECTION I: | | MPLAINT | | | COM | PLAINT#: | 2332 | <u>. </u> | |
|--|--|---|--|--|--|---|---|--|-------------|
| TAKEN BY: | | TUTTI GOULD | | | DATE OF CO | | | | |
| PRODUCT: | | BABY TEETHING 1 | TABLETS | | • | | BTETT250 | | |
| SIZE: | | 250 TABLETS | | | | LOT NO.: | 115032 | | |
| REPORTER: | (b) (6) | | | | | | | | |
| ADDRESS: | | | | 141- | | | | | |
| | | | | | | (b) (6) | | | |
| CITY: | | | | | STATE: | - | | | |
| COUNTRY: | USA | | | | ZIP CODE: | | | | |
| PHONE #: | (b) (6) | | | | | | | | |
| E-MAIL: | | 17 MONTH (| OLD CHILD EXPERIEN | NCED " IERKING ERI | SODE" FOR 1 M | INUTE AT | THE DAYCARE | I WEEK AGO | |
| OUTPATIENT D TABLETS AND 1 HE HAS A HISTO MEDICATIONS: LAST IMMUNICA | GO, HE HAD EPARTMENT 1 ½ HOURS L ORY OF ASTI ALBUTEROI ATIONS WER | WHICH THE A SEIZURE AND TRI AND THEY SCHEDU ATER HE BROKE OL HMA AND HAD AN AG ., PULMICORT, OMN E ON DEC. 2012. JE 5/20/13; AND RASH O | E MOTHER INITIALLY I IEMORS WHILE ASLE JULED HIM FOR A FUTI UT IN A RASH, SAME . CUTE EPISODE AT TH IICEF, AND ORAPRED ERKING LASTED 1 MIN DN 05/22/13. | DISREGARDED. HE EP, WITH A LOW GR URE EEG AND MRI. AS BEFORE. HE AL: HE END OF APRIL (A). HE ALSO HAD THI NUTE; SEIZURE WAS | ALSO BROKE (ADE FEVER OF YESTERDAY, F SO WAS IRRITA PPROX. 3 WEE RUSH AND WAS DURING SLEE | DUT IN A RA 100.9°F. M HE WAS AG TED AND H KS AGO). I S TAKING N IP; RASH — | ASH. HE SEEME MOTHER TOOK I AIN GIVEN BAB' HAD DECREASE HE WAS ON THE MYSTATIN A FEW NOT KNOWN. J | ED FINE AFTER. HIM TO THE Y TEETHING D URINE OUTPU FOLLOWING / WEEKS AGO. 1 | ⊣IS |
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| PRODUCT REC | | , - | RCLE ONE) | PRODUC | T BEING RETU | RNED FOR | INSPECTION: | Y (CIRCLE ON | N E) |
| 05/24/13: ALL I DISCONTINUED | EARLIER IN | | ~ - | DATE | REQUESTED PR | RODUCT BE | E RETURNED: | | |
| | | lecy kepor | | | | UPS CALL | TAG ISSUED: | Y (CIRCLE ON | N E |
| 941 | 12659-0 | 1-00-04 | 181 81 8 81 | | DAT | E PRODUC | T RECEIVED: | | |
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| LIMITS. INSPEC | CTED RETAIL | NED SAMPLES AND I | EVERYTHING LOOKS | OKAY. | | | | | |
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| ADVEDSE EVE | NIT EODW AD | | ST / NURSE FOR EVAI | LIIATION ON: | | 05/22/13 | | | |
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| SECTION III: | | CORRECTIVE ACTION | | EOAHOR DT. | | 101110 | 3025 | | |
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| CORRECTIVE A | ACTION(S) CO | OMPLETED BY: | | | | DATE: | | | |
| | AD | ERSE EVENT REPO | <u>ORTS</u> | | | AE #: | 1382 | | |
| SECTION IV: | | | (N | | | | | | |
| | NT SERIOUS | | | | | | | | |
| ADVERSE EVE | | | 05/22/13 | | BX: ED | YTA FRACK | IEWICZ | | |
| ADVERSE EVE | | | 05/22/13 | / | BY: ED | YTA FRACK | SEWICZ | | |
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| ADVERSE EVE ADVERSE EVE SECTION V: | NT REPORTE | ED ON: | 05/22/13 | Solf | BY: ED | DATE: | | _ | JUN 0 |

cc: QA / QC Packaging Production Shipping / Receiving 2013 a N 2 5013





SERIOUS ADVERSE EVENT DATA FORM

| 1 | AE #: _ | 1382 | | | | | COMPLAINT | #: 2332 | |
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| į | SECTION I | <u>.</u> | PATIENT INFOR | MATION (IF D | IFFERENT | FROM REPO | RTER ON FOR | M VD1) | |
| | NAME: | (| 0) (6) | | | | | | |
| | ADDRESS: | :] | | | | | | | |
| | CITY: | | | | | | STATE | (b) (6) | |
| | COUNTRY | _ | USA b) (6) | | | | ZIP CODE | : | |
| | PHONE #: | | | | | | | | |
| | E-MAIL: | _ | | | | | | | |
| | SECTION I | <u>II:</u> | PACKAGING INF | ORMATION: | | | | | |
| | | AFFIX | PACKAGING LABE | EL HERE | | | FIX COPY OF (E DRUG FACT PA | | TON HERE NCIPAL DISPLAY |
| | The syndromic of the sy | Country 10 5 Listed I best for the Type In the State of the Type In the State of the In | Baby Baby Beathing Teething Tablets Beaths pan is Denticon BEATHS PAN AND | intrologist De sall sets an total or handstade, who toes that it is a set of sets set of the set of it is a set of set of set of the set of the set of sets of the set of the set of sets of the set of the set of sets of sets of the sets of the the sets of the sets of the sets of the sets of the sets of the the sets of the sets of the the sets of the sets of the the sets of the the sets of the the sets of the the sets of the the the the the the the the | | Teething Tablets Teething Tablets Teething Tablets Teething Tablets Tablets Tablets Tablets | A STATE OF THE STA | Figure 1 and | William State of Stat |
| | SECTION | <u>III:</u> | CORRECTIVE | ACTION: | | | | | |
| Indivi | dual Ca | ase Sa | fety Report | | | | | | |
| | | | | | . 4 | | | | |
| | | | 1-00-05 ION(S) COMPLETE | D BY: | | | | DATE: _ | |
| | SECTION REVIEWE BY: | | NAGEMENT BY: | U.S. DIRECTOR | Jak | | | | 65-30-13 05-30-13 |

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PLEASE TYPE OR USE BLACK INK

CaseID: 9412660

| | Form Approved: OM | B No. 09 10-029 1, Expires 12/31/1 See OMB statement on reverse |
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| r use by user-facilities, | |
| distributors and manufacturers | |
| IANDATORY reporting | |
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Page 1 of 4

| UF/Importer Report # | * | |
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| | | F DA USE ONLY |

| FORM FDA 3500A (6/10) | Page | 101 | | F DA Use Only |
|---|--|--------------------------------------|------------------|--|
| A. PATIENT INFORMATION | | C. SUSPECT PRODU | | |
| 1. Patient Identifier 2. Age at Time of Event: | 3. Sex 4. Weight | Name (Give labeled streng | , | - |
| (b) (6) of Event: | Female lbs | #1 HYLAND'S TEETH | ING TABLETS | |
| Date | □ Male or | #2 | | |
| In confidence of Birth: | kys | 2. Dose, Frequency & Rout | e Used | Therapy Dates (If unknown, give duration) from/to (or best estimate) |
| B. ADVERSE EVENT OR PROD | UCT PROBLEM | #1 UNKNOWN | | #1 |
| | Product Problem (e.g., defects/malfunctions) | #2 | | #2 |
| Outcomes Attributed to Adverse Event (Check all that apply) | | 4. Diagnosis for Use (Indica | tion) | 5. Event Abated After Use |
| Death: | Disability or Permanent Damage | #1 TEMP RELIEF TEM | • | Stopped or Dose Reduced? |
| (mm/dd/yyyy) Life-threatening | Congenital Anomaly/Birth Defect | 1 | | #1 Yes No Doesn't |
| ✓ Hospitalization - initial or prolonged | Other Serious (Important Medical Events) | 6. Lot # | 7. Exp. Date | #2 Yes No Doesn' |
| Required Intervention to Prevent Pe | rmanent Impairment/Damage (Devices) | #1 | #1 | 8. Event Reappeared After |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of This Report (mm/dd/yyyy) | | | Reintroduction? |
| UNKNOWN | 05/29/2013 | #2 | #2 | #1 Yes No Apply |
| 5. Describe Event or Problem | | 9. NDC# or Unique ID 54973-7504-1 | | #2 Yes No Doesn't |
| MY DAUGHTER HAS A SEIZURE, | AND WE WERE ADMITTED TO (b) (6) | 1 1 | roducts and The | rapy Dates (Exclude treatment of event) |
| | | | | |
| ř | 9 : | D. SUSPECT MEDIC 1. Brand Name | AL DEVICE | |
| <i>(</i> * | TECEIVE- | 2. Common Device Name | | |
| | " ED | 3. Manufacturer Name, City | and State | |
| • | RECEIVED JUN 0 5 2013 CDR | | | |
| | 20/3 | 4. Model # | Lot# | 5. Operator of Device |
| | CDP | | | Health Professional |
| | | Catalog # | Expiratio | n Date (mm/dd/yyyy) |
| | | Serial # | Other # | Other: |
| | | | | |
| | | 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. If Explanted, Give Date (mm/dd/yyyy) |
| 6. Relevant Tests/Laboratory Data, Include | ding Dates | 8. Is this a Single-use Devi | ce that was Repr | ocessed and Reused on a Patient? |
| UNKNOWN | ECEIVE | 9. If Yes to Item No. 8, Ente | er Name and Add | ress of Reprocessor |
| | 0.5 2013 | | | |
| | | 10. Device Available for Ev | aluation? (Do no | t send to FDA) |
| |) [2 | Yes No | Returned to M | fanufacturer on:(mm/dd/yyyy) |
| | 3.6 | 11. Concomitant Medical P | roducts and The | rapy Dates (Exclude treatment of event) |
| Other Relevant History, Including Pre- race, pregnancy, smoking and alcohol us | existing Medical Conditions (e.g., allergies, se, hepatic/renal dysfunction, etc.) | 11 | | |
| UNKNOWN | | E. INITIAL REPORT | ER . | |
| | | Name and Address | Phone | · # |
| | | | L | Doo |
| | | (b) (6) | 1. | D22 |
| | | | JUN D | 5 2013 JUN 0 6 2013 |
| Submission of a report does not o | constitute an admission that medical | 2. Health Professional? 3 | Occupation | 4. Initial Reporter Also Sen |
| personnel, user facility, importer, caused or contributed to the even | distributor, manufacturer or product | Yes Vo | | Report to FDA Yes No Unk |

CaseID: 9412660

| ģ | 3412660 | -01-00-0 | 02 | Page 2 |
|--|------------------|------------------------|--------------|-------------------------------------|
| F. FOR USE BY U | ISER FACI | ITY/IMPO | RIER (L | evices Only) |
| Check One | | | | Report Number |
| User Facility | Importer | | | |
| . User Facility or Imp | orter Name/Ad | dress | | |
| , | | | | |
| . Contact Person | | | 5. Phone N | lumber |
| Date User Facility of Importer Became Aware of Event (mn | | Type of Repor | | 8. Date of This Report (mm/dd/yyyy) |
| . Approximate | 10. Event Pro | blem Codes (| Refer to cod | ling manual) |
| Age of Device | Patient - | | | |
| | Code | | <u>-</u> | |
| | Device | | - | |
| | Code | | | |
| 1. Report Sent to FD. | A? 1 | 12. Location V | | |
| Yes | | Hospita | ai | Outpatient Diagnostic Facility |
| No (mm/do | <i>√yyyy)</i> | Home | | Mmbulatory |
| 3. Report Sent to Ma | nufacturer? | | g Home | Surgical Facility |
| Yes | | Outpat Facility | ient Treatmo | ent |
| (mm/de | Ууууу) | Other: | | |
| No | | ☐ Other. | | (Specify) |
| G. ALL MANUF | | | urina Site | 2. Phone Number |
| for Devices) | iller Audi ess (| and wanterdoor | aring one | 310-768-0700 |
| DDIMO DDACKI | DIAT CO | | | 3. Report Source |
| EDYTA FRACKI HYLAND'S, IN | | | | (Check all that apply) |
| 154 W. 131ST | | | | Foreign |
| LOS ANGELES, | CA 9006 | 1 | | Study |
| | | | | Literature |
| | | | | Consumer |
| | | | | Health Professional |
| 4. Date Received by | | 5. | | User Facility |
| Manufacturer (mm | /dd/yyyy) | (A)NDA # _ | | Company Representative |
| | | IND#_ | | Distributor |
| 6. If IND, Give Protoc | ol# | STN#_ | | Other: |
| 7 From at Depart | | PMA/ | | <u>.</u> |
| 7. Type of Report (Check all that app | ly) | 510(k) # _ | - | - |
| 5-day 30- | day | Combination Product | Yes | |
| | riodic | Pre-1938 | Yes | |
| ☐ 10-day 🗸 Init | ial | OTC Produc | | 1 |
| 15-day Fol | low-up# | | . A 1 162 | |
| 9. Manufacturer Rep | ort Number | 8. Adverse l | vent Term | (s) |
| 54973 RAE052 | 213EF004 | SEIZURE | | |
| | | 1 | | |
| | | 1 | | |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| 1 | | FDA USE ONLY |
|------------------------------------|---------------------------------|---|
| | | |
| f <u>4</u> | | · |
| H. DEVICE MANUFAC | TURERS ONLY | Y |
| 1. Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death | | Correction |
| Serious Injury | | Additional Information |
| Malfunction | | Response to FDA Request |
| Other: | | Device Evaluation |
| 2 2 | ufanturar? | 4. Device Manufacture Date |
| 3. Device Evaluated by Man | | (mm/yyyy) |
| Not Returned to Manu | | |
| | Summary Attached | 5. Labeled for Single Use? |
| No (Attach page to exprovide code: | xplain why not) or | |
| , | | Yes No |
| 6. Evaluation Codes (Refer t | o coding manual) | |
| 6. Evaluation codes (Neich | | |
| Method | | |
| Results | |]_[|
| r/esuits | | |
| Conclusions | \ <u>-</u> \ | - |
| 7. If Remedial Action Initiate | ed, Check Type | 8. Usage of Device |
| | | Initial Use of Device |
| | Notification | Reuse |
| | nspection Patient Monitoring | Unknown |
| 1 = ' =. | Modification/ | 9. If action reported to FDA under |
| | Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | - |
| | | |
| 10. Additional Manufac | turer Narrative | and / or 11. Corrected Data |
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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850
Please DO NOT RETURN this form to this address.

OMB Statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

スパンパン

HOMEOPATHIC MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD



| SECTION I: | COMPLAINT | COMPLAINT #: | RVD052213EF004 | |
|------------------------------|--|---------------------------------------|------------------------------|-------------|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 05/24/13 | _ |
| PRODUČT: | TEETHING TABLETS | ITEM CODE: | TEET | |
| SIZE: | | LOT NO.: | | _ |
| REPORTER: | (b) (6) | | | _ |
| ADDRESS: | | | | |
| | | | | |
| CITY: | | | | |
| COUNTRY: | USA | ZIP CODE: | | |
| PHONE #: | (b) (6) | | | _ |
| E-MAIL: | | HTER HAD A SEIZURE AND WAS ADMITTED | TO(b)(6) FOR A WEEK | _ |
| NATURE OF COM | PLAINT: RECEIVED E-MAILED THAT DAUG | HTER HAD A SEIZURE AND WAS ADMITTED | TO FOR A WEER. | _ |
| | | | | |
| | FOR ADDITIONAL SPACE PLEASE U | ISE REVERSE OR ATTACH A SEPARATE SHE | ĒΤ | |
| | | | | 4 |
| PRODUCT RECE INSPECTION: | IVED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: Y N (CIRCLE ONE) | i |
| 3 ATTEMPTS MA CUSTOMER ON | 05/22, 05/23, AND 5/24 | DATE REQUESTED PRODUCT BE | E RETURNED: | |
| VIA E-MAIL. CUS RESPOND. | STOMER DOES NOT | | Y | _ |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) | , |
| | | DATE PRODUC | CT RECEIVED: | |
| SECTION II: | INVESTIGATION | | | |
| SECTION II. | **** | | | |
| INVESTIGATION: | | EET RECALL AS A SERVICE RELATED CONCE | ERN AND FORWARDED DIRECTLY | |
| TO THE PHARMA | ACIST AND MEDICAL DIRECTOR FOR TIMELY AE DAT | A CAPTURE AND EVALUATION. | | |
| | | | | _ |
| | | | | NO C |
| ADVERSE EVEN | T FORWARDED TO PHARMACIST / NURSE FOR EVAI | .UATION ON: 05/22/13 | | 2 2 |
| ADVERSE EVEN | T FORWARDED TO PHARMACIST / NURSE FOR EVAI | LUATION BY: EDYTA F | FRACKIEWICZ | D 07 |
| SECTION III: | CORRECTIVE ACTION: | | = | 2013 |
| Individual (| Case Safety Report | | | |
| | | | | |
| | | | | |
| | 2660-01-00-03 | DATE | | |
| CORRECTIVE A | CTION(S) COMPLETED BY: | DAIL. | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: | :RAE052213EF004 | |
| ADVERSE EVEN | IT SERIOUS: (Y)/ N | | | |
| | T REPORTED ON: 05/22/13 | BY: EDYTA FRAC | KIEWICZ | |
| SECTION V: | | . 1 | |)SS |
| | i// | 1.11 | 85-30-176N | 0.000 |
| REVIEWED BY 1 | MANAGEMENT BY: | | | |
| BY: N/ | | DATE: | | |
| | QA / QC DIRECTOR | | | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

JUN 0 5 2013





SERIOUS ADVERSE EVENT DATA FORM

| AE#: RA | E052213EF004 | COMPLAINT #: RVD052213EF004 |
|--------------|--|---|
| SECTION I: | PATIENT INFORMATION (IF | DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | | STATE: |
| COUNTRY: | USA | ZIP CODE: |
| PHONE #: | | |
| E-MAIL: | (b) (6) | |
| SECTION II: | PACKAGING INFORMATION | N: |
| A | FFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| | In the second of the single or man's control of the second | Industry Teething Tablets Teething Tablets Tabletas para la Dentición Syngrousik Reiel Frechia in Childres Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas Serva la Dentición Tabletas Serva la Dentición Tabletas Serva la Dentición Tabletas Serva la Dentición |
| 941268 | Safety Report O-01-00-04 CORRECTIVE ACTION: | 1 2011 |
| SECTION III: | <u>John Land</u> | |
| CORRECTIVE | E ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: | |) II. |
| REVIEWED E | BY MANAGEMENT BY: | DATE: 65-30-13 DS 6 |
| BY: N/A | QA / QC DIRECTO | DATE: |

9412682-02-00-01

orters, distributors and manufacturers for MANDATORY reporting

CaseID: 9412682

| orm Approved: OMB No. | 00 10,020 1 | Eynires 12/31/11 |
|-----------------------|-------------|------------------|

| | See OMB statement on revers |
|----------------------|-----------------------------|
| Mfr Report # 54.773 | See page 2 |
| UF/Importer Report # | |
| | |

| A. PATIENT INFORMATION | tara <u>a conservacio</u> | | |
|---|--|--|-----------------|
| . Patient Identifier 2. Age at Time | | 3. Sex | 4. Weight |
| of Event: 10 |) Months | J | - Trongin |
| or | | Female | fbs |
| In confidence of Birth: | | Male | or kgs |
| 3. ADVERSE EVENT OR PROD | DUCT PROBLE | M | |
| Adverse Event and/or | Product Problem | e.g., defects/malf | unctions) |
| Outcomes Attributed to Adverse Even (Check all that apply) | nt | | |
| Death: | Disability | or Permanent Da | mage |
| (mm/dd/yyyy) Life-threatening | Congenit | al Anomaly/Birth [| Defect |
| Hospitalization - initial or prolonged | Other Se | rious (Important M | ledical Events) |
| Required Intervention to Prevent Pe | ermanent Impairme | nt/Damage (Devic | es) |
| Date of Event (mm/dd/yyyy) | 4. Date of Thi | s Report (mm/do | (/уууу) |
| FEB. 2013 MAY 2013 | | 06/14/2013 | 3 . |
| TIFFENING EPISODES WHEN W ECONDS. HAPPENED 2 - 3 T ESOLVED AFTER TEETHING TA | TIME A WEEK | FOR 2 MONTH | S. |
| | | | |
| | | | |
| | | prompts and | |
| | | COZ | |
| | | AUG 20 | 2013 |
| | | CDF | 3 |
| | | | |
| Delevent Testall shoutons Date Lealing | dia Data | | |
| Relevant Tests/Laboratory Data, Include | unig Dates | | |
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| | | | |
| | | | |
| Other Relevant History Including Pro- | Wieting Medical C | onditions (a.g. ci | larnia e |
| race, pregnancy, smoking and alcohol us | :xisting Medical С :ә, hepatic/renal dys | onditions (e.g., al function, etc.) | llergies, |
| o Known Allergies. | ıxisting Medical С ые, hepatic/renal dys | onditions (e.g., al function, etc.) | lergies, |
| o Known Allergies. O ILLNESSES. | existing Medical С не, hepatic/renal dys | onditions (e.g., al function, etc.) | lergies, |
| race, pregnancy, smoking and alcoholus O KNOWN ALLERGIES. O ILLNESSES. ULL TERM BABY. | existing Medical Cose, hepatic/renal dys | onditions (e.g., al function, etc.) | lergies, |
| race, pregnancy, smoking and alcoholus O KNOWN ALLERGIES. O ILLNESSES. ULL TERM BABY. | existing Medical Co se, hepatic/renal dys | onditions (e.g., a function, etc.) | lergias, |
| Other Relevant History, Including Pree race, pregnancy, smoking and alcohol us O KNOWN ALLERGIES. O ILLNESSES. ULL TERM BABY. O NEW FOODS AT THE TIME. | existing Medical Cose, hepatic/renal dys | onditions (e.g., a function, etc.) | lergies, |
| race, pregnancy, smoking and alcoholus O KNOWN ALLERGIES. O ILLNESSES. ULL TERM BABY. | existing Medical Co se, hepatic/renal dys | onditions (e.g., a function, etc.) | lergios, |
| race, pregnancy, smoking and alcoholus O KNOWN ALLERGIES. O ILLNESSES. ULL TERM BABY. | existing Medical Core, hepatic/renal dys | onditions (e.g., al function, etc.) | ilergios, |

PLEASE TYPE OR USE BLACK INK

| <u>15</u> | | | FDA Use Or |
|------------------------------|----------------------|-----------------|---|
| C. SUSPECT PROD | UCT(S) | | |
| I. Name (Give labeled street | - , | | |
| #1 HYLAND'S BABY | TEETHING TA. | BLETS | |
| #2 | | | |
| Dose, Frequency & Rou | ute Used | | tes (If unknown, give duration est estimate) |
| #1 2-3TABS Q6 QD | X 4 MONTHS | #1 | |
| #2 | | #2 | |
| Diagnosis for Use (India | cation) | | vent Abated After Use |
| #1 TEMP RELIEF TE | EETHING PAIN | 1 | lopped or Dose Reduced? |
| #2 | | | Apply |
| i. Lot# | 7. Exp. Date | #2 | Yes No Apply |
| #1A27212/A02813 | #1 | | vent Reappeared After eintroduction? |
| #2 | #2 | 1 . | Yes No Doesi |
| NDC# or Unique ID | | #2 | Type Does |
| 54973-3127-1 | Draduate and Th | I | С Дрргу |
| Concomitant Medical I | Products and Ther | apy Dates (Exc | ude treatment of event) |
| | | | |
| | | | |
| | | | |
| D. SUSPECT MEDIC | CAL DEVICE | | |
| . Brand Name | | | |
| . Common Device Name | | | |
| Manufacturer Name, Cit | ty and State | | |
| . manaradia name, on | ty and otate | | |
| . Model # | 1 # - | | IF 0 |
| . Model# | Lot # | | 5. Operator of Device |
| Catalog # | Expiration | Date (mm/dd/y | (Yyy) Health Professional |
| Serial # | Other # | | Other: |
| Settal # | Other# | | |
| . If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/dd/yyyy) |
| la this a Single use Day | ion that was Barra | d and D | need on a Dathersto |
| Is this a Single-use Dev | ice triat was Repro | cessed and Re | used on a Patient? |
| . If Yes to Item No. 8, Ent | er Name and Addre | ss of Reproce | ssor |
| | | | |
| | | , | |
| 0. Device Available for Ev | valuation? (Do not s | send to FDA) | |
| | Returned to Ma | , | |
| Concomitant Medical F | Producte and There | ny Dates (Evo | (mm/dd/yyyy) |
| Joneonitant medical P | TOURIS AND THEFE | P) Pates (EXC | add addinion of eventj |
| | | | |
| E. INITIAL REPORT | ER | | |
| Name and Address | Phone # | (b) (6) | |
| 0) (6) | | | |
| ., (3) | | | DSS |
| | AUG - | A 46 | ALIC O T COLO |
| | AUG 2 | U 2013 | AUG 2 1 2013 |
| | | | |
| Health Professional? 3 | . Occupation | | Initial Reporter Also Sen Report to FDA |
| Yes No | | | Yes No Unk |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

9412682-02-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes .

☐ No

Yes Yes

No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

> Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ HYLAND'S, INC.

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

☐ 5-day ☐ 30-day

7-day Periodic

54973 AE # 1405

☐ 15-day Follow-up # 19. Manufacturer Report Number

10-day Initial

06/07/2013

154 W. 131ST STREET LOS ANGELES, CA 90061

1. Contact Office - Name/Address (and Manufacturing Site

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial
Follow-up #

2. UF/Importer Report Number

5. Phone Number

 Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number
310-768-0700

3. Report Source
(Check all that apply)

Foreign

Company

Distributor

Other:

Representative

Study
Literature
Consumer
Health Professional
User Facility

Page 2 of 9

| of <u>9</u> | |
|--|--|
| H. DEVICE MANUFACTURERS ONL 1. Type of Reportable Event | Y 2. If Follow-up, What Type? |
| Death Serious Injury Malfunction Other: | Correction Additional Information Response to FDA Request Device Evaluation |
| Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached | 4. Device Manufacture Date (mm/yyyy) |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? Yes No |
| 6. Evaluation Codes (Refer to coding manual) Method Results | - - - |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Repair Inspection Replace Patient Monitoring Relabeling Modification/ Adjustment | Reuse Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | and / or 11. Corrected Data |
| | |
| | |
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| | DSS |
| | AUG 2 1 2013 |

CaseID: 9412682

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(A)NDA#

IND#

STN#

510(k) # ___ Combination

Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s) POSSIBLE SEIZURES

Yes

☐ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



9412682-02-08-03



CASALDZB41368FN 1d 247iClc#71008 1830000048628 5442

June 14, 2013

(b) (6)

RECEIVED

AUG 20 2013

CDR

Dear (b)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 9.19 each. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach

President

Enc: Refund Check - \$ 30.26

DSS AUG **2** 1 2013



STOMER COMPLAINT RECORD



9412682-02-00-05

| 2002 02 | 00-03 | COMPLAINT #; | | _ |
|---|--|---|---|----------|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 06/12/13 (E-MAIL RECEIVED 6/7/13) | - |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 | _ |
| SIZE: | 135 TABLETS | LOT NO.: | A27213 (1 BOTTLE); A02813 (2 BOTTLES) | _ |
| REPORTER: (b) (6) | | | - A. | |
| ADDRESS: | | | | _ |
| | | | | |
| CITY: | | STATE: _(b) (6) | | |
| COUNTRY: USA | | ZIP CODE: | | - |
| (b) (6) PHONE #: | | | | - |
| E-MAIL: | | | | _ |
| DISCONTINUING PRODUCT. FOR 3 BOTTLES OF BABY TO | STARTED USING BABY TEETHING TABLETS WHEN 6 HOURS EVERY DAY FOR 4 MONTHS. WHEN CHIL NED OUT FOR 5 – 10 SECONDS. HAPPENED 2 – 3 TIME A WIPPENDIATELY 05/20/13). DOCTOR SAID TO STOP BABY TEE PEDIATRICIAN CALLED THEM EPISODES AND MOTHER CASETHING TABLETS. CUSTOMER ON VACATION AND UNABLE DILLNESSES. FULL-TERM BABY. NO NEW FOODS AT THE TOTAL TOWN AND WIPPENDIATELY OF ADDITIONAL SPACE PLEASE USE REVERSE OR ADDITIONAL SPACE PLEASE USE PLEASE U | D WAS 6 MONTHS, STARTE EEK FOR 2 MONTHS. STOP THING TABLETS AND SEE LLED THEM MINI SEIZURES E TO CALL EARLIER AND DI IME | D HAVING SHAKING AND PED USING BABY TEETHING IF SYMPTOMS WENT AWAY AFTER CUSTOMER WANTS A REFUND ID NOT HAVE BOTTLES AVAILABLE. | - |
| PRODUCT RECEIVED FOR INSPECTION: | Y N PRODUC | T BEING RETURNED FOR I | | |
| INSFECTION, | (CIRCLE ONE) | DEGUSCIER CO.C. | (CIRCLE ONE) | |
| | DATE | REQUESTED PRODUCT BE | RETURNED: | _ |
| | | UPS CALL 1 | TAG ISSUED: (CIRCLE ONE) | |
| | | DATE PRODUCT | FRECEIVED: | |
| SECTION II: INV | ESTIGATION | | | _ |
| IND/ECTION TION | | | | |
| | BULK LOT # 117628 (A27212), BULK LOT # 117318 (A02813). F | | | - |
| ING AND PACKAGING WERE | DONE ACCORDING TO ESTABLISHED PROCEDURES TO EN | ISURE PRODUCT QUALITY. | | - |
| | | | | - |
| | | | | - |
| ADVERSE EVENT FORWARD | ED TO PHARMACIST / NURSE FOR EVALUATION ON: | 06/12/13 | | _ |
| ADVERSE EVENT FORWARD | ED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDYTA FR | ACKIEWICZ | |
| SECTION III: | ORRECTIVE ACTION: | | | |
| 06/14/13: PREPARED REFUN | ID DECLIEST TOTALING \$ 20.25 07/25/42, MAILED DESLING | OUE OV. # 500 (00 TOT.) | | |
| 000486285442. | ID REQUEST TOTALING \$ 30.26. 07/26/13: MAILED REFUND | CHECK # 509489 TOTALING | 6 \$ 30.26 ON ARTICLE # 70081830 | |
| | | | | - |
| | | | | |
| CORRECTIVE ACTION(S) CO | MPLETED BY: | DATE: | 06/14/13 & 07/26/13 | |
| SECTION IV: ADVI | ERSE EVENT REPORTS | AE #: _ | 1405 | |
| ADVERSE EVENT SERIOUS: | $(v)_{l}$ N | | - | _ |
| ADVERSE EVENT REPORTED | | BY: EDYTA FRACKIE | wicz D | SS |
| SECTION V: | | | | 2 1 2013 |
| REVIEWED BY MANAGEMENT | TBY: PWNH | DATE: | 08-06-13 | , T 2013 |
| BY: Ou | QA/QC DIRECTOR | | 8-05-13 | |
| 11 | WALL OF DIVECTOR | | | |

cc: QA / QC Packaging Production Shipping / Receiving

AUG 2 0 -2013/01



9412689-02-00-01

For use by user-facilities, orters, distributors and manufacturers for MANDATORY reporting

| 131 | an | CaseID: 9412689 |
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| | | Form Approved; OMB No. 09 10-029 1, Expires 12/31/11 |
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| Mfr Report # 5/1924 | | OIVID State | ement on rev | erse |
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| UF/Importer Report # | See | proe | | |
| | • | | EDA Head |)ntv |

PLEASE TYPE OR USE BLACK INK

| FORM FDA 3500 | 0A (6/10) | | | Page 1 | of [5] | | | | | EDA Has Onl |
|---|--------------------------|---------------------------|------------------------------|--------------------|--------------------------|---------------------|----------------|---------------------------------------|---|--------------------------------|
| A. PATIENT4NF | ORMATION | Maria San | 1 | searly 1.1.1 | C. SUSPECT | PRODUCT | Γ(S) | e e e e e e e e e e e e e e e e e e e | my say sága ya ya ya | FDA Use On |
| 1. Patient Identifier | | | 3. Sex | 4. Weight | 1. Name (Give lab | eled strength | & mfr/labeler) | | | |
| (b) (6) | of Event: | Montha | Female | lbsi | #1 HYLAND'S | BABY TEE | ETHING TA | BLETS | | |
| | Date | | | Or | #2 | | | | | |
| In confidence | of Birth: | | Male | kgs | 2. Dose, Frequence | cy & Route Us | sed | 3. Therapy Dat | tes (If unknown, | give duration) |
| B. ADVERSE EV | ENT OR PRODU | CT PROBLE | М | | #1 1 TABLET | | | | est estimate) | |
| 1. Adverse Event | | oduct Problem (e | .g., defects/mal | functions) | | 01101 | | | | |
| 2. Outcomes Attribut (Check all that appl) | ed to Adverse Event | | | l | #2 4. Diagnosis for U | le e d'estie etie e | h | #2 | | |
| Death: | | Disability o | r Permanent Da | amage | #1 TEMP RELI | | • | St | ent Abated Afte opped or Dose | |
| Life-threatening | (mm/dd/yyyy) a | Congenital | Anomaly/Birth | Defect | #1 15/15 KDD. | ICT ICCIN | ING PAIN | #1 [| ✓ Yes 🗌 No | Doesn' Apply |
| 1 = | - initial or prolonged | | | Medical Events) | #2 | | | 40. | | — Docen |
| | vention to Prevent Perm | لت | | 1 | 6. Lot# | 7. E | xp. Date | #2 | YesNo | L Apply |
| 3. Date of Event (mm | | 4. Date of This | | | #1A22713 | #1 | | | ent Reappeare | d After |
| 06/0 | 3/2013 | 1 | 06/07/201 | | #2 | #2 | | 1 . | Yes No | Doesn |
| 5. Describe Event or | Problem | | | | 9. NDC# or Uniqu | e ID | | | | Apply Doesn |
| USED 1 TÄBLET BECAME "LOCKE! | ON POW AND VOMIT | ND 20 MINUTI CED. WENT | ES LATER (TO HOSPITA | | 54973-3127 | | | #2 [| | L Apply |
| | SED AS SEIZURE. | | | | 10. Concomitant N | Medical Produ | icts and The | rapy Dates (Excl | ude treatment of | event) |
| AND NO SUBSEQU | JENT SEIZURES C | BSERVED. | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | D. SUSPECT | MEDICAL | DEVICE | | | |
| | | | | l | 1. Brand Name | | | | | |
| | | | | | 2. Common Devic | e Name | | | | |
| | | | | | 3. Manufacturer N | lame. City and | d State | | | |
| | | • | | | | | | | | |
| | | | | | | | | | | |
| | | | | | 4. Model# | | Lot# | | 1_ | or of Device |
| | | | | | Catalog # | | Expiration | Date (mm/dd/y) | /yy) I 🗀 | h Professional |
| | | | | | | | | | 1 | Jser/Patient |
| | | | | 1 | Serial # | | Other # | | Other | : |
| | | | | | 6. If Implanted, Gi | ve Date (mm/ | dd/vyvy) | 7. If Explanted | , Give Date (mm | n/dd/vvvv) |
| 6 Polevent Testall ob | oratory Data, Includin | - D-1 | | | | | ,,,,, | - w Explained | , orro Dato (min | ,,,,,,, |
| o. Relevant Tests/Lab | or atory Data, including | g Dates | | | 8. Is this a Single- | | nat was Repr | ocessed and Re | used on a Patie | nt? |
| UNKNOWN | | | | | 9. If Yes to Item N | | me and Add | race of Paproca | | |
| · | | | | 1 | 5. If Yes to item N | O. O, Eliter Na | ine and Add | ress of Reproces | 880F | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | 10. Device Availab | ole for Evalua | tion? (Do not | send to FDA) | | |
| | | | | | Yes 🗌 | No F | Returned to M | anufacturer on: _ | (mm/dd/y | 0000 |
| | | | | | 11. Concomitant N | fedical Produ | cts and Ther | apy Dates (Excl | | |
| 7. Other Relevant Hist | tory, Including Preexis | ting Medical Cor | nditions (e.g., a | allergies, | | | | | | , |
| race, pregnancy, sm | oking and alcohol use, I | hepatic/renal dysft | unction, etc.) | | | | | | | |
| NO OTHER MEDIC | ATIONS. NO FA | MILY HISTOR | Y OF SEIZ | URES. | E. INITIAL RE | DODTED | | | | |
| | | | | | Name and Addr | | Phone | # (b) (6) | | |
| | | | | | | | Filone | # (b) (b) | | |
| | | | | | (b) (6) | | | | | 22 |
| | | | | 1 | | | | | | 9 SS 2 1 2013 |
| | | | | | | | | | AUG | 2 7 2010 |
| | | | | | | | | | | # 1 ZU13 |
| Submission of a | nort dessered | -4'4 | -l! (1 - : | | 0.11. | 10.10 | | | 2 1 1 1 1 1 2 | |
| Submission of a re personnel, user fac | cility, importer, dis | stitute an adn | nission that ufacturer or | medical product | 2. Health Profession | | upation | | Initial Report Report to FE | DA |
| aused or contribu | ited to the event. | , | | | Yes 📝 N | No | | | | No Unk. |

January Report

9412689-02-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became
Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

EDYTA FRACKIEWICZ

HYLAND'S, INC. 154 W. 131ST STREET

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

10-day Initial

54973 AE # 1403

5-day

7-day

26/05/2013

30-day

Periodic

Contact Office - Name/Address (and Manufacturing Site

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

Type of Report

10. Event Problem Codes (Refer to coding manual)

☐ Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial
Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Study
Literature
Consumer
Health Professional
User Facility

Company

Distributor

Other:

Representative

 Report Source (Check all that apply)

(mm/dd/yyyy)

Page 2 of 9

| of 9 | |
|--|--|
| H. DEVICE MANUFACTURERS ONL | Υ |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | i' |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| provide code. | Yes No |
| 6 Evolution Codes (Cotto) | |
| 6. Evaluation Codes (Refer to coding manual) | |
| Method | |
| Results - | |
| Tesuns | |
| Conclusions - | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| 10 🗆 Addis - III. | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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| | AUG 2 1 2013 |

CaseID: 9412689

FDA USE ONLY

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

STN#

510(k) # __ Combination

Product

Pre-1938

OTC Product

SEIZURES

8. Adverse Event Term(s)

Yes

Yes

√ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rookville, MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



9412689-02-00-03



Case 104-9412689 mld 34 Fick # 7008 1830 00048628 5428

June 7, 2013

(b) (6)

Dear

Pursuant to your phone call regarding our Hyland's Baby Teething tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 9.19. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach

President

Enc: Refund Check - \$ 9.58

DSS AUG **2** 1 2013



STOMER COMPLAINT RECORD



9412689-02-00-05

| 3412009-02-00-05 | COMPLAINT #: 2375 | |
|--|---|------------|
| TAKEN BY: EDYTA FRACKIEWICZ | DATE OF COMPLAINT: 06/05/13 LEFT MESSAGE | |
| PRODUCT: HYLAND'S BABY TEETHING TABLETS | ITEM CODE: BTETT135 | |
| SIZE: 135 TABLETS | LOT NO.: A22713 | |
| REPORTER: (b) (6) | | |
| ADDRESS: | | |
| | (b) (6) | |
| CITY: | STATE: | |
| COUNTRY: USA (b) (6) | ZIP CODE: | |
| PHONE #: E-MAIL: | | |
| SPOKE WITH CUSTOMER ON 06/06/13 LIS | NO INFORMATION ON TEETHING TABLETS RECALL ON THE INTER | EN RNET |
| FOR ADDITIONAL SPACE PLEASE USE REVE | RSE OR ATTACH A SEPARATE SHEET | |
| PRODUCT RECEIVED FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE O | N NE |
| | DATE REQUESTED PRODUCT BE RETURNED: | - |
| RECEIVED | UPS CALL TAG ISSUED: (CIRCLE O | NE) |
| | | |
| AUG 2 0 2013 | DATE PRODUCT RECEIVED: | |
| SECTION II: INVESTIGATION | DATE PRODUCT RECEIVED: | |
| SECTION II: INVESTIGATION CDR | | |
| SECTION II: INVESTIGATION CDR INVESTIGATION: BULK LOT # 118687. REVIEWED BATCH RECORD. N | MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO | |
| SECTION II: INVESTIGATION CDR | MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO | |
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| SECTION II: INVESTIGATION CDR INVESTIGATION: BULK LOT # 118687. REVIEWED BATCH RECORD. N | MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO TAINED SAMPLE AND EVERYTHING LOOKS OK | |
| INVESTIGATION BULK LOT # 118687. REVIEWED BATCH RECORD. IN ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RE | MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO TAINED SAMPLE AND EVERYTHING LOOKS OK. N: | |
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| INVESTIGATION: BULK LOT # 118687. REVIEWED BATCH RECORD. IN ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RE ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY SECTION III: CORRECTIVE ACTION: 06/07/13: PREPARED REFUND REQUEST TOTALING \$ 9.58. 07/26/13: MAILED RE 86285428. CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTE ADVERSE EVENT REPORTED ON: 06/05/13 | MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO TAINED SAMPLE AND EVERYTHING LOOKS OK 1. 06/05/13 EDYTA FRACKIEWICZ EFUND CHECK # 509487 TOTALING \$ 9.58 ON ARTICLE # 70081830 DATE: 06/07/13 & 07/26/13 AE #: 1403 | 00004 |
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cc: QA / QC Packaging Production Shipping / Receiving

AUG 2 10-2013

9412695-02-00-01

rters, distributors and manufacturers for MANDATORY reporting

CaseID: 9412695

| Fo | orm Approve | ed: OMB I | No. 09 10- See OM | 029 1, E B staten | xpires 12/31/1 ent on revers | 1 e. |
|-----|-------------|-----------|----------------------|----------------------|---------------------------------|---------|
| t # | 54073 | Cen | | 2 | | ٦ |

| | | See OMB statement on reverse | | | |
|-----------------------|--------|------------------------------|-------------|--|--|
| Mfr Report # 54075 Se | e 0458 | 2 | | | |
| UF/Importer Report # | 1 - 1 | | | | |
| | | F | DA Usa Only | | |

| A. PATIENT INF | | the substances | | |
|--|---|-------------------------|--|-----------|
| Patient Identifier (b) (6) | 2. Age at Time of Event: | Months | 3. Sex | 4. Weight |
| | or | HOHEHA | ✓ Female | ibs |
| In confidence | Date of Birth: | | Male | kgs |
| B. ADVERSE E | VENT OR PRODU | CT PROBLE | M | |
| 1. 🗸 Adverse Even | | oduct Problem (e | .g., defects/malfu | inctions) |
| Outcomes Attribut (Check all that appl | ted to Adverse Event | | | |
| Death: | (mm/dd/yyyy) | Disability o | r Permanent Dar | nage |
| Life-threatening | | Congenital | Anomaly/Birth D | efect |
| | - initial or prolonged | [22] | ous (Important M | - ' |
| | vention to Prevent Pern | , , | | <u> </u> |
| Date of Event (mn 06/2 | 23/2013 | 4. Date of This | Report (mm/ddi 06/26/2013 | , |
| 5. Describe Event or | Problem | .1 | | |
| THAT DAY. WE | SHAKING ON (b) AND HAD A BLA NT TO THE ER. TO A NEUROLOGI: | NK STÄRE. DOCTOR DIA | LSO NOT HAPPENED TI GNOSED AS : ZURES SINCI | SEIZURES |
| | | | | |
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| | | | | |
| | | | | |
| Relevant Tests/Lai | poratory Data, Includir | ng Dates | | |
| BLOOD TESTS W | ERE NORMAL. | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| 7. Other Relevant His | tory, Including Preexi | sting Medical Co | nditions (e.g., all | ergies, |
| | | | | |
| NO NEW FOODS / | SEIZURES IN TH FORMULA FED. | E FAMILY. | | |
| HAD A FEVER OF | 100.3 SOMETIM | | THAT MOTH | IER |
| INOUGHT IT WAS | FROM TEETHING | | | |
| | | | | |
| | | | | |
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| 11 | | | |
|---|--------------------|------------------|--|
| 1/5 | | | FDA Use Only |
| C. SUSPECT PRO | DUCT(S) | e e jama jego | T DA OSC OTH |
| Name (Give labeled street) | | | |
| #1 HYLAND'S BABY | TEETHING GE | L | |
| #2 | | | |
| 2. Dose, Frequency & Ro | ute Used | | es (If unknown, give duration) |
| #1 ONE DAB TO GU | MS 2-3XDAY | from/to (or be | est estimate) |
| | | | |
| #2 | in allow) | #2 | Ab Ab II |
| Diagnosis for Use (Ind #1 TEMP RELIEF 0 | | St | ent Abated After Use opped or Dose Reduced? |
| | T TEETHING T | #1 [| Yes No Doesn' |
| #2 | 7 | #2 [| Yes No Doesn' |
| 6. Lot# | 7. Exp. Date | | Д Д Д |
| #1130135A | #1 | | ent Reappeared After introduction? |
| #2 | #2 | #1 [| Yes No Doesn't |
| 9. NDC# or Unique ID | - | #2 [| Type IT No IT Doesn't |
| 54973-7521-2 | | | Tes INO Apply |
| 0. Concomitant Medical | Jaude and The | opy baces (EXCA | iou accoment of eventy |
| D. SUSPECT MEDI | CAL DEVICE | | |
| | | | |
| 2. Common Device Name | • | | |
| 3. Manufacturer Name, C | ity and State | | |
| 4. Model# | Lot# | | 5. Operator of Device |
| Catalog # | Expiration | Date (mm/dd/y) | (7y) Health Professional Lay User/Patient |
| Serial# | Other # | | Other: |
| Serial# | Other # | | Oliver. |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explanted, | Give Date (mm/dd/yyyy) |
|) I- 41: 0:- I D | | | |
| 3. Is this a Single-use De ☐ Yes ☐ No | vice that was Repr | ocessed and Re | used on a Patient? |
| 9. If Yes to Item No. 8, En | ter Name and Addi | ress of Reproces | ssor |
| | | | |
| | | | |
| 10 Daving Assettation | halustin o (Co.) | andt- Fr. | |
| 10. Device Available for E | | , | |
| ∐ Yes ∐ No | Returned to Ma | anulacturer on: | (mm/dd/yyyy) |
| 11. Concomitant Medical | Products and Ther | apy Dates (Excl | ude treatment of event) |
| | | | |
| | | | |
| E. INITIAL REPORT | TER | | |
| . Name and Address | Phone | # (b) (6) | |
| | L | | - DSS |
| b) (6) | | | DSS AUG 2 1 2013 |
| | | | AUG 2 1 2013 |
| | | | |
| | | | |
| 2. Health Professional? | 3. Occupation | | Initial Reporter Also Sent Report to FDA |
| | | 1 | - special and a men |

Yes No Unk.

Yes No

Individual Case Safety Report

9412695-02-00-02

Importer

3. User Facility or Importer Name/Address

Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

No.

Date User Facility or

11. Report Sent to FDA?

Importer Became
Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

HYLAND'S, INC.

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

10-day Initial

54973 AE#1422

5-day

7-day

06/25/2013

30-day

Periodic

15-day Follow-up # 19. Manufacturer Report Number

Contact Office - Name/Address (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

☐ Home

Other:

12. Location Where Event Occurred

☐ Initial ☐ Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Company

Distributor

Other:

Representative

Study
Literature
Consumer
Health Professional
User Facility

3. Report Source (Check all that apply)

(mm/dd/vvvv)

Page 2 of 10

| H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event |
|--|
| Death |
| Serious Injury Additional Information Response to FDA Request Device Evaluation Device Evaluation Provide Evaluation Provide Evaluation Summary Attached Not Returned to Manufacturer Pyes Evaluation Summary Attached No (Attach page to explain why not) or provide code: Pyes No Several Evaluation Codes (Refer to coding manual) Nethod Provide Evaluation Initiated, Check Type Several Evaluation Initiated, Check Type Several Evaluation Initiated, Check Type Instal Use of Device Provide Evaluation Provide Evaluatio |
| Malfunction Device Evaluation Device Manufacture Date (mm/yyyy) Device Evaluation Device Devi |
| Other. Device Evaluation |
| 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached Not (Attach page to explain why not) or provide code: Method Fesults Foundation Summary Results Foundation Summary Tonder of the coding manual Summary Method Foundation Initiated, Check Type Recall Notification Repair Inspection Replace Patient Monitoring Modification/ Adjustment Summary Mothication Foundation Summary Mothication Adjustment Summary Mothication Foundation Summary Mothication Foundat |
| Not Returned to Manufacturer Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: S. Labeled for Single Use? Yes No |
| Not Returned to Manufacturer Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: Yes No |
| No (Attach page to explain why not) or provide code: S. Labeled for Single Use? Yes No |
| Yes No |
| Yes No |
| Results |
| Results |
| Results |
| Conclusions |
| 7. If Remedial Action Initiated, Check Type Recall Notification Repair Inspection Replace Pattent Monitoring Relabeling Modification/Adjustment Other: 10. Additional Manufacturer Narrative Resuse Unknown 9. If action reported to FDA under 21 USC 360(ff), list correction/removal reporting number: 10. Additional Manufacturer Narrative Additional Manufacturer Narrative 7. If Remedial Action Initiated, Check Type Reuse Unknown 9. If action reported to FDA under 21 USC 360(ff), list correction/removal reporting number: |
| 7. If Remedial Action Initiated, Check Type Recall Notification Repair Inspection Replace Patient Monitoring Relabeling Modification/Adjustment Other: 10. Additional Manufacturer Narrative Remedial Action Initiated, Check Type Initial Use of Device Reuse Unknown 9. If action reported to FDA under 21 USC 360(ff), list correction/removal reporting number: |
| Recall Notification Repair Inspection Revise Unknown Replace Patient Monitoring Relabeling Modification/ Adjustment Other: Patient Monitoring Initial Use of Device Reuse Unknown 9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number: 10. Additional Manufacturer Narrative Narrative |
| Repair Inspection Unknown Retabeling Modification/ Adjustment Other: Patient Monitoring Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: 10. Additional Manufacturer Narrative and / or 11. Corrected Data |
| Replace Patient Monitoring Unknown Relabeling Modification/ Adjustment Other: 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: 10. Additional Manufacturer Narrative and / or 11. Corrected Data |
| Relabeling Modification/ Adjustment 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: 10. Additional Manufacturer Narrative and / or 11. Corrected Data |
| Adjustment 21 USC 360i(f), list correction/ removal reporting number: |
| Other: |
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| AUG 2 1 2013 |
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CaseID: 9412695

FDA USE ONLY

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(A)NDA#

IND#

STN#

510(k) # ___ Combination

Product

Pre-1938

SEIZURES

OTC Product Yes

8. Adverse Event Term(s)

☐ Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

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9412695-02-00-03



OCASEPE 38 173695 NO) OKTO CH 7 008 183 00048628589

June 26, 2013

(b) (6)

Dear (b) (6)

Pursuant to your letter regarding our Hyland's Baby Teething Gel, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 7.59 per bottle. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely.

Dan Krombach

President

Enc: Refund Check - \$8.43

DSS AUG 2 1 2013

AUG 2 0 2013

CUSTOMER COMPLAINT RECORD



| TAKEN BY: PRODUCT: | EDVE | | | | | |
|--|--|--|---|--|--|---------------------|
| PRODUCT: | _ EUTTA | A FRACKIEWICZ | • | COMPLAINT #: | 2407 | |
| 1100001. | | TEETHING GEL | DATE | OF COMPLAINT: | 06/25/13 | |
| SIZE: | 0.5 OUI | | | ITEM CODE: | _TGELU0.5 | Z |
| REPORTER: | (b) (6) | | | LOT NO.: | _130135A | |
| ADDRESS: | | | | | | |
| CITY; | - | | | (b) (6) | | |
| COUNTRY: | USA (b) (6) | | STA | - | | |
| PHONE #: | (b) (b) - | | ZIP Co | DDE: | | |
| E-MAIL: | | | | | | |
| NATURE OF COMPL TO THE ER. HAD BE MONITOR. NO SEIZ DOCTOR. NO FAMIL THOUGHT FROM TE FEVER BROKE ON F | LUCES SINCE. OFFE LY HISTORY OF SEI ETHING (100°F) SOI FRIDAY. | RE NORMAL. REFERRED TO I ERED A REFUND AND SHE WA IZURES. NO NEW FOODS / FO METIME ON FRIDAY. MOTHE | ES A DAY FOR 3 – 4 DAYS (JUN G, BLANK STARE. LASTED AB NEUROLOGIST. DOCTOR DIAG ANTS IT. TOLD HER NO TO USE RMULA FED. FULL TERM BAB R STATED THAT DOCTOR SAID | NOSED AS SEIZU BABY TEETHING Y. NO HEAD INJU FEVER WAS OK | . HAD ABOUT : JRES AND REC G GEL AND TAL JRY. HAD A FE AY AND DUE TO | OMMENDED TO |
| | FOR A | DDITIONAL SPACE PLEASE | USE REVERSE OR ATTACH A S | SEPARATE SHEE | r | |
| PRODUCT RECEIVED | | | | | | |
| INSPECTION: | D FOR | RECEIVE | PRODUCT BEING RE DATE REQUESTED | | | Y N (CIRCLE ONE) |
| | | AUG 20 2013 | | | | |
| | | MAG = 2 East | | UPS CALL TAG | G ISSUED: | Y (N) |
| SECTION II: | INVESTIGATION | CDR | 0 | ATE PRODUCT R | RECEIVED: | |
| the man | | - | | | | |
| INVESTIGATION: | PLEASE SEE | ATTACHED INVESTIGATION F | EPORT. | | | |
| | | | | | | |
| | | | | | | |
| DVERSE EVENT FOR | WARDED TO PHARM | MACIST / NURSE FOR EVALUA | TION ON: | 00/05/4- | | |
| DVERSE EVENT FORV | WARDED TO PHARM | MACIST / NURSE FOR EVALUA MACIST / NURSE FOR EVALUA | TION DN: | 06/25/13 | | |
| DVERSE EVENT FOR | WARDED TO PHARM WARDED TO PHARM CORRECTIVE | MACIST / NURSE FOR EVALUA | ATION ON: TION BY: | _06/25/13 EDYTA FRACE | √IEWICZ | |
| DVERSE EVENT FORV | WARDED TO PHARM | MACIST / NURSE FOR EVALUA ACTION: | ATION BY: | EDYTA FRACE | | |
| DVERSE EVENT FORV | WARDED TO PHARM | MACIST / NURSE FOR EVALUA ACTION: | ATION BY: | EDYTA FRACE | | #7008183000n4 |
| DVERSE EVENT FORV | WARDED TO PHARM | MACIST / NURSE FOR EVALUA ACTION: | ATION ON: ATION BY: AILED REFUND CHECK # 50949 | EDYTA FRACE | | #700818300004 |
| DVERSE EVENT FORV ECTION III: 5/26/13: PREPARED R 5/285510. | WARDED TO PHARM <u>CORRECTIVE</u> EFUND REQUEST T | MACIST / NURSE FOR EVALUA ACTION: | ATION BY: | EDYTA FRACE | | #700818300004 |
| DVERSE EVENT FORVECTION III: 5/26/13: PREPARED R 5/285510. DRRECTIVE ACTION(S | WARDED TO PHARM <u>CORRECTIVE</u> EFUND REQUEST T | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M | ATION BY: | EDYTA FRACE | 43 ON ARTICLE | |
| DVERSE EVENT FORVECTION III: 5/26/13: PREPARED R 5/285510. DRRECTIVE ACTION(S | WARDED TO PHARM <u>CORRECTIVE</u> EFUND REQUEST T | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M | ATION BY: | EDYTA FRACE 6 TOTALING \$ 8.4 DATE:06/2 | 43 ON ARTICLE 26/2013 & 07/26 | |
| ECTION III: 6/26/13: PREPARED R 6/28/5510. DRRECTIVE ACTION(S | CORRECTIVE A CORRECTIVE A EFUND REQUEST T COMPLETED BY: ADVERSE EVENT R | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M (b) (6) REPORTS | ATION BY: | EDYTA FRACE | 43 ON ARTICLE 26/2013 & 07/26 | |
| ECTION III: 6/26/13: PREPARED R 6285510 DRRECTIVE ACTION(S CTION IV: | CORRECTIVE A CORRECTIVE CORRECT | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M (b) (6) | ATION BY: | EDYTA FRACE 6 TOTALING \$ 8.4 DATE:06/2 | 43 ON ARTICLE 26/2013 & 07/26 | |
| ADVERSE EVENT FORWARD RIEGION III: 6/26/13: PREPARED R 6/28/510. ORRECTIVE ACTION(S ECTION IV: OVERSE EVENT SERION OVERSE EVENT REPORT | CORRECTIVE A CORRECTIVE CORRECT | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M (b) (6) REPORTS | ATION BY: AILED REFUND CHECK # 50949 | EDYTA FRACE 6 TOTALING \$ 8.4 DATE:06/2 | 43 ON ARTICLE 26/2013 & 07/26 2 | |
| ADVERSE EVENT FORM DECTION III: 6/26/13: PREPARED R 6/28/510. ORRECTIVE ACTION(S ECTION IV: OVERSE EVENT SERIOR OVERSE EVENT REPOR | CORRECTIVE A CORRECTIVE C | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M (b) (6) | ATION BY: AILED REFUND CHECK # 50949 | EDYTA FRACE 96 TOTALING \$ 8.4 DATE: 06/2 AE #: 1422 | 43 ON ARTICLE 26/2013 & 07/26 2 | |
| ECTION IV: OVERSE EVENT FORWARD R 6/26/13: PREPARED R 6/28/5510. ORRECTIVE ACTION(S OVERSE EVENT SERION OVERSE EVENT REPORE | CORRECTIVE A CORRECTIVE C | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M (b) (6) | ATION BY: AILED REFUND CHECK # 50949 | DATE: 06/2 AE #: 142: | 43 ON ARTICLE 26/2013 & 07/26 2 | DSS |
| ECTION III: 6/26/13: PREPARED R 6/28/5510. DRRECTIVE ACTION(S CTION IV: VERSE EVENT SERIO VERSE EVENT REPOR | CORRECTIVE A CORRECTIVE C | MACIST / NURSE FOR EVALUA ACTION: TOTALING \$ 8.43. 07/26/13: M (b) (6) | ATION BY: AILED REFUND CHECK # 50949 | DATE: 06/2 AE #: 142: | 43 ON ARTICLE 26/2013 & 07/26 2 | |

cc: QA / QC Packaging

Production Shipping / Receiving

AUG 2 0 2013 " VD1





| CaseID: 9424540 | |
|--|--|
| Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 | |

| | See OMB statement on reverse |
|----------------------|------------------------------|
| Mfr Report# 54973 | |
| UF/Importer Report # | |
| | |

Page 1 o FORM FDA 3500A (6/10) A. PATIENT INFORMATION 1. Patient Identifier 2. Age at Time 4. Weight 3. Sex (b) (6) of Event: Months Female or . or Date ✓ Male In confidence of Birth kgs **B. ADVERSE EVENT OR PRODUCT PROBLEM** 1. Adverse Event and/or Product Problem (e.g., defects/malfunctions) Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/vvyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 11/00/2012 07/02/2013 5. Describe Event or Problem HAD 3 SEPARATE SEIZURES IN (b)(6)
AND (b)(6) WHILE USING HY (b) (6) WHILE USING HYLAND'S BABY TEETHING TABLETS. SEIZURES WERE ON THE LEFT SIDE OF THE BODY AND CHILD UNRESPONSIVE. HOSPITALIZED AFTER TWITCHING, JERKING, FOAMING AT MOUTH, AND TURNED BLUE ON THIRD SEIZURE. 6. Relevant Tests/Laboratory Data, Including Dates NEUROLOGICAL TESTS WERE NORMAL. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) NO OTHER MEDICATIONS. NOT PRE-MATURE. NO HISTORY OF HEAD INJURY. NO FAMILY HISTORY OF SEIZURES. BOTTLE FED. HAD A FEVER DURING THE FIRST SEIZURE (100.1 -101F); NO FEVER DURING THE OTHER SEIZURES.

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| - | | | |
|------------------------------------|--------------------|-----------------------|--|
| of <u>5</u> | | | FDA Use Only |
| C. SUSPECT PROD | UCT(S) | | 1 DA OSE OTRY |
| 1. Name (Give labeled stre | <u></u> | | |
| #1 HYLAND'S BABY | TEETHING TA | RBLETS | |
| #2 | | | |
| 2. Dose, Frequency & Ro | uto llead | 3 Therapy Da | ites (If unknown, give duration) |
| | | | est estimate) |
| #1 AS NEEDED FOR | 3 MONTHS | #1 | |
| #2 | | #2 | |
| 4. Diagnosis for Use (India | cation) | | vent Abated After Use topped or Dose Reduced? |
| #1 TEMP RELIEF TO | EETHING PAIN | | Yes No Doesn't |
| #2 | | | Apply Apply |
| 6. Lot # | 7. Exp. Date | #2 | ☐ Yes ☐ No ☐ Doesn't |
| #1114465 | #1 | | vent Reappeared After |
| #2 | #2 | 1 | eintroduction? |
| 9. NDC# or Unique ID | 1#2 | #1 | Yes No Apply |
| 54973-3127 - 1 | | #2 | Yes No Doesn't |
| 10. Concomitant Medical | Products and The | rapy Dates (Exc | |
| | | , | , |
| | | | |
| | | | |
| | | | |
| D. SUSPECT MEDIC | CAL DEVICE | | |
| 1. Brand Name | | | |
| 2. Common Device Name | | | |
| 2. Common Device Name | | | |
| 3. Manufacturer Name, Ci | ity and State | | |
| | | | |
| 4. Model # | Lot# | | 5. Operator of Device |
| | | | Health Professional |
| Catalog # | Expiration | n Date (mm/dd/y | |
| 8 | Other # | | Other: |
| Serial# | Other# | | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explanted | i, Give Date (mm/dd/yyyy) |
| | | | |
| 8. is this a Single-use Dev | rice that was Repr | ocessed and Re | eused on a Patient? |
| Yes No 9. If Yes to Item No. 8, En | tor Name and Add | rose of Bancose | |
| 5. II Tes to itelli No. 6, Ell | ter Name and Add | ress or Reproce | SSOI |
| | | | |
| | | | Da- |
| 10. Device Available for E | valuation? (Do not | send to FDA) | D22 |
| Yes No | Returned to M | anufacturer on:_ | (mth Mc/honny) - |
| 11. Concomitant Medical I | Products and The | apy Dates (Exc | dude treatment of event 2013 |
| | | ,,, | , |
| [| | | |
| F INITIAL DESCRIPTION | | | |
| E. INITIAL REPORT | | # (b) (c) | |
| Name and Address | Phone | # (b) (6) | |
| (b) (6) | | | |
| | | | |
| | | $\boldsymbol{\sigma}$ | 164 |
| | | */ | ISA |
| | | • | |
| 2. Health Professional? | 3. Occupation | | Initial Reporter Also Sent Report to FDA |
| Yes No | | | Yes No Unk. |



| 1. Check One | | 2. UF/Impor | ter Report Number |
|---|-----------------|--|--|
| User Facility | impor impor | ter | - |
| 3. User Facility or Imp | orter Name/ | Address | |
| | | | |
| 4. Contact Person | | 5. Pho | ne Number |
| 6. Date User Facility o Importer Became Aware of Event (mn | | Type of Report Initial Follow-up# | 8. Date of This Report (mm/dd/yyyy) |
| 9. Approximate Age of Device | 10. Event P | roblem Codes (Refer to | coding manual) |
| | Patient Code | - | - |
| | Device Code | | |
| 11. Report Sent to FD/ | 17 | 12. Location Where Ev | |
| Yes(mm/dd | nufacturer? | Hospital Home Nursing Home Outpatient Trea | Outpatient Diagnostic Facility Ambulatory Surgical Facility |
| □ No (mm/dd | <i>(УУУУ</i> У) | Other: | (Specify) |
| 14. Manufacturer Nam | e/Address | | (Specify) |
| G. ALL MANUFA 1. Contact Office - Nat for Devices) EDYTA FRACKIE HYLAND'S, INC 154 W. 131ST LOS ANGELES, | me/Address | (and Manufacturing Site | 310-768-0700 3. Report Source (Check all that apply) Foreign |
| | | | Study Literature Consumer Health Professional |
| 4. Date Received by Manufacturer (mm/c | d/yyyy) | 5. | Literature Consumer Health Professional User Facility |
| | , | (A)NDA # | Literature Consumer Health Professional User Facility Company Representative |
| Manufacturer (mm/c | 013 | 1 | Literature Consumer Health Professional User Facility Company |

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| | FDA USE ONLY |
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| f <u>5</u> | |
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| ☐ Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | Device Manufacture Date (mm/yyyy) |
| Not Returned to Manufacturer | (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| provide code. | Yes No |
| Evaluation Codes (Refer to coding manual) | L |
| C. Evaluation codes (Neigh to coding manual) | |
| Method | |
| Results - | |
| | |
| Conclusions - | |
| 7. If Remedial Action Initiated, Check Type 8. | Usage of Device |
| Recall Notification | ☐ Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| I Relabelling Informations | If action reported to FDA under 21 USC 360i(f), list correction/ |
| , iajaotinon | removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative and | d / or 11. Corrected Data |
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Food and Drug Administration
Office of Chief Information Officer
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Rockville, MD 20850
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IPLAINT RECORD



| 9424540-01-00-03 | COMPLAINT #: | 2421 |
|--|---|--|
| | DATE OF COMPLAINT: | |
| PRODUCT: HYLAND'S BABY TEETHING TABLETS | | BTETT135 |
| SIZE: 135 TABLETS (b) (6) | LOT NO.: | 114465 |
| REPORTER: | | |
| ADDRESS: | | JUL 2 5 2013 |
| | (b) (6) | - VEIVE |
| OITY: | STATE: | 1111 9 5 00 |
| COUNTRY: USA (b) (6) | ZIP CODE: | 50L Z 5 Z913 |
| PHONE #: | | CDD |
| NATURE OF COMPLAINT: AND 3 DAYS LATER IN (⁽⁶⁾ WITCHING, JERKING LEFT HALF OF BODY. AMBULANCE PICKED HIM UP SAID IT WAS ODD THAT ONLY HALF HIS BODY SEIZED. STAYED IN HOSPI | AND WENT TO (b) (6) TAL / ER FOR 6 HOURS. THEY CONTINUI BED. HAD A THIRD SEIZURE IN (b) (6) FTER THAT. THIRD SEIZURE WORSE BE TO ER AND STAYED OVERNIGHT. DOCTO ABY TEETHING TABLETS IN (b) (6) A SETTLEMENT. OFFERED A REFUND FO A RESULT OF CHILD'S SEIZURES. | MING UNRESPONSIVE, TESTING SHOWED NOTHING. ED USING TEETHING TABLETS. GOT A TABLET BEFORE BED CAUSE HE STOPPED BREATHING, DRS NOT SURE OF THE CAUSE. TER THIRD SEIZURE AND HAS R THE BOTTLE BUT DECLINED. RTMENT. HE HAD MEDICAL |
| PRODUCT RECEIVED FOR NSPECTION: NO OTHER MEDICATIONS. NOT PRE- MATURE. NO HISTORY OF HEAD NJURY. NO FAMILY HISTORY OF SEIZURES. BOTTLE FED. HAD A | PRODUCT BEING RETURNED FOR I | (CIRCLE ONE) |
| EVER DURING THE FIRST SEIZURE 100.1 – 101: NO FEVER DURING THE DTHER SEIZURES. | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| STATE OF THE STATE | DATE PRODUC | T RECEIVED: |
| SECTION II: INVESTIGATION | | |
| | | |
| NVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPO | ORT. | |
| | · · · · · · · · · · · · · · · · · · · | |
| | | |
| | | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION | ON ON: 07/01/13 | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION | ON BY: EDYTA FF | RACKIEWICZ |
| SECTION III: CORRECTIVE ACTION: | | |
| | | |
| | | |
| | A-44 | |
| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: | |
| SECTION IV: ADVERSE EVENT REPORTS | AE #: | 1430 |
| | . – | |
| ADVERSE EVENT SERIOUS: | | Dec |
| ADVERSE EVENT REPORTED ON: 07/01/13 | BY: EDYTA FRACKI | |
| SECTION V: | | IJUL 26 201 |
| REVIEWED BY MANAGEMENT BY: | DATE: | 67-11-13 |
| | | |
| 94: Olyman Lah. | DATE: <u></u> | 7-10-13 |

cc: QA / QC Packaging

Production Shipping / Receiving JUL 50 2 2013





Serious Adverse Event SAE-0029-2013

| Product in Inventory: |
|---|
| No units of Hyland's Baby Teething Tablet (BTET), lot #114465, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (In the Interval of |
| Review of Records: |
| The BTET lot #114465 was manufactured using (b) (4) Interpretation of the boundary of the break and below |
| Atropine and Scopolamine testing was conducted on the final container product BTET # 114465, and it was within specification, with results $\leq_{(4)}^{(5)}$ ppm. |
| The final product lot #114465 was submitted for microbiological testing to on 01/12/2012 and the results met the criteria for acceptance for Microbial Limits Test for Aerobic Plate Count, Yeast and Mold Count, Escherichia cola, Salmonella sp., Pseudomonas aeruginosa, Staphylococcus aureus and Clostridia sp. |
| Retention Samples: |
| A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the product. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specification of: color – white, odor – none and taste – faintly sweet. |
| The inspection did not yield any results that may be related to this incident. |
| Other investigations: |
| A review of the Deviation System was conducted and no issues were reported for this lot or the associated intermediate powder. |
| Of the units manufactured a total of 2 complaints, including this one, have been received on Hyland's Baby Teething Tablet (BTET), lot #114465. |
| A review of the Customer Complaint system did reveal that on 5/25/2012 a report of "tablets are crumbly and lots of powder in the bottle" was reported for this same BTET lot #114465. That complaint was investigated under Complaint # 1487. The incident was investigated and no issues with the manufacturing or packaging process that could have contributed to that incident was identified. |
| The two incidents are not considered related. |
| Conclusion: |
| The investigation did not reveal any issues with the manufacturing or packaging processes for this lot of Hyland's Baby Teething Tablet (BTET), lot #114465. Manufacture and processing occurred within established procedures to ensure product quality. |
| Prepared by Date |
| Prepared by Date DSS JUL 2 6 2013 |
| JUL 26 2013 |

SAE-0029-2013 AE-0233-2013 CC-0393-2013 Complaint # 2421 Page 1 of 1

JUL 2 5 2013





E EVENT DATA FORM

| AE #:1430 | COMPLAINT #: 2421 |
|---|--|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: ADDRESS: | (b) (6) |
| CITY: | STATE: (b) (6) |
| COUNTRY: | USA ZIP CODE: |
| PHONE #: | (b) (6) |
| E-MAIL: | |
| SECTION II: | PACKAGING INFORMATION: |
| AFF | FIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| Andiscussions: Service value of the consistency of any processor and service and service of the consistency | destrict places of and in a creation of the cr |
| SECTION III: | CORRECTIVE ACTION: |
| | |
| CORRECTIVE AC | CTION(S) COMPLETED BY: DATE: |
| SECTION IV: | . \ / |
| REVIEWED BY M | DATE: 07-11-13 DSS DATE: 07-10-13 DATE: 07-10-13 |
| ву: | egman Date: 07-10-13 |



The FDA Safety Information and

UNTARY reporting nts, product problems and roduct use errors

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

CaseID: 9461703

FDA USE ONLY Triage unit sequence #

| 1.5 Months | The FDA Safety Adverse Event | | | | Pag | e 2 012 ⅓ | \mathcal{CDER} | | | | |
|--|---------------------------------|----------------------|---------------------|----------------------------|------------------|-----------------------|-------------------|-----------------|---|--------------|---------------------|
| Date of Birth Display Date Date Display Date | | | | | | 1 · | or Amount | Frequ | ency Rou | te | |
| S. Months | . Patient Identifier b) (6) | | Event or | 3. Sex | 4. Weight | #1 as | needed | | | | |
| Application | ,, (0) | | | Female | Ib | | | | | | |
| ADVERSE EVENT, PRODUCT PROBLEM OR ERROR with a literal type with a literal type Product Problem (e.g., electromaturations) Product Use Error Problem (e.g., electromaturation) Product Institution Product Instituti | in confidence | (6) | | ✓ Male | or k | | | | | | |
| About Servent Product the Servent Prod | B. ADVERSE | | UCT PRO | BLEM OR E | RROR | (or bes | t estimate) | | Sto | pped or l | Dose Reduced? |
| Outcomes Attributed to Adverse Event Check all that all processions Description | | = | | | | 1/2 | 3/2010 - 12/ | 31/2013 | | | Apply |
| Death: (mm/65/yyy) Chaptely or Permanent Danage Chaptely and Apply Chaptely | (Check all that ap | | _ | | | 11 . • | | or Use (Indical | tion) 8. I | vent Rea | Apply Apply |
| Proprietation - inflat of polonged Other Serious (Important Medical Events) F. Expiration Date Product Pro | | | _ | • | • | #2 | | | #1 | √ Yes | Apply Apply |
| Date of the Report (mmodayyyy) 08/14/2013 08/14/201 | | | | | | 6. Lot # #1 | | | Date | | Apply |
| Describe Event, Problem or Product Use Mass taking Hylands teething was taking Hylands teething by an born limit in a half old, 8c since the was a month in a half old, 8c since the was a month in a half old, 8c since the was a month in a half old, 8c since the was a month in a half old, 8c since the was a month in a half old, 8c since the was a month of the was taking were the teething delayed speech, vision problems, urination problems and respiratory as well. There were many times when the only medication he was taking were the teething tablets. Alfo 15 2013 | Date of Event (n | ım/dd/yyyy) | 4. Date | of this Report (r | nm/dd/yyyy) | #2 | | #2 | | | |
| The stablets since he was a month in a half old. So since to 00.00 | | | 08/3 | 14/2013 | ***** | E. SUS | SPECT MEDIC | CAL DEVIC | E | | |
| Common Device Name Common | | | | | | 1. Brand | Name | | | | |
| Numerous times for Dhknown reasons of high fever, constipation, agitation, respiratory problems, skin problems, selegency shows surgery. He is now having delayed speech, vision problems, urination problems and respiratory problems, and respiratory problems and respiratory as well. There were many times when the only medication he was taking were the teething tablets. Augustation Augusta | tablets sin | | taking H onth in | ylands teet a half old. | ning So since | | | | • | CTU | |
| Constipation, agitation, respiratory problems, skin problems emergency simus surgery. He is now having delayed speech, vision problems, urination problems and respiratory as well. There were many times when the only medication he was taking were the teething tablets. A. Model # Lot # Lot # Lot # Health Professional | | | | | | 2. Commo | on Device Name | | | | |
| A manufacturer Name, City and State | | | | | | | | | AUG | 1 5 20 | 013 |
| respiratory as well. There were many times when the only medication he was taking were the teething tablets. 4. Model # Lot # Lot # Soperator of Device Health Professional | problems, e | mergency sinu | s surger | y. He is no | w having | 3. Manufa | cturer Name, Ci | ty and State | | | |
| 4. Model # Lot # Soperator of Device Health Professional | respiratory only medica | as well. The | re were | many times | when the | | | | | | |
| Relevant Tests/Laboratory Data, Including Dates Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: | tablets. | | | | | 4. Model | # | Lot# | | 5. C | Operator of Device |
| Cother Relevant Tests/Laboratory Data, Including Dates Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liverkidney problems, etc.) | | | | | | | | | | | Health Professional |
| Relevant Tests/Laboratory Data, including Dates Serial # Other # | | | | | | Catalog | 1# | Expiration | on Date (mm/dd/ | wwi 🗀 | Lav User/Patient |
| Serial # Other # | | | | | | | , " | Lapitude | in Date (illinoca) | | • |
| Cher Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Race: White Medical Conditions: Allergies: Important Information: RX Meds: OTC Meds: gummie vitamins | Relevant Tests/L | aboratory Data, Inc | cluding Date | es | **** | Carial | | Other # | | _ | Other: |
| S. Is this a Single-use Davice that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No S. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No S. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor No S. If Yes to Item No. 8, Enter Name and Address of Reprocessor No S. If Yes to Item No. 8, Enter Name and Address of Reprocessor No S. If Yes to Item No. 8, Enter Name and Address of Reprocessor Name | | • | | | | Serial | • | Other# | | | |
| S. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Yes No Section 1. | | | | | | 6. If Impla | nted, Give Date | (mm/dd/yyyy) | 7. If Explant | ed, Give I | Date (mm/dd/vyvv) |
| Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Race: White Medical Conditions: Allergies: Important Information: RX Meds: OTC Meds: gummie vitamins F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) G. REPORTER (See confidentiality section on back) Name Nam | | | | | | | | ice that was | Reprocessed an | d Reused | on a Patient? |
| Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Race:White Medical Conditions: Allergies: Important Information: RX Meds: OTC Meds: gummie vitamins PRODUCT AVAILABILITY Oduct Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: SUSPECT PRODUCT(S) Name: Hylands teething tablets Strength: Manufacturer: Hylands Name: Strength: Name: Strength: Name: Strength: Name: Strength: Name: Strength: Strength: Strength: Name: Strength: St | | | | | | | | | | | |
| Race: White Medical Conditions: Allergies: Important Information: RX Meds: OTC Meds: gummie vitamins F. OTHER (CONCOMITANT) MEDICAL PRODUCTS | Other Relevant F | listory, Including P | reexisting N | Medical Condition | ns (e.g., | 9. If Yes to | item No. 8, Enter | Name and Ad | dress of Reproce | essor | |
| Information: RX Meds: OTC Meds: gummie vitamins Product names and therapy dates (exclude treatment of event) G. REPORTER (See confidentiality section on back) I Name and Address Suspect Product (from product tabel) Name: Hylands Name: Strength: Manufacturer: Hylands Name: Strength: Stren | | | | | | | | | | | |
| PRODUCT AVAILABILITY oduct Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hylands Name: Strength: Manufacturer: Hylands Strength: Strength: Manufacturer: Hylands | | | | | | | | | | | S |
| PRODUCT AVAILABILITY oduct Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hylands teething tablets Strength: Manufacturer: Hylands Name: Strength: Name: Strength: Name: Strength: Name: Strength: No Manufacturer Jesu Address AUG 15 | | | | | | Product | ames and therap | oy dates (exc | ude treatment or | eventj | |
| PRODUCT AVAILABILITY oduct Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hylands teething tablets Strength: Manufacturer: Hylands Name: Strength: Name: Strength: Name: Strength: Name: Strength: No Manufacturer Strength: 1 Name and Address Manufacturer and Address Manufacturer and Address Manufacturer and Address Manufacturer and Address Manufacturer # | | | | | | G. REP | ORTER (See | confidentia | ality section o | n back) | |
| SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hylands teething tablets Strength: Manufacturer: Hylands 2. Health Professional? 3. Occupation Yes No Manufacturer Manufacturer Strength: Summary Strength: Manufacturer Summary Strength: Manufacturer Summary Summar | PRODUCT | AVAIL ABILITY | | | | | | | | | |
| SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hylands teething tablets Strength: Manufacturer: Hylands 2. Health Professional? 3. Occupation Yes No Manufacturer Manufacturer Strength: Summary Strength: Manufacturer Summary Strength: Manufacturer Summary Summar | | | not send pr | oduct to FDA) | | | | | | | 20 |
| Name, Strength, Manufacturer (from product label) Name: Hylands teething tablets Strength: Manufacturer: Hylands Name: Strength: 1. Health Professional? 2. Health Professional? 3. Occupation 4. Also Reported to: Yes No Manufacturer Strength: 5. If you do NOT want your identity disclosed User Facility | Yes 🕢 No | Returned to M | lanufacturer | | /dd/yyyy) | | | | | | AUG 1 5 |
| Name: Hylands teething tablets Strength: Manufacturer: Hylands 2. Health Professional? 3. Occupation Yes No Manufacturer Strength: 5. If you do NOT want your identity disclosed User Facility | | | | | | Phone # | | | E en all | | |
| Strength: Manufacturer: Hylands 2. Health Professional? 3. Occupation Yes No Manufacturer Strength: 5. If you do NOT want your identity disclosed User Facility | | | | el) | | (b) (6) | | | | | |
| Name: Yes No Manufacturer Strength: 5. If you do NOT want your identity disclosed User Facility | Strength: | | DIECS | | | | | | | | |
| Strength: 5. If you do NOT want your identity disclosed User Facility | | ylands | | | | | | Occupation | | 1 | • |
| of the year addition want year addition disclosed | | | | | | | | | *************************************** | _ = | |
| | | | | | | | | | | = | |

OTC For the by user-facilitie

For use by user-facilities, ers, distributors and manufacturers or MANDATORY reporting

| | CaseID: 9471241 | |
|-------------|--|--|
| Form Approv | red: OMB No. 09 10-029 1, Expires 12/31/11 | |

| | See OMB statem ent on revers |
|----------------------|------------------------------|
| Mfr Report# 54973 | |
| UF/Importer Report # | |

| | MEDVA | 1 | | | | • | | | | |
|-----------|-----------------------|------------------------------------|---------------------------------------|---------------------------|------------------|------------------------------------|---------------------|-------------------|------------------------------------|----------------|
| | FORM FDA 3500 | DA (6/10) | | | Page 1 | of <u>5</u> | | | | FDA Use Only |
| | A. PATIENT INF | ORMATION | e La grafi kraljeta aliaja ka lima | in Markety in | South Section 1 | C. SUSPECT PROD | UCT(S) | | | |
| | Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight | Name (Give labeled street | ngth & mfr/labeler) | | | |
| | (b) (6) | of Event: | Months | [[Comple | lbs | #1 HYLAND'S TEETI | HING TABLETS | | | |
| | | or Date | | Female | or | #2 | | 1 | | |
| | In confidence | of Birth: | | [✓] Male | kgs | 2. Dose, Frequency & Rou | ıta Head | 3 Therany Dat | tes (If unknown, g | nive duration) |
| | B. ADVERSE EV | ENT OR PRODU | CT PROBLE | M | | | ne osed | from/to (or be | | pro daranony |
| | 1. Adverse Event | and/or Pro | oduct Problem (| e.g., defects/mall | functions) | #1 UNKNOWN | | #1 | | |
| | 2. Outcomes Attribut | | | | | #2 | | #2 | | |
| | (Check all that appl) | y) | | | | 4. Diagnosis for Use (India | cation) | | ent Abated Afte opped or Dose F | |
| | Death: | (mm/dd/yyyy) | | or Permanent Da | | #1 TEMP RELIEF TE | EETHING PAIN | | Yes √ No | ☐ Doesn't |
| | ✓ Life-threatenin | | | l Anomaly/Birth | | #2 | | | | Apply |
| | | - initial or prolonged | | ious (Important N | - 1 | 6. Lot# | 7. Exp. Date | #2 [| Yes No | Doesn't Apply |
| | | vention to Prevent Perm | | | | #1 | #1 | | ent Reappeared | After |
| | 3. Date of Event (mm | <i>vdd/yyyy)</i> O TO PRESENT | 4. Date of This | Report (mm/d 08/01/201 | | #2 | #2 | | eintroduction? | [Doesn't |
| | 5. Describe Event or | | | 00/01/201 | | 9. NDC# or Unique ID | 1 | | | L Apply |
| | o. Describe event of | FIODIeni | | | | 54973-7504-1 | | #2 [| Yes No | Doesn't Apply |
| | | O CHILD BEGAN E | | | | 10. Concomitant Medical I | Products and The | rapy Dates (Excl | ude treatment of | |
| | | SYMPTOMS OF BI D DILATED, MOUT | | , | | | | | | |
| | | HING. SEIZURES | | | | | | | | |
| NK INK | | 15 MONTHS OF AC | | | | | | | | |
| - 1 | | EVERAL LONGER S ACHING MILESTON | | | HILD HAS WITH | | | | | |
| Č | AUTISM DISORDA | ER. | | | | D. SUSPECT MEDIC | CAL DEVICE | | | |
| BLACK | | | | | | 1. Brand Name | | | | |
| E | | | | | | 2. Common Device Name | | | | - |
| USE | | | | | | 3. Manufacturer Name, Ci | ty and State | | | |
| OR | | | | | | | | | | |
| Ä | | | | | | | | | | |
| TYPE | | | | | | 4. Model # | Lot # | | | r of Device |
| H | | | | | | Catalog # | Expiration | n Date (mm/dd/y | 2004 | Professional |
| Ä | | | | | | | | | 1 - | ser/Patient |
| PLEASE | | | | | | Serial# | Other # | | Other: | |
| | | | | | | 6. If Implanted, Give Date | (mm/dd/vvvv) | 7. If Explanted | I, Give Date (mm. | /dd/vvvv) |
| | | | | | ~ | | (| | , | ,,,,,, |
| | 6. Relevant Tests/Lat | boratory Data, Includin | ng Dates | | | 8. Is this a Single-use Dev | vice that was Repr | ocessed and Re | used on a Patie | nt? |
| | EKG, EEG, MRI | WITH NORMAL RE | ESULTS. | | | Yes No 9. If Yes to Item No. 8, En | tor Name and Add | ross of Bonross | | |
| | | | | | | 9. If Yes to Item No. 8, En | ter Name and Add | ress of Reproce | ssor | |
| | | | | | | | | | | |
| | | | | | | 1 | | | | |
| | | | | | | 10. Device Available for E | valuation? (Do not | send to FDA) | | - |
| | | | | | | Yes No | Returned to M | anufacturer on: _ | (mm/dd/y | 'yyv) |
| | | | * | | | 11. Concomitant Medical | Products and The | rapy Dates (Exc | | |
| | 7. Other Relevant His | story, Including Preexi | sting Medical C | onditions (e.g., | allergies, | | | | | |
| | race, pregnancy, sn | noking and alcohol use, | hepatic/renal dy. | sfunction, etc.) | | | | | | |
| | CHILD HAS ALSO | UNDERGONE DEV | /ELOPMENTAI | TESTING E | BECAUSE | E. INITIAL REPORT | FR | | | |
| | OF DIFFICULTY | REACHING MILES | STONES. | | | Name and Address | | #(b)(6) | | |
| | | | | | | (b) (6) | | | | - |
| | | | | | | (b) (6) | | | DS DS | 5 S |
| | | | | | | | | | Alla :- | _ |
| | | | | | | | | 2013 | AUG 1 | 9 2013 |
| | | | | | | | | - • • | | |
| | Submission of a re | eport does not co | nstitute an ac | lmission that | t medical | 2. Health Professional? | 3. Occupation | | 4. Initial Repor | |
| | personnel, user fa | cility, importer, di | stributor, ma | nufacturer o | r product | ☐ Yes ☑ No | • | | Report to FE | No. Tallok |

9471241-01-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

☐ No

6. Date User Facility or Importer Became

11. Report Sent to FDA?

Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

EDYTA FRACKIEWICZ HYLAND'S, INC. 154 W. 131ST STREET

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

Type of Report (Check all that apply)

7-day Periodic

15-day Follow-up # ____ 9. Manufacturer Report Number

☐ 10-day 🗸 Initial

54973 AE #1484

5-day

07/25/203

30-day

Contact Office - Name/Address (and Manufacturing Site

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

| Initial | Follow-up # | 10. Event Problem Codes (Refer to coding manual)

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Outpatient Treatment

Hospital

Nursing Home

Facility

Other:

Home

 Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

(Specify)

2. Phone Number 310-768-0700 3. Report Source (Check all that apply)

Foreign

Company Representative

Distributor

✓ Other:

LAWYER

Yes

Yes

Study

Literature

Consumer

Health Professional

User Facility

Page 2 of ⁵

| | | FD | A USE ONLY | |
|-----------------------------|----------------------------|--------|----------------|-----------------------------------|
| 5 | | | | - |
| 5 | | | | |
| I. DEVICE MANUFAC | TURERS ONL | Υ | <u> </u> | and the second |
| Type of Reportable Event | | 2. | If Follow-up | , What Type? |
| Death | | | Correc | tion |
| Serious Injury | | | Additio | onal Information |
| Malfunction | | | Respo | nse to FDA Request |
| Other: | | | Device | Evaluation |
| Device Evaluated by Man | ufacturer? | = 4 | Device Man | ufacture Date |
| Not Returned to Manu | ufacturer | | (mm/yyyy) | |
| Yes Evaluation | n Summary Attached | | | |
| No (Attach page to ea | xplain why not) or | 5. | Labeled for | Single Use? |
| provide code: | | | Yes | □ No |
| | | | | |
| Evaluation Codes (Refer to | o coding manual) | • | | |
| Method | - | |]- | |
| | | | | |
| Results | | -[| | |
| Conclusions | | | | |
| | | [| | |
| If Remedial Action Initiate | d, Check Type | 8. Us | age of Device | |
| Recall N | lotification | - | Laurent III | of Device |
| | nspection | | Reuse | |
| | atient Monitoring | 0 If a | Unknown | d to FDA under |
| | Aodification/ djustment | 21 | USC 360i(f), I | ist correction/ |
| Other: | | ren | noval reporti | ng number: |
| | | | | |
| . Additional Manufact | uror Narrativo | and/ | or 11 [| Corrected Data |
| | arci maratire | ano, | | Corrected bata |
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| | . A150 • | c | | DSS |
| | AUG 1 | 6 2 | 013 4 | DSS Aug 1 9 2013 |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

STN#

510(k) # __ Combination

Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)
NON-CONVULSANT SEIZURES

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9471241

Please DO NOT RETURN this form to this address.



CUSTOMER COMPLAINT RECORD



| | | COMPLAINT #: | 2490 |
|--|--|--|---|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 07/25/13 |
| PRODUCT: | TEETHING TABLETS | ITEM CODE: | TEETT125 |
| SIZE: | 125 TABLETS | LOT NO.: | NOT AVAILABLE |
| REPORTER: | b) (6) | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: | USA (b) (6) | ZIP CODE: | |
| PHONE #: | | | |
| E-MAIL: | SPRING OF 2010 CHILD BEGAN | EXPERIENCING NON-CONVULSANT SEIZURE | S WITH SYMPTOMS OF BUILDING |
| FROM UNCOMPLICAT (b) (6) REACHING MILESTON | D EVERY OTHER WEEK UNTIL HE WAS 15 MO CHILD HAS DIFFICULTY REACHING MILESTOI FO VAGINAL DELIVERY. CHILD RECEIVED TR CHILD HAS HAD AN EKG, EEG, AND MRI. HES. ALSO SEEN AT (b) (6) HOS RI WERE NORMAL. THERE WAS NO PRENATA | ANK AND DILATED, MOUTH HUNG OPEN AND INTHS OF AGE AND THEN STOPPED AND WERNES AND IS DIAGNOSED WITH AUTISM DISORIES AND INTHE NEUROLOGY CLINIC AT (**). HAS ALSO UNDERGONE DEVELOPMENTAL TO PITAL NEUROLOGY AND (**). LEXPOSURE TO CIGARETTES, ALCOHOL, OR THE SHORY AS A SPARATE SHOWN AS A SPARATE SHOWN AND A SEPARATE SHOWN AN | FOLLOWED BY SEVERAL LONGER FOR CHILD WAS BORN FULL TERM BOTH TO THE TERM BESTING BECAUSE OF DIFFICULTY MEDICAL CENTER. RESULTS TOXIC SUBSTANCES. |
| PRODUCT RECEIVED INSPECTION: | FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: Y N (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT B | RETURNED: |
| | RECE | EIVED UPS CALL | TAG ISSUED: Y (N) |
| | 1120 | and the state of t | (CINCLE ONE) |
| SECTION II: | AUG 1 | 6 2013 DATE PRODUC | T RECEIVED: |
| SECTION II: | | 6 2013 DATE PRODUC | T RECEIVED: |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION PLEASE SEE ATTACHED INVESTIGATION WARDED TO PHARMACIST / NURSE FOR EVA | LUATION ON: 07/25/13 | T RECEIVED: |
| INVESTIGATION: ADVERSE EVENT FOR | INVESTIGATION PLEASE SEE ATTACHED INVESTICE | LUATION ON: 07/25/13 | T RECEIVED: |
| INVESTIGATION: ADVERSE EVENT FOR ADVERSE EVENT FOR SECTION III: | PLEASE SEE ATTACHED INVESTIGATION PLEASE SEE ATTACHED INVESTIGATION WARDED TO PHARMACIST / NURSE FOR EVA | LUATION ON: 07/25/13 | |
| INVESTIGATION: ADVERSE EVENT FOR ADVERSE EVENT FOR SECTION III: | WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report | LUATION ON: 07/25/13 | |
| ADVERSE EVENT FOR ADVERSE EVENT FOR SECTION III: | WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report 11-00-03 | LUATION ON: 07/25/13 | |
| ADVERSE EVENT FOR ADVERSE EVENT FOR SECTION III: | WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report 11-00-03 | LUATION ON: O7/25/13 EDYTA F DATE: | |
| ADVERSE EVENT FOR ADVERSE EVENT FOR SECTION III: 9471241-C CORRECTIVE ACTION(SECTION IV: | WARDED TO PHARMACIST / NURSE FOR EVA WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report 11-00-03 S) COMPLETED BY: ADVERSE EVENT REPORTS | LUATION ON: O7/25/13 EDYTA F DATE: | RACKIEWICZ |
| ADVERSE EVENT FOR SECTION III: 9471241-C CORRECTIVE ACTION SECTION IV: | WARDED TO PHARMACIST / NURSE FOR EVA WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report 11-00-03 S) COMPLETED BY: ADVERSE EVENT REPORTS OUS: Y N | LUATION ON: 07/25/13 LUATION BY: EDYTA F DATE: AE #: | RACKIEWICZ |
| ADVERSE EVENT FOR ADVERSE EVENT FOR SECTION III: | WARDED TO PHARMACIST / NURSE FOR EVA WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report 11-00-03 S) COMPLETED BY: ADVERSE EVENT REPORTS OUS: Y N | LUATION ON: O 7/25/13 LUATION BY: EDYTA F DATE: AE #: | RACKIEWICZ 1484 EWICZ |
| ADVERSE EVENT FOR SECTION III: 9471241-C CORRECTIVE ACTION(SECTION IV: ADVERSE EVENT SERI | WARDED TO PHARMACIST / NURSE FOR EVA WARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: afety Report ### ADVERSE EVENT REPORTS OUS: ORTED ON: 07/25/13 | LUATION ON: 07/25/13 LUATION BY: EDYTA F DATE: AE #: | 1484 EWICZ AUG 1 |

cc: QA / QC Packaging Production Shipping / Receiving

AUG 1 6 70 13

CaseID: 9471241



Serious Adverse Event SAE 117

Product in Inventory:

The reporter was only able to provide the product name, Hyland's Baby Teething Tablets, no the lot number for the units involved and no confirmation if it was a Hyland's product.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

08/02/13

Individual Case Safety Report

9471241-01-00-04

DSS AUG 1 9 2013



CaseID: 9471241

SERIOUS ADVERSE EVENT DATA FORM

| | AE #: | 1484 | COMPLAINT #: 2490 | _ |
|-------|----------|-------------|--|-----------------------------|
| | SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| | NAME: | | (b) (6) | |
| | ADDRESS | 3 : | | |
| | CITY: | | STATE: | |
| | COUNTRY | ′ : | USA ZIP CODE: | |
| | PHONE #: | | | |
| | E-MAIL: | | | |
| | SECTION | <u>II:</u> | PACKAGING INFORMATION: | |
| | | AFFI | X PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| Indiv | | | A few many more of the state of | |
| | SECTION | <u>III:</u> | CORRECTIVE ACTION: | - |
| | CORRECT | IVE AC | TION(S) COMPLETED BY: DATE: | |
| | SECTION | IV: | WINDL | DSS |
| | REVIEWE | D BY MA | ANAGEMENT BY: DATE: 08-06-13 | <u> 1</u> 06 1 9 201 |
| | BY: | Ðη, | DATE: 08-05-13 | |
| | _ | - | QA / QC DIRECTOR | |

Consumer Report

CaseID: 9486434

User Facility

Distributor/Importer

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse. FDA USE ONLY

| OLUNTARY reporting of |
|-----------------------------|
| vents, product problems and |
| product use errors |

| errors CDER | Triage unit sequence # | 522124 |
|---|-------------------------|--|
| f2 (DD2) | | |
| . Dose or Amount | Frequency | Route |
| "' | | |
| #2 | | |
| | | |
| Dates of Use (If unknown | wn, give duration) from | 5. Event Abated After Use Stopped or Dose Reduced? |
| (or best estimate) 1 03/01/2013 - 07 | /01/2013 | #1 Ves No Does |
| 2 | | Аррі |
| Diagnosis or Reason | for Use (Indication) | #2 Yes No Does |
| #1 Teething | | 8. Event Reappeared After Reintroduction? |
| #2 | | #1 Yes No Does |
| | | #2 Dyes DNs Does |
| . Lot# 1 | 7. Expiration Dat | te #2 Tes Tes Appl |
| 2 | _ | 9. NDC # or Unique ID |
| | #2 | |
| E. SUSPECT MED Brand Name | ICAL DEVICE | |
| | | CTU |
| Common Device Nam | | ₩1 ₩ |
| . Common Device Nam | e | AllC Om con |
| | | AUG 27 2013 |
| . Manufacturer Name, (| City and State | |
| | | |
| . Model # | Lot# | 5. Operator of Device |
| . Widdel # | 200 | Health Professio |
| | | |
| Catalog # | Expiration Da | te (mm/dd/yyyy) Lay User/Patient |
| | | Other: |
| Serial # | Other # | |
| | | |
| . If Implanted, Give Dat | e (mm/dd/yyyy) 7 | . If Explanted, Give Date (mm/dd/yyy |
| Is this a Single-use D | evice that was Repr | ocessed and Reused on a Patient? |
| Yes No | ovice that has hope | |
|). If Yes to Item No. 8, En | ter Name and Address | s of Reprocessor |
| | | |
| | | |
| OTHER (CONC | | |
| Product names and the | rapy dates (exclude l | treatment of event) |
| | | |
| | | |
| G. REPORTER (Se | e confidentiality | section on back) |
| Name and Address | | D.9 |
| Name: (b) (6) Address: | | DS AUG 2 |
| Address. | | AUG 2 |
| City: | | State: ZIP: |
| City: | Té | -mail |
| b) (6) | |) (6) |
| Lineth Destantian 10 | 2 Occupation | 4. Also Reported to: |
| 2. Health Professional? | 5. Occupation | 4. Also Reported to: |
| | | |

The FUA Safety Information and Page : Adverse Event Reporting Program A. PATIENT INFORMATION 1. Patient Identifier | 2. Age at Time of Event or Date of Birth: (b) (6) 16_{lb} √ Female 8 Months (b)(6) ☐ Male kg In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERRO 1. 🕢 Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Check all that apply) Disability or Permanent Damage Death: Congenital Anomaly/Birth Defect ✓ Life-threatening ✓ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 06/18/2013 08/26/2013 5. Describe Event, Problem or Product Use Error My daughter started teething around 4 months. A family member recommended Hyland's Teething Tablet about a month later and I started giving them to her. In $^{(b)}(6)$ (b)(6) she had her first seizure. I took her to the ER and eventually ended up at the neurologist. They ran an EEG and then an MRI and both came back normal. I TYPE OR USE BLACK heard from a friend that there was a recall. 6. Relevant Tests/Laboratory Data, Including Dates EEG and MRI both came back normal Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Race:Other Medical Conditions: None Allergies: None Important Information: None RX Meds: None OTC Meds: C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label) #1 Name: hyland teething tablet Strength: Manufacturer: #2 Name

Strength:

Manufacturer:

5. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

se by user-facilities, ributors and manufacturers IDATORY reporting

| | | See OMB | statement on reverse. |
|---|----------------------|---------|-----------------------|
| (| Mil Report # 1973 | POUF | 18 30000, |
| | UF/Importer Report # | 81025 | X5770 |

FDA Use Only

| FORM FDA 3500A (6/10 _. |
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| OLINI LDY 2200Y (0) IO |

PLEASE TYPE OR USE BLACK INK

| A. PATIENT INFO | | | | |
|--|---|--|---|------------------|
| r. rauem identitief 13 | 2. Age at Time | | 3. Sex | 4. Weight |
| b) (6) | of Event: | Months | J. 36X | 4. Weight |
| | or | rontina | √ Female | It |
| In confidence | Date of Birth: | | Male | or ks |
| | ENT OR PRODUC | T PROBLE | VI | |
| . Adverse Event | | | | |
| Outcomes Attribute | | duct Problem (e | .g., derects/main | unctions) |
| (Check all that apply) | | | | |
| Death: | (mm/dd/yyyy) | Disability o | r Permanent Da | mage |
| Life-threatening | 1 | Congenital | Anomaly/Birth D | efect |
| | initial or prolonged | | ous (Important M | |
| | ention to Prevent Perma | | | |
| Date of Event (mm/ | | 4. Date of This | | |
| Describe Event or P | 3/2013 | | 09/10/2013 | 3 |
|) (6) | Toblem | | | |
| H | ER DAUGHTER WO | | | |
| ER 1 TABLET O SLEEP. 20 MI | F BABY TEETHIN NUTES LATER WH | G TABLETS, EN SHE WOV! | THEN SHE | FELL |
| HE PICKED HER | UP AND SHE HA | D A SEIZUR | E. HER EY | |
| ROLLED BACK IN | TO HER HEAD, S | HE WAS STI | FF AND BAR | ELY |
| KEATHING. CH | ILD COULD NOT : UT REGAINED HE | MOVE HER AF | RMS OR LEG | S AFTER |
| HEY REACHED T | HE HOSPITAL, A | K LEG MOVER ND 1.5 HOUR | MENT BY THE | E TIME ER ARM |
| OVEMENT RETUR | | | to British III | DIC THAT |
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| | | | DR | |
| Relevant Tests/Labo | oratory Data, Including | | DR | |
| | | Dates | | L: URINE |
| LOOD AND URINE | E TESTS. BLOOK | | | L; URINE |
| LOOD AND URINE | E TESTS. BLOOK | Dates | | L; URINE |
| LOOD AND URINE | E TESTS. BLOOK | Dates | | L; URINE |
| LOOD AND URINE | E TESTS. BLOOK | Dates | | L; URINE |
| LOOD AND URINE | E TESTS. BLOOK | Dates | | L; URINE |
| LOOD AND URINE | E TESTS. BLOOK | Dates | | L; URINE |
| LOOD AND URINE | E TESTS. BLOOM | Dates) TEST RESU | ILTS NORMAI | |
| SLOOD AND URING | E TESTS. BLOOK | Dates TEST RESU | ILTS NORMAI | |
| LOOD AND URING EST RESULTS PE Other Relevant Historace, pregnancy, smo. | E TESTS. BLOOM ENDING. ory, Including Preexist king and alcohol use, he | Dates TEST RESU | ILTS NORMAI | ergies, |
| LOOD AND URING EST RESULTS PE Other Relevant Historace, pregnancy, smo. ISTORY OF A MI | E TESTS. BLOOM ENDING. ory, Including Preexist king and alcohol use, he LD SEIZURE 1 M | Dates TEST RESU | ILTS NORMAI | ergies, |
| LOOD AND URINE EST RESULTS PE Other Relevant Historace, pregnancy, smo | E TESTS. BLOOM ENDING. ory, Including Preexist king and alcohol use, he LD SEIZURE 1 M | Dates TEST RESU | ILTS NORMAI | ergies, |
| Other Relevant Historace, pregnancy, smooth | TESTS. BLOOK ENDING. Ory, Including Preexist king and alcohol use, he LD SEIZURE 1 M ONE MINUTE) ILD GIVEN TYLE | Dates O TEST RESU ing Medical Con opatic/renal dysfu ONTH AGO (| ditions (e.g., allenction, etc.) | ergies , |
| Other Relevant Historace, pregnancy, smo | TESTS. BLOOK ENDING. Ory, Including Preexist king and alcohol use, he LD SEIZURE 1 M ONE MINUTE) ILD GIVEN TYLE | Dates O TEST RESU ing Medical Con opatic/renal dysfu ONTH AGO (| ditions (e.g., allenction, etc.) | ergies , |
| Other Relevant Historace, pregnancy, smo. ISTORY OF A MIERKING LASTING HOSPITAL, CHAIN AND STIFFN | E TESTS. BLOOM ENDING. ENDING. ENDING. LD SEIZURE 1 M E ONE MINUTE) ILD GIVEN TYLE ESS. | Dates O TEST RESU ing Medical Con patic/renal dysfu ONTH AGO (| ditions (e.g., all nction, etc.) SHAKING AN | ergies , |
| Other Relevant Historace, pregnancy, smo | TESTS. BLOOK ENDING. Ory, Including Preexist king and alcohol use, he LD SEIZURE 1 M ONE MINUTE) ILD GIVEN TYLE | Dates O TEST RESU ing Medical Con patic/renal dysfu ONTH AGO (| ditions (e.g., all nction, etc.) SHAKING AN | ergies , |
| Other Relevant Historace, pregnancy, smo | E TESTS. BLOOM ENDING. ENDING. ENDING. LD SEIZURE 1 M E ONE MINUTE) ILD GIVEN TYLE ESS. | Dates O TEST RESU ing Medical Con patic/renal dysfu ONTH AGO (| ditions (e.g., all nction, etc.) SHAKING AN | ergies , |

| 1. Name (Give tabeled attent | | | | |
|--|-------------------|-------------|--------------|----------------------------|
| 1. Name (Give labeled street #1 HYLAND'S BABY | - , | BLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & Rou | te Used | 3. Thera | py Dates (| funknown, give duration) |
| #11 TABLET ONCE | / 2 MONTHS | from/l | o (or best e | stimate) |
| #2 | | - | | |
| 4. Diagnosis for Use (Indic | ation) | #2 | Is Event | Abated After Use |
| #1 TEMP RELIEF OF | , | AIN | | ed or Dose Reduced? |
| #2 | | | #1 Y | es No Doesn't Apply |
| 6. Lot # | 7. Exp. Date | | #2 🔲 Y | es Nio Doesn't |
| #1A40313/A79913 | #1 | | | Reappeared After |
| #2 | #2 | | Reintro | oduction? es No Doesn't |
| 9. NDC# or Unique ID | | | 1 | Apply |
| 54973-3127-3 | | | #2 🗌 Y | es No Doesn't |
| 10. Concomitant Medical P | roducts and Ther | apy Dates | s (Exclude I | reatment of event) |
| D. SUSPECT MEDIC | AL DEVICE | | | |
| 2. Common Device Name | | | | |
| 3. Manufacturer Name, City | and State | | | |
| 4. Model# | Lot # | | | 5. Operator of Device |
| Catalog # | Evaluation | Data (m | | Health Professional |
| outurog # | Expiration | Date (IIIII | vaca yyyy) | Lay User/Patient |
| Serial # | Other # | | | Other: |
| 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. If Expl | anted, Give | e Date (mm/dd/yyyy) |
| 8. Is this a Single-use Devi | ce that was Repro | ocessed a | nd Reused | on a Patient? |
| Yes No | | | | |
| If Yes to Item No. 8, Ente The Item No. 10, Enter The Item No. 10, Enter | | | | DSS SEP 27 2013 |
| | Returned to Ma | | | Ĭ |
| | | | | (mm/dd/yyyy) |
| 11. Concomitant Medical Pr | oducts and Thera | apy Dates | (Exclude to | rearment of event) |
| | | | | |
| E. INITIAL REPORTE | R | | , | |
| 1. Name and Address | Phone # | ¥(b) (6) | | |
| (b) (6) | | | | |
| | SA | | SEP 2 | 6 2013. |
| 2. Health Professional? 3. | Occupation | | 4. In | itial Reporter Also Sent |
| ☐ Yes ☑ No NA | • | | Re | eport to FDA Yes No Unk. |
| | | | L | 7 |

caused or contributed to the event.

Individual Case Safety Report 9570361-01-00-02 36

| | FDA USE ONLY |
|--------------------|--------------|
| _ | |
| ⊇2 of ⁵ | |
| | |
| H DEVICE MANUEAG | TURERS ONLY |

CaseID: 9570361

| r. rukuse bi u | DEN PAU | ALTE TAIMING | KU-K (E | vevices Only) | H. DE | VICE MANU | FACTURERS ONL | Υ. | |
|---|-----------------|------------------|------------------------|--|----------|----------------------------------|-----------------------------|------------|--|
| 1. Check One | | | F/Importer I | Report Number | 1. Type | of Reportable E | vent | 2. If | f Follow-up, What Type? |
| User Facility | [] Impor | | | | | Death | | - 1 | Correction |
| 3. User Facility or Impo | orter Name/A | Address | | | | Serious Injury | | | Additional Information |
| | | | | | | Malfunction | | | Response to FDA Request |
| | | | | | | Other: | | | Device Evaluation |
| | | | | | 3. Devi | ce Evaluated by I | Manufacturer? | | Device Manufacture Date |
| | | | | | | Not Returned to I | Manufacturer | " | mm/yyyy) |
| 4. Contact Person | | | 5. Phone N | umber |] 🗆 | Yes Evalu | ation Summary Attached | , L | |
| | | | | |] 🗆 | No (Attach page provide code: | to explain why not) or | 5. L | abeled for Single Use? |
| Date User Facility or Importer Became | | Type of Repor | t | 8. Date of This Report (mm/dd/yyyy) | | provide code. | | | Yes No |
| Aware of Event (mm/ | aa/yyyy) [| Initial | | | 6 Eval | untion Codes /Do | for to podice view 0 | | |
| | [| Follow-up# | | | 0. Evan | ration Codes (Re | fer to coding manual) | | |
| 9. Approximate Age of Device | 10. Event Pr | oblem Codes (| Refer to codi | ng manual) |] | Method | | - _ | |
| | Patient Code | - | - | - | | Results | _ | | |
| | Device [| | | | | | | | |
| I I | Code | | - | | | Conclusions | | -[_ | |
| 11. Report Sent to FDA | ? | 12. Location W | here Event | Occurred | 7. If Re | medial Action Ini | tiated, Check Type | 8. Usag | e of Device |
| Yes | | Hospita | ı | Outpatient Diagnostic Facility | | Recall | Notification | | Initial Use of Device |
| No (mm/dd/) | YYYY) | Home | | Ambulatory | | Repair [| Inspection | | Reuse |
| 13. Report Sent to Manu | ufacturer? | Nursing Outpoti | i Home ent Treatmer | Surgical Facility | | Replace [| Patient Monitoring | | Unknown |
| Yes | and a | Facility | ent rreatmen | н | | Relabeling | Modification/ Adjustment | 9. If acti | ion reported to FDA under SC 360i(f), list correction/ |
| No (mm/dd/y | 7777) | Other: | | (Specify) | | Other: | , ajacanon | remo | val reporting number: |
| 14. Manufacturer Name | Address | | | (эреспу) | _ | | | | |
| | | | | | 10. | Additional Manu | facturer Narrative | and / or | 11. Corrected Data |
| G. ALL MANUFAC | TURERS | | | | | | | | |
| 1. Contact Office - Name | e/Address (a | and Manufactur | ing Site | 2. Phone Number | 1 | | | | |
| for Devices) | | | | 310-768-0700 | | | | | |
| TUTTI GOULD | | | | Report Source (Check all that apply) | 11 | | | | |
| HYLAND'S, INC. 154 W. 131ST S | | | | Foreign | | | | | |
| LOS ANGELES, C | | 1 | | Study | | | | | |
| | | | | Literature | | | | | |
| | | | | Consumer | | | | | |
| | | | | Health Professional | | | | | |
| 4. Date Received by | ,,T | 5. | | User Facility | | | | | |
| Manufacturer (mm/dd/ 09/08/201 | | (A)NDA # | | Company Representative | | | | | Doo |
| 6. If IND, Give Protocol | | IND# | | Distributor | | | | | 200 |
| o. II IND, GIVE PIGIOCOL | * | STN# | | Other: | | | | | SEP 9700 |
| 7. Type of Report (Check all that apply) | | PMA/ 510(k) # | | | | | | | DSS SEP 27 2013 |
| | , 1 | Combination | | | | | | | |
| 5-day 30-day | | Product | ∐ Yes | | | | | | $\mathcal{L}_{\mathcal{A}} = \mathcal{L}_{\mathcal{A}} + \mathcal{L}_{\mathcal{A}} = \mathcal{L}_{\mathcal{A}} + \mathcal{L}_{\mathcal{A}} = \mathcal{L}_{\mathcal{A}} + \mathcal{L}_{\mathcal{A}} = \mathcal{L}_{\mathcal{A}} + \mathcal{L}_{\mathcal{A}} = $ |
| 10-day Initial | | Pre-1938 | Yes | | | | | | |
| 15-day Follow- | up# | OTC Product | ✓ Yes | | | | | | |
| 9. Manufacturer Report | 1 | 8. Adverse Eve | nt Term(s) | | | | | | ^- |
| 54973 AE # 1506 | 6 | SEIZURE | | | | | | (| SEP 2 6 2013 |
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



CUSTOMER COMPLAINT RECORD



| | | | COMPLAINT #: | 2515 | |
|--|---|--|---|--|--|
| TAKEN BY: | TUTTI GOULD | | DATE OF COMPLAINT: | 09/08/13 | |
| PRODUCT: | | BY TEETHING TABLETS | ITEM CODE: | BTETT40 | |
| | | TEETHING PADLETS | | A40313 | |
| SIZE: | 40 TABLETS | | LOT NO.: | A79913 | |
| REPORTER: | | | | | |
| ADDRESS: | | | | | |
| _ | | | (b) (6) | | |
| CITY: | ICA | | STATE: | | |
| (b) | JSA) (6) | | ZIP CODE: | | |
| PHONE #: | | | | | |
| E-MAIL: | MOTHER | | Y TO INQUIRE ABOUT THE TEETHING | | |
| MINUTES LATER WHEN WAS STIFF AND BAREL BY THE TIME THEY REACTEETHING TABLETS FOR THE SIN THE TOTAL TO THE MENTION THE MENTI | N SHE WOKE UP SCRE, LY BREATHING. CHILD CHED THE HOSPITAL, AN THE PAST 2 MONTHS (N IE PAST 2 MONTHS AS N NED THAT A MONTH AGG ED HER IMMUNIZATION " | CREAMING, SHE GAVE HER 1 1 AMING, SHE PICKED HER UP A 1 COULD NOT MOVE HER ARM IN THE SHOULD NOT SHE ARM IN MIXED CONTENTS OF REMAINING NEEDED. MOTHER SAID SHE HAD A BRIEF SHOTS' BLOOD AND URINE TES | UGHTER FOR A SEIZURE THAT LASTE TABLET OF BABY TEETHING TABLETS, IND SHE HAD A SEIZURE. HER EYES F SOR LEGS AFTER THE SEIZURE, BUT IOVEMENT RETURNED. SHE HAS BEEN GOTABLETS OF ONE BOTTLE INTO SECON DALSO BEEN GIVING TYLENOL. THE DOC EPISODE OF JERKING AND SHAKING LASTS CONDUCTED ON 09/08/13. BLOOD TE | THEN SHE FELL ROLLED BACK IN REGAINED HER SIVING HER DAUG D BOTTLE). SHE IT TORS SAID "THEY THING ONE MINUTISTS NORMAL; UR | ASLEEP. 20 TO HER HEAD SHE LEG MOVEMENT HTER BABY ESTIMATES SHE HAD T DON'T KNOW WHAT E. AUGUST 20, 19 |
| | FOR ADDITI | ONAL SPACE PLEASE USE RE | VERSE OR ATTACH A SEPARATE SHE | EET | |
| PRODUCT RECEIVED F | (| Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: | Y (CIRCLE ONE) |
| dividual Cas | se Safety Rej | port | DATE REQUESTED PRODUCT BE | E RETURNED: | |
| | | | UPS CALL | TAG ISSUED: | Y N (CIRCLE ONE) |
| 95703 | 61-01-00-03 | | | | |
| | | | DATE PRODUC | T RECEIVED: _ | |
| SECTION II: | INVESTIGATION | | | | |
| INVESTIGATION: | PLEASE SEE ATTA | ACHED INVESTIGATION REPOR | RT. | | |
| | | | THE RELIGION OF THE PERSON OF | | |
| | | | | | |
| | | | | | |
| | | CIST / NURSE FOR EVALUATION | N ON: 09/08/13 | | |
| ADVERSE EVENT FORV | WARDED TO PHARMAC | | | | |
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| ADVERSE EVENT FORV | WARDED TO PHARMAC | CIST / NURSE FOR EVALUATION | | DULD | |
| ADVERSE EVENT FORV | | CIST / NURSE FOR EVALUATION | | DULD | |
| ADVERSE EVENT FORV | WARDED TO PHARMAC | CIST / NURSE FOR EVALUATION | | DULD | |
| ADVERSE EVENT FORV | WARDED TO PHARMAC | CIST / NURSE FOR EVALUATION | | DULD | DSS |
| ADVERSE EVENT FORV SECTION III: | WARDED TO PHARMAC | CIST / NURSE FOR EVALUATION | | | DSS SEP 27 20 |
| ADVERSE EVENT FORV SECTION III: CORRECTIVE ACTION(S | WARDED TO PHARMAC CORRECTIVE ACT S) COMPLETED BY: | CIST / NURSE FOR EVALUATION | NBY; TUTTI GO | | DSS SEP 27 20 |
| ADVERSE EVENT FORV SECTION III: CORRECTIVE ACTION(S | WARDED TO PHARMAC | CIST / NURSE FOR EVALUATION | N BY: TUTTI GO | | DSS SEP 27 20 |
| ADVERSE EVENT FORV SECTION III: CORRECTIVE ACTION(S | CORRECTIVE ACT S) COMPLETED BY: ADVERSE EVENT REI | CIST / NURSE FOR EVALUATION | N BY: TUTTI GO | | DSS SEP 27 20 |
| | CORRECTIVE ACT S) COMPLETED BY: ADVERSE EVENT REI OUS: | CIST / NURSE FOR EVALUATION | DATE: | | DSS SEP 27 20 |
| ADVERSE EVENT FORV SECTION III: CORRECTIVE ACTION(S SECTION IV: ADVERSE EVENT SERIO | CORRECTIVE ACT S) COMPLETED BY: ADVERSE EVENT REI OUS: | CIST / NURSE FOR EVALUATION TION: PORTS N | DATE: | | DSS SEP 27 20 SEP 2 6 |
| ADVERSE EVENT FORV SECTION III: CORRECTIVE ACTION(S SECTION IV: ADVERSE EVENT SERION ADVERSE EVENT REPO | CORRECTIVE ACT S) COMPLETED BY: ADVERSE EVENT REI OUS: | CIST / NURSE FOR EVALUATION TION: PORTS N | DATE: AE #: BY:TUTTI GOULD | 1506 | SEP 2 6 |
| ADVERSE EVENT FORV SECTION III: CORRECTIVE ACTION(S SECTION IV: ADVERSE EVENT SERION ADVERSE EVENT REPO | CORRECTIVE ACT S) COMPLETED BY: ADVERSE EVENT REI OUS: DRITED ON: | CIST / NURSE FOR EVALUATION TION: PORTS N | DATE: AE #: BY:TUTTI GOULD | 1506 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0041-2013

The customer provided two (2) lot numbers that were associated with this complaint for Hyland's Baby Teething Tablets. The lot numbers were A79913 and A40313; however lot number A40313 is associated with Hyland's Baby Cold Tablets and not Baby Teething Tablets. A review of both batches was conducted.

Product in Inventory:

No units of Hyland's Hyland's Baby Teething Tablets (BTET), lot #A79913, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b) (4) units, has been distributed.

No units of Hyland's Hyland's Baby Cold Tablets (BCLD), lot #A40313, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (SHC) units, has been distributed.

Review of Records:

The BTET lot # A79913 was manufactured using bulk lot # 120264 and BCLD lot # A40313 was manufactured using bulk lot # 119279. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

BTET lot # A79913 and BCLD lot # A40313 were inspected against the Commercial Specifications and all results met the specification. Both lots were submitted for Microbial testing and the results were within specification.

The BTET lot # A79913, bulk lot # 120264 was tested for Total Atropine and Scopolamine levels and was found to meet the specification of \leq (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specification of: color – white, odor – none and taste – faintly sweet.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation System was conducted and no investigations were associated with these lots.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets (BTET), lot # A799143, or Hyland's Baby Cold Tablets, lot # A40313.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets (BTET), lot # A799143, or Hyland's Baby Cold Tablets, lot # A40313. Manufacture and processing occurred SS within established procedures to ensure product quality.

SEP 272013

<u>09/13/2013</u> Date

SEP 2 6 2013

Prepared by

CC-0570-2013 AE-0354-2013 SAE #123

Page 1 of 1

CaseID: 9570361



E EVENT DATA FORM



| AE #:1506 | COMPLAINT #: 2515 | |
|---------------------|--|-------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | STATE: (b) (6) | |
| COUNTRY: | USA ZIP CODE: | |
| PHONE #: E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | |
| | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) TOURISM TOU | |
| | | |
| | | DSS |
| CORRECTIVE AC | CTION(S) COMPLETED BY: DATE: | SEP 27 2013 |
| REVIEWED BY M. BY: | ANAGEMENT BY: DATE: 09-16-13 QA/QC DIRECTOR DATE: 09-16-13 SEP 2 6 | 2013 |

9570446-01-00-01

Mf

CaseID: 9570446 Form Approved: OMB No. 09 10-029 1, Ex pires 12/31/11

Therapy Dates (If unknown, give duration) from/to (or best estimate)

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No

| | See OMB statement | on re | verse |
|----------------------|-------------------|-------|-------|
| Mfr Report # 54973 | | | : |
| UF/Importer Report # | | | |

| : by user-facilities, | ١ |
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| ibutors and manufacturers | ŀ |
| DATORY reporting | ١ |
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FIDA Use Only

| FORM FDA 3500A A. PATIENT INFOR | | | | Page 1 | | PODUCT/S) | |
|---|---------------------------|---|---------------------|----------------|---|----------------------|------------|
| 1. Patient Identifier 2. A | | | 3. Sex | 4. Weight | 1. Name (Give labeled | <u> </u> | er) |
| | f Event: | Months | | | 1 | ABY TEETHING " | , |
| | r Date | | Female | or lbs | | | |
| | of Birth: | | ✓ Male | kgs | #2 2. Dose, Frequency 8 | & Route Used | 3. The |
| B. ADVERSE EVEN | IT OR PRODUC | CT PROBLE | M | | | | fror |
| 1. 🗸 Adverse Event | and/or Prod | duct Problem (e | e.g., defects/malfu | ınctions) | #1 UNKNOWN DOS | SAGE | - #1 |
| 2. Outcomes Attributed to (Check all that apply) | o Adverse Event | | , | | #2 | | #2 |
| Death: | | Disability of | or Permanent Dar | nage | 4. Diagnosis for Use | | *** |
| Life-threatening | nm/dd/yyyy) | Congenita | l Anomaly/Birth D | efect | | F TEETHING PAI | TIM |
| Hospitalization - ini | tial or prolonged | Other Seri | ous (Important M | edical Events) | #2 | 17 5 5 | |
| Required Interventi | on to Prevent Perma | anent Impairmen | t/Damage (Device | es) | 6. Lot # | 7. Exp. Date | |
| Date of Event (mm/dd/ | <i>YYYY)</i> | 4. Date of This | Report (mm/dd | <i>'yyyy)</i> | #1 | #1 | |
| 09/00/2 | | | 09/05/2013 | | #2 | #2 | |
| Describe Event or Prof | lem | | | | 9. NDC# or Unique IE 54973=3127=1 | | |
| CHILD SUFFERED M | | | | | 10. Concomitant Med | | herapy Da |
| EETHING TABLETS | . HAD 5 MIN | I SEIZURES | IN 10 MIN | UTES. | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | _ | | | |
| | 1 | RFC | EIVE | \mathbf{D} | D. SUSPECT M | EDICAL DEVICE | |
| | 1 | 1/20 | | | 1. Brand Name | | |
| | | CED | 26 2012 | | 2. Common Device N | lame | |
| | | SEF | 20 2012 | | 3. Manufacturer Nam | ne City and State | |
| | | | DR | | o manaractarer nam | e, ony and other | |
| | | U | אטי | | | | |
| | | | | | 4. Model# | Lot# | |
| | | | | | Catalog # | Expirat | ion Date (|
| | | | | | 6 | | |
| | | | | | Serial # | Other | # |
| | | | | | 6. If Implanted, Give | Date (mm/dd/yyyy) | 7. If E |
| Relevant Tests/Labora | tory Data, Including | n Dates | | | | | |
| | , satu, moroumi | , | | | 8. Is this a Single-use | | processe |
| INKNOMN | | | | | 9. If Yes to Item No. 8 | | ddress of |
| | | | | | | ., | |
| | | | | | | | |
| | | | | | | | |
| | | | | | 10. Device Available | _ | |
| | | | | | Yes No | Returned to | Manufact |
| | | | | | 11. Concomitant Med | ical Products and Th | herapy Da |
| Other Relevant History race, pregnancy, smoking | , Including Preexist | ting Medical Co | nditions (e.g., al | lergies, | | | |
| , p. agrandy, ordani | g and additional diguipal | - panarana ufo | | | | | |
| NKNOMN | | | | | E. INITIAL REPO | ORTER | |
| | | | | | 1. Name and Address | s Pho | ne # |
| | | | | | | L | |
| | | | | 1 | (b) (6) | TTA | |
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Doesn't Doesn't Apply #2 Yes No 8. Event Reappeared After Reintroduction? Doesn't Apply #1 Yes No Doesn't Apply #2 Yes No herapy Dates (Exclude treatment of event) 5. Operator of Device Health Professional ation Date (mm/dd/yyyy Lay User/Patient Other: 7. If Explanted, Give Date (mm/dd/yyyy) eprocessed and Reused on a Patient? Address of Reprocessor not send to FDA) o Manufacturer on: (mm/dd/yyyy) herapy Dates (Exclude treatment of event) Initial Reporter Also Sent Report to FDA 2. Health Professional? 3. Occupation Yes No Yes No Unk.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

9570446-01-00-02

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| İ | | FDA USE ONLY | |
|--------------------------------|-------------------|--|------------------------------|
| of <u>5</u> | | | |
| H. DEVICE MANUFAC | TURERS ONLY | | |
| 1. Type of Reportable Event | | 2. If Follow-up, | What Type? |
| Death | | Correct | ion |
| Serious Injury | | | nal Information |
| Malfunction | | 1 = | ise to FDA Request |
| Other: | | 1 = ' | Evaluation |
| | | - | E-variable of |
| 3. Device Evaluated by Manu | ıfacturer? | 4. Device Manu (mm/yyyy) | facture Date |
| Not Returned to Manu | ıfacturer | (11111033333) | |
| Yes Evaluation | Summary Attached | | |
| No (Attach page to ex | plain why not) or | 5. Labeled for 8 | Single Use? |
| provide code: | | □Yes | □ No |
| | | _ | |
| 6. Evaluation Codes (Refer to | coding manual) | | |
| Method | - |]_[| |
| Method | | | |
| Results | - | - - | |
| | | | |
| Conclusions |]-[| | |
| 7. If Remedial Action Initiate | d, Check Type | . Usage of Device | |
| ☐ Recall ☐ N | lotification | Initial Use | of Device |
| | spection | Reuse | |
| | atient Monitoring | Unknown | |
| | _ | . If action reported | to FDA under |
| | djustment | 21 USC 360i(f), li removal reportin | st correction/ ig number: |
| Other: | | | • |
| | | | |
| 10. Additional Manufacto | uror Narrativo a | nd/or 11. [| Corrected Data |
| Additional mandiacti | area real active | | _ corrected bara |
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F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) 2. UF/Importer Report Number User Facility [] Importer 3. User Facility or Importer Name/Address 4. Contact Person 5. Phone Number Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) Date of This Report (mm/dd/yyyy) 7. Type of Report Initial Follow-up # 9. Approximate 10. Event Problem Codes (Refer to coding manual) Age of Device Patient Code Device Code 11. Report Sent to FDA? 12. Location Where Event Occurred Outpatient
Diagnostic Facility Hospital Yes (mm/dd/yyyy) Home No Ambulatory
Surgical Facility Nursing Home 13. Report Sent to Manufacturer? Outpatient Treatment Facility Yes (mm/dd/yyyy) No Other: (Specify) 14. Manufacturer Name/Address G. ALL MANUFACTURERS Contact Office - Name/Address (and Manufacturing Site for Devices) 2. Phone Number 310-768-0700 Report Source (Check all that apply) EDYTA FRACKIEWICZ HYLAND'S, INC. Foreign 154 W. 131ST STREET LOS ANGELES, CA 90061 Study Literature ✓ Consumer Health Professional User Facility Date Received by Manufacturer (mm/dd/yyyy) Company (A)NDA# Representative 39/04/2013 Distributor IND# 6. If IND, Give Protocol# Other: STN# **PMA/** 7. Type of Report (Check all that apply) 510(k) # Combination 30-day 5-day Product Yes Periodic 7-day Pre-1938 Yes ✓ Initial 10-day OTC Product √ Yes 15-day Follow-up # 9. Manufacturer Report Number 8. Adverse Event Term(s) SEIZURES 54973 AE # 1505

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

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OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9570446



CUSTOMER COMPLAINT RECORD



| | | | COMPLAINT | #: 2514 | |
|--|--|---|----------------------------|----------------------------------|-----------------|
| TAKEN BY: | | EDYTA FRACKIEWICZ | DATE OF COMPLAIN | IT: 09/04/13 | |
| PRODUCT: | | HYLAND'S BABY TEETHING TABLETS | <u>-</u> | E: BTET | |
| SIZE: | | NOT PROVIDED | | D.: NOT PROVIDE | ED |
| | (b) (6) | THO THOUSE | | | , |
| REPORTER: | | | | | |
| ADDRESS: | *************************************** | | | | |
| CITY: | | | STATE: (b) (6) | | |
| COUNTRY: | USA | | ZIP CODE: | | |
| PHONE #: | | | | | |
| E-MAIL: | | | | | |
| NATURE OF CO | MPLAINT: | PER INTERNET POST: 7 MONTH GRANDS | SON SUFFERED MILD SEIZURES | PAST WEEK AFTER | TAKING TABLETS. |
| HAD 5 MINLONE | S IN 10 MIN | UTES. NO CONTACT INFORMATION PROVIDED FO | OR THIS CUSTOMER. | | |
| | | | | | |
| | | FOR ADDITIONAL SPACE PLEASE USE REV | ERSE OR ATTACH A SEPARATE | SHEET | |
| | | | | 00 W0050T10W | , (i) |
| PRODUCT RECE INSPECTION: | | (CIRCLE ONE) | PRODUCT BEING RETURNED F | OR INSPECTION: | (CIRCLE ONE) |
| dividual | . Case | Safety Report | DATE REQUESTED PRODUC | T BE RETURNED: | |
| | | | | | Y (N) |
| | | | UPS C | ALL TAG ISSUED: | (CIRCLE ONE) |
| Q.A | 70446. | 01-00-03 | | | |
| | 71.04.40 | 01-00-93 | DATE PRO | DUCT RECEIVED: | |
| | | | DATE PRO | DUCT RECEIVED: | |
| SECTION II: | | /ESTIGATION | DATE PRO | DUCT RECEIVED: | |
| | <u>IN/</u> | | | DUCT RECEIVED: | |
| SECTION II: | <u>IN/</u> | /ESTIGATION | | DUCT RECEIVED: | |
| SECTION II: | <u>IN/</u> | /ESTIGATION | | DUCT RECEIVED: _ | |
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| SECTION II: | <u>INN</u> | /ESTIGATION PLEASE SEE ATTACHED INVESTIGATION REPORT | Γ. | - | |
| NVESTIGATION ADVERSE EVEN | IN\ I: _ | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION | ON:09/04 | /13 | |
| SECTION II: INVESTIGATION ADVERSE EVEN | IN LESS OF THE SERVICE OF THE SERVIC | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION | ON:09/04 | - | |
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| NVESTIGATION ADVERSE EVEN | IN LESS OF THE SERVICE OF THE SERVIC | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION | ON:09/04 | /13 | |
| NVESTIGATION ADVERSE EVEN | IN LESS OF THE SERVICE OF THE SERVIC | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION | ON:09/04 | /13 | |
| SECTION II: INVESTIGATION ADVERSE EVEN | IN LESS OF THE SERVICE OF THE SERVIC | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION | ON:09/04 | /13 | |
| NVESTIGATION ADVERSE EVEN | IN LESS OF THE SERVICE OF THE SERVIC | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION | ON: 09/04 BY: EDY | /13 *A FRACKIEWICZ | DSS |
| SECTION II: INVESTIGATION ADVERSE EVEN ADVERSE EVEN SECTION III: | IIN | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: | ON: 09/04 BY: EDY | /13 | DSS |
| SECTION II: INVESTIGATION ADVERSE EVEN ADVERSE EVEN SECTION III: | I INV | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: | ON: 09/04 BY: EDY | /13 *A FRACKIEWICZ | DSS SEP 2720 |
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| SECTION II: INVESTIGATION ADVERSE EVEN ADVERSE EVEN SECTION III: CORRECTIVE A | I FORWARI T FORWARI CTION(S) CO | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DMPLETED BY: VERSE EVENT REPORTS | ON: 09/04 BY: EDY | /13 TA FRACKIEWICZ TE: | DSS SEP 2720 |
| SECTION II: INVESTIGATION ADVERSE EVEN SECTION III: CORRECTIVE A SECTION IV: ADVERSE EVEN | IT FORWAR OCTION(S) CO | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DMPLETED BY: VERSE EVENT REPORTS : Y / N | ON: 09/04 BY: EDY | /13 TA FRACKIEWICZ TE: | |
| SECTION II: INVESTIGATION ADVERSE EVEN ADVERSE EVEN SECTION III: CORRECTIVE A SECTION IV: ADVERSE EVEN | IT FORWAR OCTION(S) CO | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DMPLETED BY: VERSE EVENT REPORTS : Y / N | DA BY: DA | /13 TA FRACKIEWICZ TE: E#:1505 | SEP 2 6 2 |
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| ADVERSE EVEN ADVERSE EVEN ADVERSE EVEN SECTION III: CORRECTIVE A SECTION IV: ADVERSE EVEN | INV IT FORWAR IT FORWAR IT FORWAR IT SERIOUS | PLEASE SEE ATTACHED INVESTIGATION REPORT DED TO PHARMACIST / NURSE FOR EVALUATION DED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DMPLETED BY: VERSE EVENT REPORTS ED ON: 09/04/13 | DA BY: DA | /13 TA FRACKIEWICZ TE: E#:1505 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE 122

Product in Inventory:

The reporter was only able to provide the product name, Hyland's Baby Teething Tablets, not the lot number for the unit involved

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

09/05/13

Date

DSS ^{SEP} **27** 2013

CaseID: 9570446

SEP 2 6 2013





RSE EVENT DATA FORM

| AE #: 1505 | 5 COMPLAINT #: 2514 | |
|--|--|--------------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | STATE: | 1000 |
| COUNTRY: | USA ZIP CODE: | |
| PHONE #: | | |
| E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | |
| AFF | FIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON H (INCLUDE DRUG FACTS AND PRINCIPAL PANELS) | |
| Indications: Introduction of information of information of informations and undergotted individual and individu | Control of the Control of the Name which con | |
| SECTION III: | CORRECTIVE ACTION: | DSS SEP 27 2013 |
| | | 27 2013 |
| - | | |
| CORRECTIVE AC | CTION(S) COMPLETED BY: DATE: | |
| SECTION IV: | | SEP 2 6 2013 |
| REVIEWED BY MA | ANAGEMENT BY: DATE: 09 | 19-13 |
| BY: Q | DATE: 09. | -17-13 |

| Individual (| Case Saret | y keport |
|--------------|------------|---|
| | | |
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y ser facilities, itors and manufacturers ATORY reporting

| | See OMB statement on reverse |
|----------------------|------------------------------|
| Mfr Report # 54973 | |
| UF/Importer Report # | |
| | |

Form Approved: 2008-00 1906-2 2-3-00-212/31/11

| | 00220 | 22.0 | | | | | |
|----------------------------------|--------------------------|-------|----------------|-------|-----------------|-----------|-----------|
| | . , | | | | | , | ڊر |
| A. PATIENT INF | ORMATION | | | | | | |
| 1. Patient Identifier (b) (6) | 2. Age at Time of Event: | 31 | Years | 3. | Sex ✓ Female | 4. Weigl | ht Ib: |
| In confidence | Date of Birth: | | | | Male | or | kg |
| B. ADVERSE E | VENT OR PI | RODU | CT PROBLE | M | | | |
| 1. 🕢 Adverse Even | t and/or | Pro | duct Problem (| e. g. | , defects/malfu | unctions) | |
| 2 Outcomes Attribut | ted to Adverse | Event | | | | | |

Coutcomes Attributed to Adverse Event
(Check all that apply)

Death:

(mm/dd/yyyy)

Disability or Permanent Damage

(mm/dd/yyyy)

☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)

09/19/2013

4. Date of This Report (mm/dd/yyyy)

09/23/2013

5. Describe Event or Problem

MOTHER APPLIED HYLAND'S TEETHING GEL TO HER OWN GUMS TO SEE WHAT WOULD HAPPEN. SHE GOT HIVES, ITCHING ALL OVER BODY, AND HER THROAT SWELLED. TOOK A BENADRYL AND THE SYMPTOMS RESOLVED. DID NOT HAVE DIFFICULTY BREATHING. WAS WORRIED ABOUT HER THROAT AND SHE WENT TO THE EMERGENCY ROOM. SHE WAS RELEASED FROM ER AND NOT ADMITTED.

OCT 1 0 2013

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN. ER TOOK A "WAIT AND SEE" APPROACH.

 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HAS THIS TYPE OF ALLERGIC REACTION WHEN SHE EATS MANGOS.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| DUCT(S) ength & mfr/labeler) THING GEL Dute Used ON TO GUMS | | ites (If unknown, gi pest estimate) | ive durati |
|---|--|--|----------------|
| ON TO GUMS | #1 | | ive durati |
| ON TO GUMS | #1 | | ive durati |
| ON TO GUMS | #1 | | ive durati |
| | #1 | oest estimate) | |
| lication) | #2 | | |
| lication) | | | |
| | 5. E | vent Abated After | Use |
| EETHING PAIN | | topped or Dose R | educed? Do∈ |
| | " | | ☐ App |
| 7. Exp. Date | #2 | Yes No | ☐ App |
| #1 | | | After |
| #2 | - 1 | | ☑ Doe |
| | | □ Voc □ No | □ Doe |
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| Lot # | | 5. Operator | of Devic |
| Evolention | n Date (mm/dd/s | | Profession |
| Expiration | ii Date (iiiii/du/) | Lay Us | er/Patien |
| Other# | | Other: | |
| Other # | | 1 | |
| (mm/dd/wand | 7 If Evployee | 1 Chia Data (mm/s | Idhuand |
| e (mireda/yyyy) | /. If Explainted | a, Give Date (minuc | ia/yyyy) |
| | 1 | | |
| vice that was Repr | ocessed and R | eused on a Patien | t? |
| | | | |
| nter Name and Add | ress of Reproce | essor | |
| | | | |
| | | n | 0- |
| | | D. | SC |
| Evaluation? (Do not | send to FDA) | 00- | |
| _ | • | UCT 1 | 1 20 |
| - veramed to M | andrao(dref Off; | (mm/dd/yy) | 'y) |
| Products and The | rapy Dates (Exc | dude treatment of e | event) |
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| TER | · · · · · · · · · · · · · · · · · · · | | |
| I EN | "(b) (6) | | |
| Phone | # | | |
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| | 0 | CT 1 0 20 | 13 |
| · . | 0 | | |
| 3. Occupation | 0 | CT 1 0 20 | r Also S |
| | #1 #2 Products and The CAL DEVICE Expiratio Other # Expiratio Other # Evaluation? (Do not) Returned to M Products and The | #1 #2 #1 #2 #1 #2 Products and Therapy Dates (Exc.) CAL DEVICE Expiration Date (mm/dd/) Other # Expiration Date (mm/dd/) Other # e (mm/dd/yyyy) 7. If Explanted and Reserve that was Reprocessed and Reserve that Reser | #1 |



9622302-01-00-02

2 of 5

| CaseID: 9622302 | |
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| | |

FDA USE ONLY

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|---------------------------------------|-----------------|------------------|----------|---------------------------------|----------|------------------------------------|----------|----------|-------------------|---------------------------|------|---|-----------|
| | | | - 11 | ((((((((((((((((| W1000 | -Omy) | 4 | H. DE | VICE MAN | JFACTURERS ON | | | |
| . Check One | | 2. | UFA | mporter Re | port N | ımber | 7 | 1. Type | of Reportable | Event | | 2. If Follow-up, What Type? | ı |
| User Facility | Impor | ter | | | | | 11 | | Death | | | Correction | 1 |
| 3. User Facility or Impo | orter Name/ | Address | | | | | 7 | | Serious Injury | | | Additional Information | |
| | | | | | | | | | Malfunction | | | Response to FDA Request | |
| | | | | | | | | | Other: | | | Device Evaluation | |
| | | | | | | | | 3. Devi | ce Evaluated by | y Manufacturer? | | 4. Device Manufacture Date | \exists |
| | | | | | | | | ł | Not Returned to | | | (mm/yyyy) | |
| 4. Contact Person | | | 5. | Phone Nu | mber | | - | ΙH | | aluation Summary Attach | ned | | |
| 30 | | | | | | | | l H | No (Attach pag | ge to explain why not) or | 1 | 5. Labeled for Single Use? | ٦ |
| 6. Date User Facility or | 7 | 7. Type of Re | port | | | of This Report | | Ι | provide code: | | | ☐ Yes ☐ No | - |
| Importer Became Aware of Event (mm | /da/yyyy) | Initial | | ļ | (mm | /dd/yyyy) | | | | | | | _ |
| | | Follow-up | . # | | | | | 6. Eval | uation Codes (| Refer to coding manual) | | | |
| 9. Approximate | 10. Event P | Problem Code | | fer to codin | g manu | al) | \dashv | | Metho | d - | | - | |
| Age of Device | | | | | | , | ٦ | 1 | | | | | 1 |
| | Patient Code | |]- | | | - | | | Result | s | | | |
| | Device | | ا_[| | | - | \neg | | Conclusion | s | | - | |
| | Code | 140 | <u> </u> | F | | | 4 | 7 16 19- | | Initiated, Check Type | | Usage of Device | \dashv |
| 11. Report Sent to FDA | 17 | 12. Locatio | | ere Event (| | d Outpatient | 1 | | | | | Initial Use of Device | |
| Yes(mm/dd/ | /vvv) | Hos | | | | Diagnostic Facility | 1 | 1 = | Recall | Notification Inspection | | Reuse | - [|
| ∐ No . | | | | Home | | Ambulatory Surgical Facility | | 1 = | Repair Replace | Patient Monitoring | | Unknown | 1 |
| 13. Report Sent to Man | nutacturer? | | | nt Treatmen | | corgrous ruomey | 1 | 1 = | Relabeling | Modification/ | 9. 1 | If action reported to FDA under | \dashv |
| Yes(mm/dd/ | (/vvv) | Fac | • | | | | | _ | 1 | Adjustment | | 21 USC 360i(f), list correction/ removal reporting number: | |
| □ No (mileda | ,,,,, | Oth | er: | | (Spe | cify) | - | | Other: | | | | |
| 14. Manufacturer Name | e/Address | 1 | | | | | \dashv | | | | | | |
| | | | | | | | | 10. | Additional Ma | nufacturer Narrative | and | d / or 11. Corrected Data | |
| | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | |
| G. ALL MANUFA | CTURER | RS | | | | | | | | | | | - [|
| 1. Contact Office - Nar | | | cturi | ng Site | 2. Ph | one Number | | | | | | | |
| for Devices) | | | | | 310- | 768-0700 | | | | | | | |
| EDYTA FRACKIE | EWICZ | | | | 3. Re | port Source neck all that apply | , 1 | 1 | | | | | ١ |
| HYLAND'S, INC | | | | | <u> </u> | oreign | | | | | | | |
| 154 W. 131ST LOS ANGELES, | | 061 | | | l□'s | _ | | 1 | | | | | |
| 202 /2.00000, | | | | | | terature | | | | | | | |
| | | | | | , L. | onsumer | | | | | | | |
| | | | | | I □ H | ealth Professiona | 1 | | | | | | |
| 4. Date Received by | | 5. | | | | ser Facility | | 1 | | | | | |
| Manufacturer (mm/c | dd/yyyy) | (A)NDA # | | | | ompany | | | | | | | |
| 09/23/2 | 013 | IND# | | | I | epresentative istributor | | | | | | | |
| 6. If IND, Give Protoco | ol# | | | | | | | | | | | _ | |
| | | STN# | | | 1 " | | | | | | | DSS | |
| 7. Type of Report | | PMA/ 510(k) # | | | | | | | | | | | |
| (Check all that apply | • | Combina | | | · | | _ | 1 | | | | OCT 11201 | 2 |
| 5-day 30-d | | Product | - | Yes Yes | 1 | | | | | | | · • • EUI | • |
| 7-day Perio | | Pre-1938 | | Yes | | | _[| | | | | | |
| | ап ow-up # | OTC Pro | duct | √ Yes | | | | | | | | | |
| 9. Manufacturer Repo | | 8. Advers | e Eve | ent Term(s) | | | \dashv | | | | | | |
| 1 | | | | REACTIO | | | | | | | | OCT 1 0 | |
| 54973 AE # 15 | 310 | | | | | | | 1 | | | | OCT 1 0 20 | 113 |
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

PLAINT RECORD



| 91 | 622302-01-00-03 | COMPLAINT #: | 2519 | |
|----------------------------|--|---|---------------------------------------|----------------|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 09/20/13 | |
| PRODUCT: | HYLAND'S TEETHING GEL | ITEM CODE: | TGELU0.5Z | |
| SIZE: | 0.5 OZ. | LOT NO.: | 119022 | |
| REPORTER: | (b) (6) | | | |
| ADDRESS: | | | · · · · · · · · · · · · · · · · · · · | |
| | | | | |
| CITY: | | STATE: (b) (6) | | |
| COUNTRY: | USA | ZIP CODE: | | |
| PHONE #: | (b) (6) | | | |
| E-MAIL: | The second secon | HER OWN GUMS TO SEE WHAT WOULD | HAPPEN SHE | OT HIVES |
| | | THROAT SWELLED. HAS ONLY HAD THIS DITHE SYMPTOMS RESOLVED. DID NOT CY ROOM. SHE HAD TAKEN BENADRYL: | HAVE DIFFICULT SO THEY TOOK A | Y BREATHING. |
| | FOR ADDITIONAL SPACE PLEASE USE | REVERSE OR ATTACH A SEPARATE SHI | EET | - |
| PRODUCT RECEINSPECTION: | IVED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | | Y (CIRCLE ONE) |
| | | | TAG ISSUED: | Y (CIRCLE ONE) |
| | | DATE PRODU | CT RECEIVED: | |
| SECTION II: INVESTIGATION: | INVESTIGATION PLEASE SEE ATTACHED INVESTIGATION RE | PORT. | | |
| | IT FORWARDED TO PHARMACIST / NURSE FOR EVALUA IT FORWARDED TO PHARMACIST / NURSE FOR EVALUA CORRECTIVE ACTION: | | 3 FRACKIEWICZ | ` |
| CORRECTIVE AG | CTION(S) COMPLETED BY: | DATE | : | DSS |
| SECTION IV: | ADVERSE EVENT REPORTS | AE # | 1510 | OCT 1 1 2013 |
| ADVERSE EVEN | | BY: EDYTA FRAC | KIEWICZ | 007.4.5 |
| SECTION V: | NT REPORTED ON: 09/23/13 | a At | | OCT 1 0 2013 |
| | MANAGEMENT BY: 9410 BOULL | DATE: | |)1-13)1-13 |
| BY: | ON OC DIRECTOR | | | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

CaseID: 9622302



Serious Adverse Event SAE-0045-2013

Product in Inventory:

No units of Hyland's Baby Teething Gel (TGEL), lot #119022, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (b) (4) units, has been distributed.

Review of Records:

The TGEL lot # 119022 was manufactured using bulk lot # 118923. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Certificate of Analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Gel lot # 119022. In addition it was tested for Total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Gel lot # 119022.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Gel lot # 119022.

Manufacture and processing occurred within established procedures to ensure product quality.

Individual Case Safety Report

9622302-01-00-04

DSS 0CT 1 1 2013

OCT 1 0 2013



Hylands 9622302

SERIOUS ADVERSE EVENT DATA FORM

| AE #: | 1510 | COMPLAINT #: 2519 |
|---------|-----------------|--|
| SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | | (b) (6) |
| ADDRESS | 8: | |
| | | (b) (6) |
| CITY: | | STATE: |
| COUNTRY | Y: | USA ZIP CODE: |
| PHONE # | : | |
| E-MAIL: | | |
| SECTION | <u> </u> | PACKAGING INFORMATION: |
| | AFF | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| 0 | tylands Rahu | Teething Gel Set your as of complete house and complete house the set of complete house and complete house and complete house and complete house and set of complete house and complete house and set of complete house and |
| SECTIO | N III: | CORRECTIVE ACTION: |
| | | DSS |
| | | OCT 1 1 2013 |
| CORRE | CTIVE A | CTION(S) COMPLETED BY: DATE: |
| SECTIO | N IV: | 0.11 |
| REVIEW | VED BY | MANAGEMENT BY: |
| BY: | | OA/OC DIRECTOR DATE: 10-01-13 |

er-facilities, s and manufa PRY reporting

| CaseID: 9627012 |
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| orm Approved: OMB No. 09 10-029 1, Expires 12/31/11 |

| | | See OMB statement on reverse. |
|---|-------------------------|-------------------------------|
| | Mfr Report # 2280705-20 | 13-00059 |
| | UF/Importer Report # | 5 |
| ١ | | EDA Has Only |

| FORM FDA 350 | 0A (1/09) | | | Page |
|--|---|-------------------|-------------------|-----------------------|
| A. PATIENT INF | ORMATION | | | |
| | 2. Age at Time | | 3. Sex | 4. Weight |
| (b) (6) | of Event: 2 | Years | ☐ Female | " |
| · | Date | | ✓ Male | or |
| In confidence | of Birth: | | | k |
| B. ADVERSE E | VENT OR PRODU | CT PROBLE | M | |
| 1. 🗸 Adverse Even | t and/or Pro | duct Problem (6 | .g., defects/malf | unctions) |
| 2. Outcomes Attribut (Check all that appl | ted to Adverse Event | | | |
| Death: | | ✓ Disability of | r Permanent Da | mage |
| ✓ Life-threatenin | (mm/dd/yyyy) | Congenita | Anomaly/Birth D | Defect |
| | - initial or prolonged | | ous (Important M | |
| 1 | vention to Prevent Perm | | | |
| 3. Date of Event (mn | | | Report (mm/do | |
| 08/0 | 05/2011 | | 10/09/13 | |
| 5. Describe Event or | Problem | <u> </u> | | |
| Approvimately | 30 minutes aft | er the chi | ld was | |
| | Baby Orajel™ he | | | ghost" |
| 1 | gernails and li | | | to the |
| hospital and | diagnosed with | methemoglo | binemia. | |
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| | | OCT 1 | 1 2013 | |
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| 6. Relevant Tests/La | boratory Data, Includin | g Dates | | • |
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| 7 Other Palevant His | story Including Pressie | ting Madical Co | nditions (e.g. c | llemies |
| race, pregnancy, sr | story, Including Preexis noking and alcohol use, I | hepatic/renal dys | function, etc.) | adigi o s, |
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|---------------------------|-------------|--------------|-----------|----------------|
| Submission of a report | | | | |
| personnel, user facility, | | stributor, ı | manufactu | rer or product |
| caused or contributed to | o the event | | | |

| and manufacturers | UF/Importer Rep | ort# | - 3 |
|--|-------------------|--------------------------------|---|
| 11 | | | EDA U O-I |
| C. SUSPECT PRODU | ICT(S) | | FDA Use Only |
| . Name (Give labeled streng | | | |
| #1 Baby Orajel™ (| Oral Pain Re | eliever for | Teething OTC |
| #2 (continued) Ber | nzocaine 7. | 5% | |
| 2. Dose, Frequency & Rout | e Used | 3. Therapy Date from/to (or be | st estimate) |
| #1 unk dose, 1X, o | oral | | 5/2011 |
| #2 | | #2 | |
| 4. Diagnosis for Use (Indica | tion) | | ent Abated After Use |
| #1 To alleviate | | | pped or Dose Reduced? |
| #1 10 dilevided | orar paris | #1 [| Yes ✓ No Doesn't Apply |
| #2 | | #2 [| Yes No Doesn't |
| | 7. Exp. Date | | Дрріу |
| #1 LL0124 | #1 | | ent Reappeared After introduction? |
| #2 | #2 | #1 | Yes No Doesn't |
| 9. NDC# or Unique ID | | | Apply Doesn't |
| 10237-735-42 | : · · · · · · · · | #2 | Yes No Apply |
| 10. Concomitant Medical Pr | roducts and There | apy Dates (Exclu | de treatment of event) |
| Clindamycin, Tyle: | nol #3, Mot | rin since (| 08/03/2011. |
| | | | |
| | | | |
| | | | |
| D. SUSPECT MEDICA | AL DEVICE | | |
| 1. Brand Name | | | |
| 2. Common Device Name | | | |
| 2. Common Device Rame | • | | |
| 3. Manufacturer Name, City | and State | | |
| | | | |
| 4. Model # | Lot # | | 5. Operator of Device |
| | 1 22.2 | | Health Professional |
| Catalog # | Expiration | Date (mm/dd/yy | |
| | | | Other: |
| Serial # | Other# | | U Outer. |
| 6. If Implanted, Give Date (r | nm/dd/vvvv) | 7. If Explanted. | Give Date (mm/dd/yyyy) |
| ······································ | | · · ·, | |
| B. Is this a Single-use Device | e that was Repro | cessed and Reu | used on a Patient? |
| Yes No | | | |
| 9. If Yes to Item No. 8, Ente | r Name and Addr | ess of Reproces | sor |
| | | | |
| | | | Doo |
| 10. Device Available for Eva | aluation? (Do not | send to FDA) | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ |
| Yes No | Returned to Ma | nufacturer on: | Of J. |
| tand to | | | (Mith/ddays0)2013 |
| 11. Concomitant Medical Pr | roducts and Thera | apy Dates (Excl | ude treatment of event) |
| | | | |
| | | | l |
| E. INITIAL REPORTE | R | | <u> </u> |
| Name and Address | Phone | (b) (6) | |
| (b) (6) | | | |
| (0) (0) | | | |
| | | | CT 1 1 2042 |
| | | | CT 1 1 2013 |
| | | | |
| 2. Health Professional? 3. | Occupation | | 4. Initial Reporter Also Sent |
| | Occupation | | Report to FDA |
| Yes 🗸 No NA | • | | Yes No Unk. |



| 1. Check One | | 1 | 2. UF/Import | er Report Number |
|---|-------------------|------------------------|-----------------|---|
| User Facility | Impo | | | · |
| 3. User Facility or Imp | orter Name | Address | | , |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| 4. Contact Person | | | 5. Phon | e Number |
| | | | | |
| 6. Date User Facility of Importer Became | or i | 7. Type of R | eport | 8. Date of This Report (mm/dd/yyyy) |
| Aware of Event (mr | n/dd/yyyy) | Initial | | (IIIIII GWYYYY) |
| | | Follow-L | ın# | |
| 9. Approximate | 10. Event F | | | oding manual) |
| Age of Device | 1 | 10010111 000 | | oung manualy |
| | Patient Code | | - | - |
| | Device - | | | |
| | Code | | | |
| 11. Report Sent to FD | A? | 12. Locatio | on Where Eve | ent Occurred |
| Yes | • | Ho | spital | Outpatient Diagnostic Facility |
| No (mm/da | Yyyy) | Ho | me | Diagnostic Facility Ambulatory |
| 13. Report Sent to Ma | nufacturer? | | rsing Home | Surgical Facility |
| ☐ Yes | | | tpatient Treate | ment |
| No (mm/dd | (yyyy) | l — | • | |
| □ NO | | | ner: | (Specify) |
| C ALL MANUEA | CTUBER | | | |
| G. ALL MANUFA 1. Contact Office - Nar | | | -4 | O Diversity |
| for Devices) | | (and manus | icturing Site | 2. Phone Number 609-806-1428 |
| Jill D. Feren | | | | |
| Regulatory Af Church & Dwig | | Inc | | 3. Report Source (Check all that apply) |
| 469 North Har | | | | Foreign |
| Princeton, NJ | 08543 | | | Study |
| | | | | Literature |
| | | | | Consumer |
| | | | | Health Professional |
| 4. Date Received by | | 5. | | User Facility |
| Manufacturer (mm/d | ld/yyyy) | 1 | - | Company |
| 02/07/20 | 012 | | | Representative Distributor |
| 6. If IND, Give Protoco | 1# | IND# | | Other: |
| | | STN# | | |
| 7. Type of Report | | PMA/ | | Attorney |
| (Check all that apply) | | 510(k) # | | - |
| 5-day 30-da | | Combinati Product | on Yes | |
| | ıy | Product | 100 | |
| 7-day Perio | - | | | |
| | dic | Pre-1938 | Yes | - |
| 7-day Perio | dic | | Yes | |
| 7-day Perio | dic w-up# | Pre-1938 OTC Prod | Yes | (s) |
| 7-day Perio 10-day Initial 15-day Follow | w-up# t Number | Pre-1938 OTC Prod | Yes | (s) |
| 7-day Perio 10-day Initial 15-day Follow Manufacturer Repor | w-up# t Number | Pre-1938 OTC Prod | Yes | (s) |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

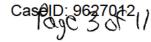
| | CaseID: 9627012 |
|---|---|
| · · · · · · · · · · · · · · · · · · · | |
| | FDA USE ONLY |
| 11 | |
| | |
| . DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | |
| | Yes No |
| 6. Evaluation Codes (Refer to coding manual) | L |
| · | |
| Method | |
| Results - | |
| Trosuis | |
| Conclusions - | - |
| 7. If Remedial Action Initiated, Check Type 8. | Usage of Device |
| Recall Notification | Initial Use of Device |
| | Reuse |
| Repair Inspection Replace Patient Monitoring | Unknown |
| Patient Monitoring | total in the second |
| Polabolina Modification/ 9. | If action reported to FDA under |
| Adjustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| Adjustment | 21 USC 360i(f), list correction/ |
| Adjustment Other: | 21 USC 360i(f), list correction/ removal reporting number: |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, MD 20857

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OCT 1 1 2013

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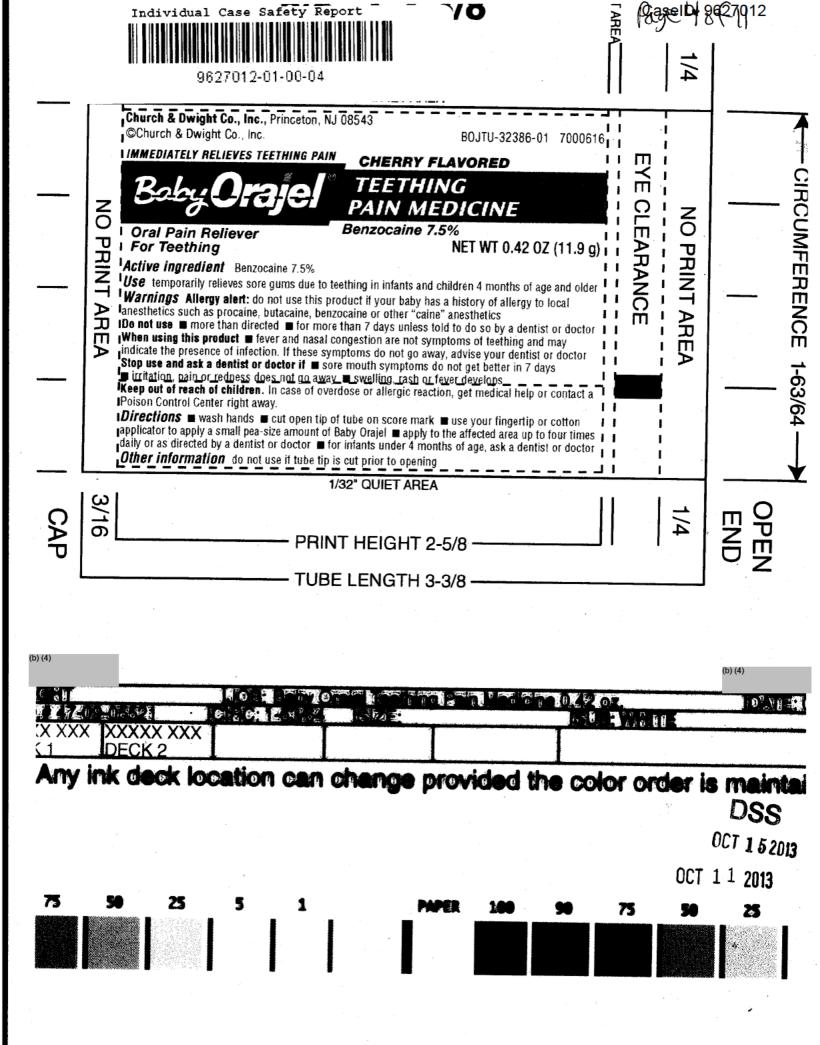
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at 12:50 pm, Dec (





(b) (6)

| ımıvalı | Date/Time: | None | Admit D | ate/Time: | (b) (6) | 5:26 | IP Adm. | (b) (6) | 5:26 |
|----------|--|--|---|---|--|---|-----------------------|---|---|
| | | | | | AM | | Date/Time: | AM | |
| dmiss | on Type: | Urgent | Admiss | ion Source: | Transfer From Hospital (Diff Facility) | | Admit Category: | None | • . |
| Aeans (| of Arrival: | Ambulance | Primary | Service: | Pediatrics | | Secondary Service: | None | |
| ransfe | r Source: | (b) (6) | Service | Area: | (b) (6) | | Unit: | (b) (6) | |
| Admit P | rovider: | Hospital | Attendir | ng Provider: | (b) (6) | | Referring Provide | er: ^{(b) (6)} | |
| al Diag | noses | | | | | | | | |
| Principa | l Code | Name | | | | POA | CC | HAC | Affects DRG |
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| | ge Date/Tir | on - Hospital Acc ne Discharge D | | | Destination | Disch | arge Provider | Unit | |
|) (6) | 9:06 A | • | • | Home | Destination | (b) (6) | MD | (b) (6) | |
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| ents | | | | | | | | | |
| Date/Tir | ne | Event | Pt Class | Unit | | | Daniel (Daniel | | |
| (b) (6) | 0526 | | | | | | Room/Bed | Service | |
| | | Admission | Inpatient | (b) (6) | | | (b) (6) (COM/Bed | Service PED INTE CARE | NSIVE |
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| | 0830 | Surgery | Inpatient Inpatient | | | | | PED INTE CARE E.N.T. PED INTE CARE PED INTE | NSIVE |
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Allergies as of (b) (6)

Date Reviewed: (b) (6)

CaseID: 9627012 1990 6 0 1

9627012-01-00-06

(b) (6)

Date

H&P Summary Notes (continued)

HPI:

is a 2 year old male with history of recent mandible fracture after fall from 10ft retaining wall on

who presented to hospital with respiratory failure. He underwent maxillomandibular fixation on hospital with respiratory failure. He underwent maxillomandibular fixation on hospital where his jaw was wired shut. He was discharged home on hospital on clindamycin, tylenol #3, and motrin.

He had been doing well at home - playing in the yard, eating macaroni & cheese and hot dogs that mom could blend for him - until about 9pm on At that time, he began to complain of abdominal pain. His parents thought he was constipated, as he had not had a bowel movement since his surgery. They gave him a children's suppository, which did not help. At that point, dad left to go home. He received a phone call from mom at 2:30am stating that she was taking (1) to the hospital because he was blue. Aside from being blue, (1) was able to walk, talk, and scream.

Upon arrival to (b) (6) was bluish-purple colored. Oxygen saturations were in the 60s. His jaw wires were cut with wire cutters to allow for intubation. During RSI, immediately after receiving etomidate, did have some posturing that was attributed to administration of etomidate. He was successfully intubated, however, with bag-mask ventilation and PEEP of up to 8, oxygen saturations were in the high 70s to low 80s. His ABG after intubation was 7.38/36/153/99. Due to the outside facility's concern for PE, therapeutic lovenox at 1mg/kg was given in a one time dose prior to transfer.

It is of note that mom had been putting Orajel on his lips along with a moisturizer.

Past Medical History

Diagnosis

- Asthma
- Prematurity

Past Surgical History:

Maxillomandibular Fixation on (b) (6)

Prior to Admission Medications: No prescriptions prior to admission

Current Inpatient Medications:

Current facility-administered medications:

| · · · · · · · · · · · · · · · · · · · | | | | |
|--|-------------------------|----------------------------|--------------------|--------------|
| acetaminophen (TYLENOL) rectal suppository D5W 1/2 NS 1000 mL with potassium chloride | 60 mg | Rectal | Q4H PRN | DSS |
| 20 mEq infusion | | Intravenous | Continuous | • |
| vancomycin 5 mg/mL in D5W IV PEDS DILUTION 100 mg | 10 mg/kg | Intravenous | Q6H | OCT 1 5 2013 |
| piperacillin/ tazobactam 100 mg/mL (of piperacillin) in D5W injection 800 mg | 240 mg/kg/day | Intravenous | Q8H | |
| heparin 1 Unit/mL in NS 60 mL premix PEDS line flush | | Intravenous | Continuous | OCT 1 1 2013 |
| fentanyl (SUBLIMAZE) 50 mcg/mL injection fentanyl (SUBLIMAZE) 50 mcg/mL PEDS | 1 mcg/kg 1 mcg/kg/hr | Intravenous Intravenous | Once Continuous | |
| | | | | |



9627012-01-00-07

| (b) (6) | | | |
|---------|--|--|--|
| | | | |
| | | | |

(b) (6)

Operative Report (continued)

stable. The mouth was rinsed with Peridex. Two 26 gauge wires were then placed to bring the patient into mandibulomaxillary fixation, one on each side of the oral cavity. The patient was then allowed to awaken and extubated by anesthesia without incident. The patient tolerated the procedure well and there were no complications. Dr. (b) (6) was present for the entire case.

(b) (6) MD Resident Department of Otolaryngology

Electronically signed by (b) (6) MD at (b) (6) 1904

(MR # (b) (6) (b) (6) Discharge Instructions

None

Discharge Summary Notes

D/C Summaries signed by (b) (6 MD at (b) (6) 1015 Author: Service: Author Type: Physician MD Filed: Note Time: (b) (6) 1651 Related Note by: (b) (6) MD filed at (b) (6) Related 0909 Notes: MD filed at (b) (6) Original Note by: (b) (6) 0909

DISCHARGE SUMMARY

PATIENT NAME:

MRN: (b) (6)

DOB:

ADMISSION DATE:

DISCHARGE DATE:

ATTENDING PHYSICIAN: (b) (6)

PRIMARY CARE PHYSICIAN: (b) (6) MD

ADMISSION DIAGNOSIS: Methemoglobinemia **DISCHARGE DIAGNOSIS:** Methemoglobinemia

Hospital Problems

1 Methemoglobinemia

Date Noted:

OCT 1 5 2013

OCT 1 1 2013

Respiratory failure

Date Noted: (b) (6)

Resolved Hospital Problems No resolved problems to display.

Individual case safety Report

Case D. 96272721

(b) (6)

(b) (6)

9627012-01-00-08

Discharge Summary Notes (continued)

Chronic Problems

Fall

Date Noted: 07/31/2011

Symphysis of body of mandible open fracture

Date Noted: 07/31/2011

Lacerations of face

Date Noted: 07/31/2011

Sacral Dimple

Date Noted: 03/12/2009

(b) (6)

MD

DISCHARGE MEDICATIONS: Current Discharge Medication List

CONTINUE these medications which have NOT CHANGED

acetaminophen (TYLENOL) 80 mg/0.8 mL Drop/Susp

take 160 mg by mouth Every 4 hours as needed.

acetaminophen-codeine (TYLENOL WITH CODEINE) 120-12 mg/5 ml. Elix

take 4.48 mL by mouth Every 4 hours as needed.

Qty: 480 mL Refills: 0

clindamycin (CLEOCIN) 75 mg/5 mL SoIR

take 5 mL by mouth once every 6 hours for 8 days.

Qty: 200 mL Refills: 0

ibuprofen (MOTRIN) 50 mg/1.25 mL Drop/Susp

take 2.8 mL by mouth Every 6 hours as needed.

Qty: 1 Bottle Refills: 1

DSS 001 **1 5 2012**

DISCHARGE INSTRUCTIONS:

No discharge procedures on file.

Individual Case Safety Report 9627012-01-00-09 LMR REPORT Discharge Summary Notes (continued) He had been doing well at home - playing in the vard, eating macaroni & cheese and hot dogs that mom could blend for him - until about 9pm on (b) (6) At that time, he began to complain of abdominal pain. His parents thought he was constipated, as he had not had a bowel movement since his surgery. They gave him a children's suppository, which did not help. At that point, dad left to go home. He received a phone call from (b) (6) mom at 2:30am stating that she was taking (b) (6) the hospital because he was blue. Aside from being blue. (b) (6) was able to walk, talk, and scream. Upon arrival to (b) (6) was bluish-purple colored. Oxygen saturations were in the 60s. His jaw wires were cut with wire cutters to allow for intubation. During RSI, immediately after receiving etomidate, did have some posturing that was attributed to administration of etomidate. He was successfully intubated, however, with bag-mask ventilation and PEEP of up to 8. oxygen saturations were in the high 70s to low 80s. His ABG after intubation was 7.38/36/153/99. Due to the outside facility's concern for PE, therapeutic lovenox at 1mg/kg was given in a one time dose prior to transfer. It is of note that mom had been putting Orajel on his lips along with a moisturizer. DURING ADMISSION: His work up in this hospital revealed an elevated methemoglobin level. He was given methylene blue and the symptoms resolved with improvement of saturations. ENT was consulted and his jaw was rewired for forced occlusion. He was given Tylenol & morphine for pain control. He received vancomycin & zosyn for 2 days then was switched to clindamycin. He will continue the clindamycin at home. CONDITION ON DISCHARGE: A. Ambulation: ambulate well B. Self-care Ability: taken care by mom. C. Cognitive Status alert & oriented **DISCHARGE DISPOSITION:** Home discharge

cc: Primary Care Physician:

cc: Referring Physician:

(b) (6)

OCT 1 5 2013

(b) (6) MD

OCT 1 1 2013

MD at (b) (6) Electronically signed by 1015



(b) (6)

(b) (6)

Patient Education (continued)

Title: Patient Information Guide (Resolved) (continued)

Point: Speak Up Handout (Resolved)

| | | | | gress Summary | | | |
|---------|------------|--------|----------|--|-----------------|------|--------|
| Learner | Readiness | Method | Response | Comment | Given by | | Status |
| Family | Acceptance | E | VU | Mom at bedside for rounds. See IPOC for plan of care. MOm stated understanding and denies any additional questions at this time. | (b) (6) (b) (6) | 1224 | Done |

| User Key | | | | | | _ |
|----------|-----------------|---------|----|------------------|------------|---|
| Initials | Effective Dates | Name | | Provider Type | Discipline | |
| (b) (6) | 01/17/09 - | (b) (6) | RN | Registered Nurse | Nurse | |
| | | | | | | |

Ancillary Notes

| Ancillary N | otes signe | d by ^{(b) (6)} | | MD at | (b) (6) | 1358 | | | |
|-------------|-----------------|-------------------------|------------|---------|---------|--------------------|------------|----------|--|
| Author: | (b) (6) | | Service: | Emerger | су | Author T | уре: | Resident | |
| Filed: | MD (b) (6) 1 | 358 | Note Time: | (b) (6) | 1346 | Cosign Required | 1 : | Yes | |

Code Status: Full

No Known Allergies

| Filed Vitals: | (b) (6) 0400 | (b) (6) 0600 | (b) (6) | 0700 | (b) (6) 0800 | |
|------------------|---------------------|---------------------|---------|------|---------------------|--------------|
| BP: | 74/44 | 69/49 | | | 72/34 | |
| Pulse: | 91 | 74 | | | 83 | |
| Temp: | 36.2 °C (97.2 °F) | | | | 36.4 °C (97.5 °F) | |
| Resp: Height: | 20 | 37 | | | 19 | DSS |
| Weight: SpO2: | 97% | 97% | 99% | | 98% | OCT 1 5 2013 |

OCT 1 1 2013

HPI and Hospital Course:

In brief, patient is a 2 y.o. malewho presented to an outside facility with increase in duskiness of skin and was found to have very decreased saturations. He was recently treated operatively here at the beginning of for open mandibular fracture and in order to intubate at wires were cut. He was then transported here with decreased oxygen saturations. On arrival, blood gas showed greatly elevated methemoglobin levels. Methylene blue was given with

Individual Case Safety Report

9627012-01-00-11

(b) (6)

EITH CINE OIL

(b) (6)

Ancillary Notes (continued)

significant improvement in respiratory status and complete resolution of methemoglobinemia on multiple blood gases. Upon presentation, we were also concerned for possible aspiration, and broad spectrum antibiotics were begun. ENT took patient to OR on (b) (6) for rewiring and patient extubated without difficulty post-operatively. Has had pain controlled with IV morphine here and was switched to PO Tylenol #3 today. Playing well. Tolerating IMF diet. ENT following and recommended de-escalation of antibiotics to Clindamycin. Patient started on PO Clindamycin. Although no specific culprit can be found, our working etiology for methemoglobinemia is his oralgel use at home.

Pertinent Exam Findings:

4 wires in place on jaw
Healing laceration at midline chin
No skin duskiness
Neurologically intact and appropriate

Pertinent Imaging/Lab results:

Methemoglobin 0.0

Pending Studies:

none

Consults:

ENT

<u>Plan:</u>

Resp: monitor. No need for continued ABG. Do not give oragel.

CV: stable

Neuro: interacting well. Monitor. PO pain control.

FEN/GI: IMF diet. UOP stable.

Heme/ID: PO clindamycin for prophylaxis. HH stable despite 2 recent surgeries.

| Electron | nically signed by | y (5) (5) | | MD at | 1358 | | | |
|----------|-------------------|------------------------|------------|------------------|--------------------------------------|--------------|---|--------------|
| Care Mar | nagement No | tes | | | | | | |
| Author: | (b) (6) | RN S | Service: | (none) | | Author Type: | CLINICAL CARE | |
| Filed: | (b) (6) 104 | 4 N | lote Time: | (b) (6) | 528 | | COORDINATOR | DSS |
| Related | Original Note | by: ^{(b) (6)} | RN | filed at (b) (6) | 1607 | | | OCT 4 FANO |
| Notes: | | | | | | | | OCT 1 5 2013 |
| == | | | | | | | | |
| Patie | ent Name: |) | | | AND THE COLUMN AND AND AND AND AND A | | enter come pare serie tomo usua socia come. | |
| DOB: | (b) (6) | | | ' | | | | |
| Age: | | | | | | | | |
| Accou | int Number: | (b) (6) | | | | | | OCT 1 1 2013 |
| MR Nu | umber: (b) (6) | | | | | | | OCT 1 1 2013 |
| | · | | | | | | | |
| Admis | sion Inform | ation | | <u> </u> | | | | |
| | nter Type: | | | | | | | |

The FDA Salety Information and

Report

CaseID: 9630574

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

Y reporting of uct problems and e errors

FDA USE ONLY Triage unit sequence #

CDER Page 1 of 2

| Adverse Event Reporting Program | | | |
|--|--|---|---|
| A. PATIENT INFORMATION | 2. Dose or Amount | Frequency | Route |
| 1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight Date of Birth: | #1 2 pills | Four times daily | Taken by mouth |
| Date of Birth: 4 Months Female 15 lb | #2 | | <u> </u> |
| (b) (6) ✓ Male or kg | 11 "-1 | | |
| In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR | | nown, give duration) from/to | 5. Event Abated After Use |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply: | (or best estimate) | | Stopped or Dose Reduced? |
| . Adverse Event Product Problem (e.g., defects/malfunctions) | #1 08/20/2007 - | 10/20/2009 | #1 Yes No Doesn't |
| ✓ Product Use Error ☐ Problem with Different Manufacturer of Same Medicin | e #2 | | #2 Yes No Doesn't |
| 2. Outcomes Attributed to Adverse Event | 4. Diagnosis or Reaso | , , | Apply |
| (Check all that apply) | #1 Teething pai | n for infant/ | 8. Event Reappeared After Reintroduction? |
| Death: Disability or Permanent Damage | #2 | | #1 Yes No Doesn't |
| Life-threatening Congenital Anomaly/Birth Defect | | T= | |
| Hospitalization - initial or prolonged Other Serious (Important Medical Events |) 6. Lot# | 7. Expiration Date #1 | Apply |
| Required Intervention to Prevent Permanent Impairment/Damage (Devices) | _ " | | 9. NDC # or Unique ID |
| 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) | 1 | #2 | |
| 08/20/2007 10/16/2013 | E. SUSPECT ME | DICAL DEVICE | |
| 5. Describe Event, Problem or Product Use Error when my son was four months old, I began giving him | State Name | | |
| Hylands Teething Tablets. I gave him the recommended | | | A. 1994 |
| dose. As time progressed I noticed he would never put things in this mouth to teeth, didn't like spoons in | 2. Common Device Na | me | CTU |
| his mouth and wasn't really babbling like most infants | | | 005 |
| his age. I did continue giving him the Hylands Teething Tablets all the way through his 1-2 years. At | 3. Manufacturer Name | , City and State | OCT 1 6 2013 |
| the age of two we began noticing this blank staring | | | |
| spells where we'd almost have to shake him back to consciousness. We went to a development pediatrician | | | |
| because he was exhibiting flapping behaviors, food | 4. Model # | Lot# | 5. Operator of Device |
| avoidance, not saying | | | Health Professional |
| | Catalog # | Expiration Date (n | nm/dd/yyyy) Lay User/Patient |
| | | | Other: |
| 6. Relevant Tests/Laboratory Data, Including Dates | Serial# | Other# | |
| EEG's performed in 2010 and 2013 both show conclusive results for absence seizures. | | | |
| Genetic blood work 2011 to rule out Fragile X, Prader- | 6. If Implanted, Give D | ate (mm/dd/may) 7 14 E- | xplanted, Give Date (mm/dd/yyyy) |
| Willi and any other genetic disorders. Vineland assessments, ABBLS assessments and many other | . II misplanted, Give D | I I E | Apidineu, Give Date (Hill/Duryyyy) |
| psychological assessments to conclude the Autism | | Device that was Reproces | sed and Reused on a Patient? |
| diagnosis and | Yes No | ata Mana and Adding to | |
| | 9. IT Yes to Item No. 8, E | nter Name and Address of R | eprocessor |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) | | | |
| Race: White Medical Conditions: at the time of taking | F OTHER (CONG | OMITANT) MEDICAL | PRODUCTS |
| the teething tablets, his only known medical issue was jaundice at birth for which he spent four days under a | | erapy dates (exclude treatn | |
| billi ruben light. Allergies: eggs, cats, sulfa | 11 | - Janaara Wallin | y |
| Important Information: n/a RX Meds: at the time of the incident there were no medications | | | |
| | | | |
| | | ee confidentiality sec | |
| C. PRODUCT AVAILABILITY | 1. Name and Address (b) (6) | | DS 007 1 |
| Product Available for Evaluation? (Do not send product to FDA) | | | |
| Yes V No Returned to Manufacturer on: | | | OCT 1. |
|). SUSPECT PRODUCT(S) | | | 4 |
| Name, Strength, Manufacturer (from product label) | Phone # | E-mail | |
| 1 Name: Hyland's Teething Tablets | (b) (6) | (b) (6) | |
| Strength: | 2 Hoolth Destantion | 2 2 Occupation | A Alea Boundades |
| Manufacturer: | 2. Health Professional | r 3. Occupation | 4. Also Reported to: Manufacturer |
| 2 Name: Strength: | | avy identification - 1 | User Facility |
| Manufacturer: | 5. If you do NOT want y to the manufacturer, | our identity disclosed place an "X" in this box: | Distributor/Importer |



ine FDA Safety Information and Adverse Event Reporting Program

TION PAGE)
ARY reporting of d product problems

Page 2 of 2

| B.5. De | escribe Eve | ent or Pro | oblem (co | ntinued) |
|---------|-------------|------------|-----------|----------|
| | | | | |

... words and some fine motor delays. Our son was diagnosed with Autism in January of 2010 at 33 months of age. We are military and upon returning to the US in April of 2010 we took him in for an EEG and received a diagnosis of epilepsy with absence seizures occuring at a rate of 20 seizures every 10 minutes. He was placed on seizure medication and began ABA therapy and early intervention services for his Autism. He still at the age of six has oral motor issues, food avoidance and unable to speak. We have continued therapy, medication and intervention services to help with his Autism, Epilepsy and Oral Motor sensory issues. I pray to God that I did not poison my son with these teething tablets, however with reading other reports and seeing similar symptoms from other families, I am very concerned this product brought on not only my son's neurologicial issues, but his inablity to speak.

| I | B.6. Relevant | Tests/Laboratory | Data, Including | Dates (continued) |
|---|---------------|------------------|-----------------|-------------------|
| | | | | |

... sensory issues.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

... or medical devices being used. OTC Meds: only Hyland's teething tablets and Advil infant's motrin when needed.

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

DSS ^{OCT} 16 2013 Individual Case Safety Report

9661367-01-00-01

| (b) (6) | of Event: 8 | Months | Female | |
|--|--|-----------------------------|----------------------------|----------------------|
| | or Date | | = | or |
| In confidence | of Birth: | | ✓ Male | 7.6 k |
| B. ADVERSE E | VENT OR PRO | DUCT PROBLE | EM | |
| 1. Adverse Ever | | Product Problem | (e.g., defects/malf | unctions) |
| Outcomes Attribu (Check all that app | | nt | | |
| Death: | | Disability | or Permanent Da | mage |
| ✓ Life-threateni | (mm/dd/yyyy) ng | Congeni | tal Anomaly/Birth (| Defect |
| ✓ Hospitalizatio | n - initial or prolonged | Other Se | rious (Important M | fedical Even |
| Required Inte | rvention to Prevent P | ermanent Impairme | ent/Damage (Devi | es) |
| 3. Date of Event (m. | m/dd/yyyy) | 4. Date of Th | is Report (mm/do | t/yyyy) |
| | 06/2012 | | 10/29/2013 | 3 |
| the day. The | experienced a Ls mother gave e methg level osis of mether | e Orajel 15- was elevate | 20 times th d at >20% l | roughou |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| 6. Relevant Tests/L | aboratory Data, Incl | uding Dates | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Event occurre | listory, including Prosmoking and alcoholused POD#2 afte | r explorator | y laparoton | allergies, ny and |
| | | | | |
| | , | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| er-facilities, |
|---------------------|
| s and manufacturers |
| ORY reporting |

of ?

| Mfr Report # | 2280705-2013-00065 |
|--------------|--------------------|
| UF/Importer | Report# |
| | |

| 3 | | | FDA Use Only |
|----------------------------------|---------------------|--------------------|---|
| SUSPECT PRO | DUCT(S) | | |
| lame (Give labeled stre | | _ | |
| Orajel Instan | t Relief for | Teething Pa | in |
| (continued) 7 | .5% benzocai | ne | |
| ose, Frequency & Ro | oute Used | | (If unknown, give duration) |
| unk, 15-20 ti | mes, oral | #1 days pric | or to 08/04/2012 |
| | | | and 08/06/2012 |
| iagnosis for Use (Ind | tication) | L | t Abated After Use |
| RECE | IVED | Stopp | ped or Dose Reduced? Yes ✓ No Doesn't |
| e. .ot# 0CT 3 0 | 7818 Data | #2 | Yes No Doesn't |
| ot# UCI 3 (| 2018xp. Date | 8 Even | t Reappeared After |
| A D | #1 | | roduction? |
| CD | 1 2 | #1 🗌 | Yes ☐ No ☑ Doesn't Apply |
| IDC# or Unique ID | | #2 🗆 | Yes No Doesn't |
| L0237-735 Concomitant Medical | Products and The | | Арріу |
| rough hospital | stay includ | ing (b) (6) | |
| etaminophen, l | Lidocaine top | ical, morphi | |
| henhydramine, | medline sol | ution, sodiu | m chloride |
| | | | |
| | | f | |
| SUSPECT MED | ICAL DEVICE | | |
| Brand Name | | | |
| Common Device Nam | е | | |
| Innufactures Name (| Titu and State | | |
| flanufacturer Name, (| ity and State | | |
| | | | |
| flodel # | Lot# | | 5. Operator of Device |
| Catalog # | Expiration | n Date (mm/dd/yyyy | Health Professional |
| | | | Lay User/Patient |
| Serial # | Other# | | Other: |
| | | Ta Me | has Data (mar/ddf) |
| f Implanted, Give Dat | e (mm/dd/yyyy) | 7. If Explanted, G | ive Date (mm/dd/yyyy) |
| s this a Single-use D | evice that was Ren | ocessed and Reus | ed on a Patient? |
| Yes No | | | |
| Yes to Item No. 8, E | nter Name and Add | ress of Reprocess | or |
| | | | |
| | | | DSS |
| Device Available for | Evaluation? (Do no. | t send to FDA) | OCT A = |
| Yes No | Returned to M | lanufacturer on: | OCT 3 1 20 |
| Concomitant Medica | I Products and The | rapy Dates (Exclud | (11111111111111111111111111111111111111 |
| | | | |
| | | | |
| | | | |
| INITIAL REPOR | | # /b) /6) | |
| lame and Address | Phone | # (b) (6) | 12 |
| (6) | | | OCT 3 0 2013 |
| | | | 2013 |
| | | | |
| | | | |
| | | | |
| lealth Professional? | 3. Occupation | 4 | . Initial Reporter Also Sen |
| Yes Vo | NA | | Report to FDA |

| | _ | 2. Or misporter report reunities |
|---|----------------------|---|
| User Facility | Importer | |
| 3. User Facility or Imp | orter Name/Address | |
| | | |
| | • | |
| | | |
| | | |
| 4. Contact Person | | 5. Phone Number |
| | | · |
| 6. Date User Facility of Importer Became | r 7. Type o | |
| Aware of Event (mm | v∕dd/yyyy) ☐ Initia | (mm/dd/yyyy) |
| | Follo | w-up# |
| 9. Approximate |] | odes (Refer to coding manual) |
| Age of Device | Patient | |
| | Code | |
| | Device Code | |
| 11. Report Sent to FDA | | ation Where Event Occurred |
| | | Hospital Octurred |
| Yes(mm/dd/ | <u> </u> | Home Diagnostic Facility |
| No | | Nursing Home Ambulatory Surgical Facility |
| 13. Report Sent to Man | ulactuler? | Outpatient Treatment |
| Yes(mm/dd/ | (vvvv) | Facility |
| ∐ No (| | Other: (Specify) |
| 14. Manufacturer Name | e/Address | (4-1-4) |
| l . | | |
| | | - |
| | | |
| | | |
| G. ALL MANUFA | CTUDEDS. | |
| 1. Contact Office - Nam | | ufacturing Site 2. Phone Number |
| for Devices) | ion taaroos jana man | 609-806-1997 |
| Lisa Burns 469 North Har | rison Street | 3. Report Source |
| Princeton, NJ | 08543 | (Check all that apply) |
| <i>(</i>) | nich + Only | gh T ☐ Foreign |
| (-) | Jren 4 On | Study |
| | Con | \^C Literature |
| | | - |
| | | Health Professional |
| 4. Date Received by Manufacturer (mm/do | 5. | User Facility |
| 10/15/20 | (A)NDA | # Company Representative |
| | חוו | # Distributor |
| 6. If IND, Give Protocol | # STN | # Other: |
| | PMA/ | |
| 7. Type of Report (Check all that apply) | 510(k) | # |
| 5-day 30-day | Combin | |
| 7-day Period | ic | |
| ☐ 10-day ✓ Initial | Pre-193 | |
| ✓ 15-day ☐ Follow | -up # OTC Pr | oduct Yes |
| | | 1 |
| 9. Manufacturer Report | Number 8. Adve | rse Event Term(s) |
| 9. Manufacturer Report 2280705-2013-00 | methe | rse Event Term(s) moglobinemia |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

2 of 23

| H. DEVICE MANUFACTURERS ONLY | |
|---|---|
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury Malfunction | Additional Information |
| Other: | Response to FDA Request Device Evaluation |
| | |
| Device Evaluated by Manufacturer? Not Returned to Manufacturer | 4. Device Manufacture Date (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | ☐ Yes ☐ No |
| | |
| 6. Evaluation Codes (Refer to coding manual) | |
| Method | |
| Results - | - |
| | |
| Conclusions | -[] |
| 7. If Remedial Action Initiated, Check Type 8. L | Jsage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse Unknown |
| Replace Patient Monitoring Relabeling Modification/ 9. If | f action reported to FDA under |
| Adjustment 2 | 21 USC 360i(f), list correction/ emoval reporting number: |
| Other: | , and the same of |
| | |
| | / or 11. Corrected Data |
| A representative label of the prod | duct is attached. |
| (pages 3, 4) | |
| The pertinent pages of the hospita | al report are attached. |
| (pages 5 through 23) | |
| This report and information submit | ted under this report |
| do not constitute an admission that Dwight, Co. Inc. or any of its emp | at the drug or Church & |
| contributed to the event described | herein or that the |
| event as reported to Church & Dwig | tht Co., Inc actually |
| occurred. | |
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| | 2013 |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

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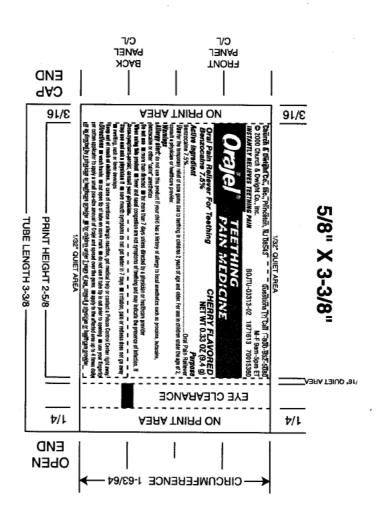
esodind

Drug Factor

To clean your baby's new teeth, try BABY ORAJEL® OCT 3 0 2013



9661367-01-00-04



DSS 0CT **31** 2013





DOB:

(b) (6)

FIN Nbr:

(b) (6)

Admit/Reg Date:

n/a

Discharge Date:

n/a

| Inpatient Con | sultation |
|---------------|-----------|
|---------------|-----------|

SIGNED BY:

(b) (6)

23:36 PDT); (b) (6)

04:53 PDT)

PICU CONSULTATION NOTE

PATIENT: (b) (6)

MRN: (b) (6)

FIN: (b) (6)

DOB: (b) (6)

LOC: (b) (6)

Admitting Service: General Surgery

Admitting Attending: (b) (6)

Date of Consultation:(b) (6)

Requesting Service: Peds Hospitalist

Reason for Consultation: Hypoxia/methemoglobinemia

Date of Admission: (b) (6)

Place of Consultation:

Requesting Physician: Dr. (b) (6)

IDENTIFICATION / CHIEF COMPLAINT: 8 month old with intussusception s/p open reduction without resection _

HISTORY OF PRESENT ILLNESS:

) is an 8 month old male (b) (6) from exploratory laparotomy and manual reduction of (goes by ileocolic intussusception. He has had an uncomplicated recovery until the afternoon of (6) (6) when he had a desaturation event to the high 80's. He was given supplemental oxygen via nasal cannula but continued to remain mildly hypoxic (while on up to 3L NC). The pulse oximetry probe was changed and his monitors were also changed but his hypoxia persisted with sats in low 90s. Of note, mom reports that he has had "teething" pain and was using oragel at home for comfort. She noticed that he was having similar discomfort yesterday and gave oragel approximately 15-20 times. The pediatric hospitalist was consulted at approx 0030 this morning for continued hypoxia and perioral cyanosis. Given the history of oragel use and possible benzocalne toxicity leading to methemglobinemia, a methg level was checked and was elevated at >20%.

I was called to consult on this patient given the diagnosis of methemoglobinemia, persiststent hypoxia, and the young age of the patient.

REVIEW OF SYSTEMS:

Constitutional:

Eyes:

ENT/Mouth: mild perioral cyanosis Respiratory: breathing comfortably_

Cardiovascular:

GI/Liver: Kidney/GU:

Heme/Oncologic/Lymphatic:

Musculoskeletal:

Metabolic/Endocrine:

Neurologic:

Allergic/Immunologic:

Skin: pale

Development/Behavior:

Print Date/Time: 12/11/2012 14:26 PST

OCT 31 2013

OCT 3 0 2013

Report Request ID:

9661367-01-00-06 (b) (6)

Patient Name:

CaseID: 9661367

FIN Nbr:

MRN:

DOB:

Admit/Reg Date: Discharge Date:

n/a

Inpatient Consultation

al

Other:

[] A complete 14 system review performed; all systems are negative, except as documented.

PAST MEDICAL HISTORY:

- Possible milk allergy On Alimentum, scheduled to have allergy panel sent next week. Symptoms mostly GERD-like.
- 2. GERD Diagnosed at 3 months of age. Changed formula several times and that seemed to help symptoms never on medications.
- 3. Intussusception See HPI. _

PAST SURGICAL HISTORY: Exploratory laparotomy and manual reduction of ileocolic intussusception. (b) (6)

see HPI.

BIRTH HISTORY: Born FT via C-section due to breech presentation to 24 yo G1 P0->1 mom. Pregnancy and delivery uncomplicated. BW 6 lbs 1 oz. Home with mom after 3 days.

HOME DIET: Alimentum (s/p several formula changes, most recently from Enfamil Premium)

ACTIVE DIET ORDER(S):

Pedialyte: (b) (6) 16:58:00 PDT, PO, Comments: 0.5-1 ounce every hour

DEVELOPMENT: _

HOME MEDICATIONS:

No Home Medication/Prescription Orders

ACTIVE MEDICATION ORDERS (as of (b) (6) 04:04):

Scheduled

acetaminophen 76 mg IV q4hr

PRN

acetaminophen 115 mg rectal q6hrPRN(discomfort/fever) lidocaine topical 1 application topically as neededPRN(procedure) morphine 0.25 mg IV q2hrPRN(pain)

Continuous Infusion

Dextrose 5% with 0.45% NaCl and KCl 20 mEq/l 1000 mL IV

diphenhydrAMINE 7.6 mg IV q6hrPRN(dry eyes) medline solution 1 bag IV as neededPRN(protocol) sodium chloride 1 mL IV as neededPRN(catheter care patency)

ALLERGIES: None recorded

IMMUNIZATIONS: UTD per mom

FAMILY HISTORY: Dad with AR; mom with asthma as child.

SOCIAL HISTORY: Lives with mom, dad. No stick contacts, travel, or daycare.

OCT 3 0 2013

OCT 3 1 2013

MEASUREMENTS:

Approx. Percentiles

Measured Weight: 7,6 kg ((b) (6) 04:20) Weight: 4 %ile

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:



Patient Name:

CaseID: 9664

DOB:

MRN:

FIN Nbr:

Admit/Reg Date: n/a **Discharge Date:** n/a

Inpatient Consultation

Height: 72.5 cm (b) (6) 04:20) BMI: 14.459 kg/m2 (b) (6) 04:20)

(b) (6)

Height: 71 %ile

Wt for Length: 1 %ile

(b) (6)

VITAL SIGNS OVER LAST 24 HOURS:

Temp HR Cuff BP

RR

SPO₂

36.7 (36.1 - 36.7) 106 (94 - 143) 117/61 (86-118/49-72)

04:00 04:02 04:02 04:02 04:02

INTAKE & OUTPUT (Calculations based on current dose calc weight of 7.6 kg on (b) (6)

Previous 0600 - 0559

1099.3 mL Intake

21 (18 - 32)

100 (88 - 100)

144.6 mL/kg/24hrs

Since 0600 946.9 mL

41 mL Meds

845.4 mL Infusions

124.6 mL/kg/22hrs

953.6 mL Infusions 101 mL Meds

45 mL Oral

Output 828 ml. 3.8 mL/kg/hr UOP

60 mL Oral 579 mL

3.2 mL/kg/hr UOP

700 mL Urine 100 mL Gastric 28 mL Stool 1 Stool Count

41 mL Stool 1 Stool Count

538 mL Urine

Balance 271.3 mL 367.9 mL

PHYSICAL EXAM:

(Time of Exam: 0345_)

General:

[x] crying but easily consolable

Head:

[x]NC/AT

[x]AFOSF

Other:

Eyes:

[x]PERRL [x]anicteric

Other:

ENT / Mouth: [x] clear oropharynx

[_] TMs clear

Other: lips- pink, no cyanosis_

Neck:

[_x] supple

Lungs: [x_] clear

[x] no distress

Other:

Cardiac:

[x] reg rate & rhythm

[x] no murmurs

Pulses: 2+ bilat fem

Other: _

Gl/Abdomen: [x] soft

non-tender

[] NL bowel sounds

[] no hepatosplenomegaly

Other: moderate distension, surgical site: c/d/i

GU:

[x] NL external genitalia

Other:

Extremities: [x] warm

[x] no edema

Capillary refill time: 2-3 sec Other: _

OCT 8 1 2013

OCT 3 0 2013

Neurologic: [_] non focal/grossly intact

[x] no rashes/lesions

Other:

Skin: Other: _

RADIOLOGY STUDIES (Completed):

XR Chest 1 View

(b) (6) 02:20

Report Request ID:

(b) (6)

Print Date/Time:

12/11/2012 14:26 PST



Patient Name:

CaseID: 9661367

MRN:

DOB:

FIN Nbr:

Admit/Reg Date: Discharge Date:

GGT:

LDH:

TG:

TChol:

n/a

n/a

Inpatient Consultation

AST:

ALT: ALKP:

UA:

LABS:

CHEM 23 (within 36 hours):

| CHILIN A | • | faairiii | 55 | | | | | | |
|-----------|-----|----------|-----|-----|---|-------------|---------|-------|---|
| 136 | 1 | 104 | l | <5 | L | / | | 8.7 | |
| | -+- | | | | | — 92 | | \ / | |
| 4.6 | į | 28 | ı | 0.4 | H | \ | | I | |
| Chem: (b) | (6) | | 01: | 50 | | | (b) (6) | 01:50 |) |

ALB: TP:

Globulin:

TBili: DBili:

CBC w/Diff (within 36 hours):

\ 11.2 / PMN: — 646 Н Bands: / 33.5 \ Lymph: Mono: Last CBC: (b)(6) 01:50 Eos: Meta: CRP: Baso:

OTHER RESULTS: _

Microbiology Results Updated in Last 48 Hours (Collect Date/Time Shown): No microbiology results found.

ASSESSMENT / PLAN: 8 mo M s/p exploratory laparotomy for manual reduction of ileocolic intussusception now with methemoglobinemia likely from benzocaine toxcitity. Pt had received a dose of methylene blue prior to my arrival. on exam, he did not have any signs of cyanosis (lips were pink) and his 02 sats were 99% on 1L NC. when weaned to room air, he maintained his O2 sat>99%. He was hemodynamically stable, appeared comfortable, and was tolerating pedialyte from his bottle. His chest xray was concerning for possible LLL atelectesis and some mild edema but was otherwise WNL.

Recommendations at this time:

1) contact poison control for further assistance

2) recheck a methemoglobin level in 3-4 hrs. consider redose of methylene blue if still >15-20%

3) continue oxygen supplementation to keep O2 sat >96%

at this time. we will check in again with the 4) given his rapid improvement, he will be safe to monitor in (b) (6) next lab draw. please feel free to contact us if he has any more episodes of desaturations and we will transfer him to the PICU for closer monitoring.

This plan was discussed with the parents at bedside.

OCT 3 1 2013

[x] I have discussed my recommendation with the requesting physician _

OCT 3 0 2013

PATIENT CARE TIME: "Only applicable if counseling or coordination time (C) is > 50% of total visit time (V):"

(V) Total attending face to face and floor/unit time with patient and/or family: _ (minutes)

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Patient Name: tal

> MRN: DOB:

CaseID: 966136(7,23

FIN Nbr:

Admit/Reg Date: Discharge Date:

n/a n/a

Inpatient Consultation

(C) Total attending Counseling/Coordination time with patient and/or family: _ (minutes) Describe the counseling performed: _

Report prepared by:

MD

Teaching Physician Attestation

I saw and examined the patient and discussed his/her management with the resident/fellow. I reviewed the resident/fellow' s note and agree with the documented findings and plan of care. Care plan, managment and recommendations discussed with fellow as described above. On re-evaluation at bedside pt had received methylene blue with return to saturaiton of 100% and resolution of cyanosis. Re-check level and treat if inidcated. Would not hesitate to transfer to PICU for evidence of further decline._ MD on (b) (6)

Entered by (b) (6)

23:35

OCT 3 1 2013

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST Report Request ID:

9661367-01-00-10 MRN: (b) (6) DOB: FIN Nbr: Admit/Reg Date: n/a Discharge Date: n/a Inpatient Consultation SIGNED BY: (b) (6) (b) (6) 03:56 PDT):(b) (6) 03:23 PDT); (b) (6) (b) (6) 02:10 PDT) Addendum by (b) (6 MD. (b) (6) on^{(b) (6)} 03:56 PDT Elevated methemoglobin percent indicative of methemoglobinemia. Called Poison Control and spoke with - he initially recommended checking repeat methemoglobin levels every 4 hours and giving subsequent methylene blue doses every 4 hours until the methemoglobin level is less than 5. He called back to revise his recommendations to repeat methemoglobin levels only if symptomatic. I informed him that we had already discussed q4 levels with mom, and given the parental anxiety this evening I will still check a level in 4 hours (at around 0630) recommended giving a subsequent dose of methylene blue in that case only if the repeat level is >20, or if symptomatic. I spoke with Dr. (b) (6) PICU fellow, several times over the course of the evening, and he was in contact with his attending Dr. (b) (6) We discussed possible PICU transfer given the risk of hypoxia and clinical decompensation in such a young infant with methemoglobinemia, but upon recheck at 0335 at the bedside with Dr. (b) (6) O2 saturations on room air were 97-98%, his lips were pink, and he continued to have no respiratory distress. We therefore agreed to not transfer to the PICU, but continue monitoring him on the floor. Spoke with Dr. (b) (6) of Surgery several times during the evening, and paged her with our final plan at 0345. Updated mom several times throughout the evening, and updated mom and dad with Dr. (b) (6) at 0335. Also updated bedside and charge RN throughout the evening. ATTENDING MD DOCUMENTATION & ATTESTATION: This patient is critically ill with a high probability of imminent or life-threatening deterioration. He requires constant monitoring and critical care interventions under my direct supervision for the following organ system(s): [x] Respiratory [x] Metabolic [_] CNS [_] Renal [_] Circulatory [_] Hepatic/GI [_] Heme/Bone Marrow [_] Immunologic [_] _ system(s) [_] to treat organ failure, and/or [_] to prevent further life-threatening deterioration. I saw and examined this patient and discussed his management with the team. I drafted the above note. I have discussed these plans with staff at the bedside. Entered by (b) (6) MD on (b) (6) 03:51 Time Based Care - Counseling IP Only applicable if counseling or coordination time (C) is > 50% of total visit time (V): (V) Total attending face to face and floor/unit time with patient and/or family: additional 90 minutes CCT (minutes) (C) Total attending Counseling/Coordination time with patient and/or family: 70 (minutes) Describe the counseling performed: see documentation above OCT 31 2013 Entered by (b) (6) MD on Addendum by (b) (6) 2012 03:23 PDT GASES (within 1 day(s)): Venous (b) (6) OCT 3 0 2013 01:50) 7.38 / 48.3 / 20.2 / 28.0 / 3.3 Methemoglobin % 20.2

Patient Name:

CaseID: 9661367

(b) (6)

Report Request ID:

Individual Case Safety Report

Print Date/Time:

12/11/2012 14:26 PST



Patient Name

MRN: DOB:

FIN Nbr:

Admit/Reg Date: Discharge Date:

n/a

n/a

Inpatient Consultation

CHEM 10 (within 36 hours):

| Chem:(b) | (6) | | 01:5 | 50 | | (b) (6) | 01:5 | 0 |
|----------|-----|-----|----------|----|---|---------|------|---|
| 4.6 | ĺ | 28 | | | \ | | 1 | |
| 136 | : | 104 | <u> </u> | <5 | | | 8.7 | |

CBC w/Diff (within 36 hours):

| | \ | 11.2 | / | | PMN: |
|---------|-----|---------|------|-------|---------------|
| 13.4 | | | - 64 | 16 H | Bands |
| | / | 33.5 | \ | | Lymph: |
| Last CE | 3C: | (b) (6) | | 01:50 | Mono: Eos: |

0220 CXR: Final read pending. Appears to have increased vascularity. No consolidation.

GENERAL PEDIATRICS CONSULT NOTE

Admitting Service: General Surgery

Admitting Attending: (b) (6)

Date of Consultation: (b) (6) 0110

Requesting Service: Pediatric Surgery

Reason for Consultation: Hypoxia

Date of Admission:

Place of Consultation: (b) (6)

Requesting Physician: Dr. (b) (6)

OCT 3 1 2012

CaseID: 966136/0673

IDENTIFICATION / CHIEF COMPLAINT: 8 month old with intussusception s/p open reduction without resection

HISTORY OF PRESENT ILLNESS: (6) (6) is an 8 month old boy with a history of possible milk allergy and GERD who is (b) (6) s/p exploratory laparotomy and manual reduction of ileocolic intussusception, who has had recent onset of hypoxia. He initially presented with 6-7 days of vomiting, diarrhea, and hematochezia to an outside hospital, where an ultrasound showed intussusception. He was transferred to (6) (6) ED, where a repeat ultrasound also showed intussusception. Air contrast enema x 4 was unsuccessful at reduction, and he was therefore treated surgically. The procedure was uncomplicated, and his recovery was apparently uneventful until he started to desaturate (b) (6) appear pale. The surgical team first attributed this to oversedation from his morphine. His morphine dose was therefore decreased from 0.5 to 0.25 mg q 2 hrs. At around 2200 on (6) (6) he was noted to desaturate to the high 80s, and nursing contacted the surgical team who ordered oxygen to be given via nasal canula. His oxygen saturations remained in the low 90s per nursing, despite trying several pulse oximetry probes and even changing out his monitor. Though he has had some mild congestion since (b) (6) and some red eyes (sclerae and eyelids), he has not had any significant rhinorrhea, cough, tachypnea, or increased work of breathing. He has been afebrile, and he has been active and alert per mom. He has been a little fussy and "gnawing" on his hands, which mom has attributed to teething pain. He has not been sleepier than usual. She had been giving him Oragel occasionally at home for a couple days prior to admission, but notes that she used it much more frequently (b) (6) (estimates 15-20 times over the course of the day). Looking back, she does note that she thought his lips looked a little purple on the afternoon of (b) (6) I was contacted at around 0030 this morning by the Oncology resident because of concern for methemoglobinemia.

REVIEW OF SYSTEMS:

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Individual Case Safety Report
9861367-01-00-12

Patient Name: (b) (6)

MRN: DOB:

FIN Nbr:

Admit/Reg Date:

Discharge Date: n/a

n/a

Inpatient Consultation

Constitutional: See HPI.

(b) (6)

Eyes: No eye discharge. See HPI. + "Poking" at eyes.

ENT/Mouth: See HPI. Respiratory: See HPI.

Cardiovascular: No concerns

Gl/Liver: No vomiting. Now stooling regularly - no evidence of gross blood.

Kidney/GU: No concerns

Heme/Oncologic/Lymphatic: No concerns

Musculoskeletal: No concerns Metabolic/Endocrine: No concerns

Neurologic: No seizures

Allergic/Immunologic: No concerns

Skin: No rash, See HPI.

Development/Behavior: See HPI

[x] A complete 14 system review performed; all systems are negative, except as documented.

PAST MEDICAL HISTORY:

- 1. Possible milk allergy On Alimentum, scheduled to have allergy panel sent next week. Symptoms mostly GERD-like.
- 2. GERD Diagnosed at 3 months of age. Changed formula several times and that seemed to help symptoms never on medications.
- 3. Intussusception See HPI.

PAST SURGICAL HISTORY: Exploratory laparotomy and manual reduction of ileocolic intussusception, - see HPI.

BIRTH HISTORY: Born FT via C-section due to breech presentation to 24 yo G1 P0->1 mom. Pregnancy and delivery uncomplicated. BW 6 lbs 1 oz. Home with mom after 3 days.

HOME DIET: Alimentum (s/p several formula changes, most recently from Enfamil Premium)

ACTIVE DIET ORDER(S):

Pedialyte: 16:58:00 PDT, PO, Comments: 0.5-1 ounce every hour

HOME MEDICATIONS:

Oragel prn

ACTIVE MEDICATION ORDERS (as of 01:13):

Scheduled

acetaminophen 76 mg IV q4hr

<u>PRN</u>

acetaminophen 115 mg rectal q6hrPRN(discomfort/fever) lidocaine topical 1 application topically as neededPRN(procedure) morphine 0.25 mg IV q2hrPRN(pain)

Continuous Infusion

Dextrose 5% with 0.45% NaCl and KCl 20 mEg/l 1000 mL IV

ALLERGIES: NKDA

Print Date/Time: 12/11/2012 14:26 PST

diphenhydrAMINE 7.6 mg IV q6hrPRN(dry eyes)
medline solution 1 bag IV as neededPRN(protocol)
sodium chloride 1 mL IV as neededPRN(catheter care patency)

OCT 3 0 2013

CaseID: 9661364 77

Report Request ID:



Patient Name: MRN: DOB:

n/a

n/a

CaseID: 9661367

FIN Nor:

Admit/Reg Date: Discharge Date:

Inpatient Consultation

IMMUNIZATIONS: UTD per mom

FAMILY HISTORY: Dad with AR; mom with asthma as child.

04:20)

SOCIAL HISTORY: Lives with mom, dad. No stick contacts, travel, or daycare.

MEASUREMENTS:

Approx. Percentiles

Measured Weight: 7.6 kg (6) (6) 04:20) Height: 72.5 cm ((b) (6)

Weight: 4 %ile Height: 71 %ile

BMI: 14.459 kg/m2 (((b) (6)

Wt for Length: 1 %ile

VITAL SIGNS OVER LAST 24 HOURS:

| Temp | 36.1 (36.1 - 36.7) | (b) (6) | 23:45 |
|---------|----------------------|---------|-------|
| HR | 114 (94 - 143) | | 23:50 |
| Cuff BP | 95/56 (86-107/41-57) | | 23:50 |
| RR | 29 (15 - 32) | | 23:50 |
| SPO2 | 91 (88 - 99) | | 23:50 |

INTAKE & OUTPUT (Calculations based on current dose calc weight of 7.6 kg on (b) (6)

Previous 0600 - 0559

Since 0600

Intake 1099.3 mL 144.6 mL/kg/24hrs

3.8 mL/kg/hr UOP

810.9 mL

725.4 mL Infusions

106.7 mL/kg/19hrs

3.7 mL/kg/hr UOP

953.6 mL Infusions 101 mL Meds

25 mL Meds

45 mL Oral

60 mL Oral

Output 828 mL

579 mL

700 mL Urine

100 mL Gastric

538 mL Urine

28 mL Stool

41 mL Stool

1 Stool Count

1 Stool Count

Balance 271.3 mL

231.9 mL

PHYSICAL EXAM: (b) (6) 0100

General: Sleeping peacefully, awoke with exam, briefly fussed with abdominal exam

Head: NCAT, AFOSF

Eyes: Bilateral eyelids a little dusky, no conjectival injection or discharge

ENT / Mouth: MMM and mildly dusky. No anterior oropharyngeal lesions. No nasal discharge or audible congestion

Neck: Supple, no significant LAD or mass.

Lungs: RR high 20s, no retractions or distress, no grunting or nasal flaring, lungs CTAB, no w/c/r, no stertor/strictor

12013

GI/Abdomen: Normoactive BS, abdomen mildly-to-moderately distended but soft, incision steri-stripped without

evidence of erythema or discharge

GU: Tanner I male

Extremities: Wwp, CR < 2 sec centrally, 2-3 sec palms and soles

Neurologic: Good tone, good eye contact; no focal deficits

Neurologic: Good tone, good eye contact; no rocal deficits

Skin: No rash. Right palm a little ruddy. Lips, tongue, and mucous membranes mildly dusky. No additional plethora or 2013 cyanosis.

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Patient Name: (b) (6)

n/a

n/a

CaseID: 9661367

FIN Nbr:

MRN:

DOB:

Admit/Reg Date: Discharge Date:

Inpatient Consultation

Other: Helped hold patient for venipuncture at 0150 - blood from right AC appeared dark, not copperish)

RADIOLOGY STUDIES (Completed): No Radiology studies found within the last 24 hours.

LABS:

CHEM 23 (within 36 hours):

| 139 | 1 | 106 | _ | <5 L | / 92 | | 8.8 |
|-------|-------|-----|------|------|-----------------|---------|-------|
| 5.2 | 1 | 27 | I | 0.3 | _ ₉₂ | | 1 |
| Chem: |) (6) | (| 06:4 | 0 | | (b) (6) | 06:40 |

ASSESSMENT / PLAN: (b) (6) is an 8 month old boy with a history of possible milk allergy and GERD who is (c) (b) (c) s/p exploratory laparotomy and manual reduction of ileocolic intussusception, who has had recent onset of hypoxia. His hypoxia seems to be refractory to supplemental oxygen, and he has possible mild central cyanosis with a history of very frequent Benzocaine administration, making methemoglobinemia a concern. With his recent surgery and general anesthesia, he is also at risk for atelectasis, aspiration, and pneumonia. His lack of respiratory distress, retractions, and adventitious breath sounds would argue against this, as would the timing (would expect symptoms sooner after surgery). My recommendations are as follows:

- -- Methemoglobin level STAT
- -- VBG with co-ox STAT
- -- CBC STAT
- -- CXR portable STAT

[x] I have discussed my recommendation with the requesting physician Dr. (b) (6)

PATIENT CARE TIME: "Only applicable if counseling or coordination time (C) is > 50% of total visit time (V):"

- (V) Total attending face to face and floor/unit time with patient and/or family: 90 (minutes)
- (C) Total attending Counseling/Coordination time with patient and/or family: 60 (minutes)

Describe the counseling performed: Discussion with notifying Oncology resident, discussion with bedside and charge nurse regarding status and work-up, obtained history from mom and provided several updates, assisted holding patient during venipuncture.

Report prepared by: (b) (6) MD

DSS OCT 31 2013

Print Date/Time: 12/11/2012 14:26 PST Report Request ID: (b) (6) UCT 3 0 2013

Individual Case Safety Report 9661367-01-00-15

Patient Name:

CaseID: 9661367

MRN: DOB:

FIN Nbr:

(b) (6)

(b) (6)

Admit/Reg Date: Discharge Date:

n/a n/a

Discharge Summary

SIGNED BY:

17:14 PDT); (b) (6)

09:51 PDT)

PEDIATRIC SURGERY DISCHARGE SUMMARY

PATIENT:

MRN:

FIN: (b) (6)

DOB:(b) (6)

LOC: (b) (6)

Admitting Service: General Surgery

PCP: (b) (6)

Admitting Attending: (b) (6)

Date of Admission: (b) (6) Discharge Date: (b) (6)

Operating Attending Surgeon:

ADMITTING DIAGNOSIS: _ intussusception

PRINCIPAL DIAGNOSIS: same

SECONDARY DIAGNOSES: methemoglobinemia

PAST MEDICAL HISTORY: _ none

PAST SURGICAL HISTORY: __none

PATIENT IDENTIFICATION: 8 month old with intussusception s/p open reduction without resection _

PRINCIPAL OPERATION(S) / PROCEDURES:

operative reduction of intussusception

CONSULTATIONS THIS ADMISSION: _ Hospitalist

DETAILED HOSPITAL COURSE:

is an 8 mo boy who presented with 6 days of bloody diarrhea, abdominal distention and pain and was found to have intussusception on abdominal ultrasound at an (b) (6) He was transferred here and intussusception was confirmed on repeat US at (b) (6) Reduction with barium enema was attempted four times unsuccesfully and he was taken to the OR for operative reduction of intussusception. He was hypokalemic on admission and his potassium was repleted to normal with a potassium of 5.1 at discharge. On the evening of (6) (6) he was markedly pale and desated to the high 80s on room air. The pediatric hospitalist service was consulted and suspected methemoglobinemia after it was discovered that mom had been giving him Orajel 15-20 times per day for teething pain. His methomoglobin level was found to be 20.2 and he was given methylene blue. His sats subsequently came back up to 99-100% on room air and remained normal on room air. He was tolerating feeds, had resolution of abdominal distention and pain was well controlled on the day of discharge.

PATIENT CONDITION UPON DISCHARGE: stable, tolerating feeds, pain controlled Last Documented Weight: 7.6 kg ((b) (6) 04:20)_

OCT 3 1 2013

OCT 3 0 2013

Discharge Vital Signs:

Temp HR

37.4 145

(b) (6) 04:00

04:00

Report Request ID:

Print Date/Time:

12/11/2012 14:26 PST



CaseID: 9661367 Patient Name: (b) (6) MRN: DOB: FIN Nbr:

n/a

Admit/Reg Date:

| Discharge Date: n/a | |
|--|---------------------------|
| Discharge Summary | |
| Cuff BP 100/55 (b) (6) 04:00 RR 26 04:00 SPO2 98 04:00 | |
| PHYSICAL EXAM: _ (Time of Exam: _) | |
| General: [x] no acute distress Other: _ | |
| Head: [x]NC [_]AFOSF Other:_ | |
| ENT /Mouth: [] clear oropharynx [] moist mucous membranes Other: _ | |
| Eyes: [_] PERRL [_] anicteric Other: _ EOMI | |
| Neck: [x] supple [_] no LAD Other: | |
| Lungs: [_] clear [_] no distress Other: | |
| Cardiac: [_] reg rate & rhythm [_] no murmurs [_] pulses | Other: _ |
| Gl/Abdomen:[x] soft, non-tender, non-distended [_] no masses Other:_ | |
| GU: [_] NL external genitalia Other: _ | |
| Extremities: [x] warm [_] no edema | : |
| Neurologic: [x] non focal/grossly intact Other:_ | |
| Skin: [_] no rashes/lesions Other: Wound / Ostomy / Line / Drain: _ Other: _ | |
| DISCHARGE MEDICATIONS: No Home Medication/Prescription Orders - | |
| DIET / FEEDS UPON DISCHARGE:feeds ad lib | |
| PHYSICAL ACTIVITY: _ as tolerated | |
| SPECIFIC INSTRUCTIONS GIVEN TO PATIENT UPON DISCHARGE: _ follow-up in Pediatric 0 1 month | General Surgery clinic in |
| Bathing/Incision: _ can bathe, wash incisions gently with soap and water | |
| FOLLOW UP CARE: [x] A Pediatric General Surgery Clinic Appointment has been requested for the patient. The familithe clinic to schedule. | ily will be conta |
| [_] PMD/Other services: Other: | OCT 3 1 2013 |
| Please call the Pediatric General Surgery Office at (b) (6) with any questions. | |
| External CC: CONTACT INFORMATION: | OCT 3 0 2013 |

CONTACT INFORMATION:

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Individual Case Safety Report

Patient Name:

CaseID: 966136/

FIN Nbr:

MRN: DOB:

Admit/Reg Date: Discharge Date:

n/a n/a

Discharge Summary

SIGNED BY:

(b) (6)

01:56 PDT)

DSS OCT 3 1 2013

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Individual Case Safety Report 9661367-01-00-18

Patient Name:

CaseID: 96613b 87673

(b) (6)

DOB:

MRN:

FIN Nbr:

Admit/Reg Date: n/a Discharge Date:

n/a

Discharge Summary

Referring MD:

Primary Care Provider: (b) (6)

Other:

Report prepared by: (b) (6)

MD

Teaching Physician Attestation

I saw and examined the patient and discussed his/her management with the resident/fellow. I reviewed the resident/fellow' s note and agree with the documented findings and plan of care. _

Entered by (b) (6)

MD or (b) (6)

OCT 3 1 2013

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Patient Name:

MRN:

DOB: FIN Nbr: CaseID: 966136

Admit/Reg Date: n/a Discharge Date: n/a

Discharge Summary

SIGNED BY:

(b) (6) 09:51 PDT)

Discharge Record Form Entered On: (6) (6)

09:56 PDT

Performed On: (b) (6)

)9:51 PDT by (b) (6)

DC Record Form

Discharge Date: PDT Attending MD on Day of Discharge: (b) (6)

Admission Date: (b) (6)

Admitting Diagnosis: intussusception Principal Diagnosis: intussusception

Principal Operations/Procedures: operative reduction of intussusception

Brief Hospital Course Summary: Admitted on (6) (6) with intussusception on abdominal ultrasound. Attempted to reduce with barium enema 4 times unsuccessfully. Taken to OR for operative reduction of intussuception. Desats to high 80s on (b) (6) found to have methemoglobinemia with methemoglobin level 20.2. Given methylene blue with return to normal oxygen saturations on room air. Discharged (b) (6) tolerating feeds and pain controlled.

Condition of Patient at Discharge: Stable

Disposition of Patient: Home

Med Reconciliation Completed for D/C: Yes

Medication List at Discharge: See "DC Instructions" for list of patient's current meds

Location of Discharge Rx Script: Electronically sent to pharmacy

Diet upon Discharge: Formula

Discharge Diet Instructions: Continue home feeding regimen Physical Activity upon Discharge: No physical limitations

Instructions for Follow-up Care: We will call to schedule an appointment to follow-up in Pediatric General Surgery clinic

in 1 month

DC Summary Record Ready to Print: Yes

(b) (6) (b) (6) 09:51 PDT [Not Validated]

Med Reconciliation Medication List

Normal Order

Acetaminophen 80mg/2.5mL

oral prepack

: Acetaminophen 80mg/2.5mL oral prepack; Status: Ordered ; Ordered As Mnemonic: Tylenol oral ; Simple Display Line: 80 mg, 2.5 mL, PO, q6hr, PRN: discomfort/fever; Ordering Provider: (b) (6 Catalog Code: acetaminophen: 20:50 ; Comment: *** Do not Order Dt/Tm:

administer any acetaminophen containing products within 4

hours of each other. ***

Standardized dosing Ordered dose: 100mg Dispensed dose:

80mg

Acetaminophen 80mg/2.5mL

oral prepack

: Acetaminophen 80mg/2.5mL oral prepack; Status: Ordered ; Ordered As Mnemonic: Tylenol oral ; Simple Display Line:

80 mg, 2.5 mL, PO, q4hr, PRN: fever/chills; Ordering Provider:

OCT 3 0 2013

OCT 3 1 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Individual Case Safety Report

Patient Name: (b)

MRN:

CaseID: 966136

FIN Nbr:

DOB:

Admit/Reg Date: Discharge Date: n/a n/a

Discharge Summary

Catalog Code: acetaminophen; Order Dt/Tm: (b) (6) 10:30; Comment: *** Do not administer any acetaminophen containing products within 4 hours of each

other. *** Standardized dosing

Ordered dose: 76mg Dispensed dose: 80mg

DiphenhydraMINE 50 mg/mL inj

Acetaminophen 10 mg/mL ini

: Acetaminophen 10 mg/mL inj ; Status: Discontinued ;
Ordered As Mnemonic: acetaminophen IV ; Simple Display
Line: 76 mg, 7.6 mL, IV, q4hr ; Ordering Provider:

(b) (6) Catalog Code: acetaminophen ; Order Dt/Tm:

11:01 ; Comment: *** Do not administer any
acetaminophen containing products within 4 hours of each
other. ***

Acetaminophen 325 mg suppository : Acetaminophen 325 mg suppository; Status: Ordered; Ordered As Mnemonic: acetaminophen rectal; Simple Display Line: 115 mg, 0.35 supp. rectal, q6hr, PRN: discomfort/fever; Ordering Provider: Catalog Code: acetaminophen; Order Dt/Tm: Do not administer any acetaminophen containing products within 4 hours of each other. ***

*** No rectal dosage forms for neutropenic patients ***

Lidocaine 4% topical cream 5 gm

: Lidocaine 4% topical cream 5 gm; Status: Ordered; Ordered As Mnemonic: lidocaine 4% topical cream; Simple Display Line: 1 application, topically, as needed. PRN: procedure; Ordering Provider: (b) (6) Catalog Code: lidocaine topical; Order Dt/Tm: (b) (6) 09:30

medline solution

: medline solution; Status: Ordered; Ordered As Mnemonic: medline solution; Simple Display Line: 1 bag, IV, as needed, PRN: protocol; Ordering Provider: Catalog Code: medline solution; Order Dt/Tm: D9:30; Comment: MEDLINE SOLUTIONS are for administration of an IV medication if no other compatible hydration fluid is ordered. Refer to the Medication Administration Guidelines or check with pharmacy for compatibility info.

OCT **3**1 2013

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

o) (6)

Patient Name:

CaseID: 966136

FIN Nbr:

MRN: DOB:

Admit/Reg Date: n/a Discharge Date: n/a

Discharge Summary

syringe

Morphine 2 mg/mL inj prefilled : Morphine 2 mg/mL inj prefilled syringe; Status: Ordered; Ordered As Mnemonic: morphine; Simple Display Line: 0.25 mg, 0.13 mL, IV, q2hr, PRN: pain ; Ordering Provider: Catalog Code: morphine; Order Dt/Tm: (b) (6) 09:30

Sodium Chloride 0.9% 10 mL prefilled syringe

: Sodium Chloride 0.9% 10 mL prefilled syringe; Status: Ordered; Ordered As Mnemonic: NS lock; Simple Display Line: 1 mL, IV, as needed, PRN: catheter care patency; Ordering Provider: (b) (6) Catalog Code: sodium chloride; Order Dt/Tm: (b) (6) 09:30 ; Comment: *** Use to lock PIV catheter after use and at least every 8 hours *** *** Refer to (b) (6) Vascular access chart for additional information ***

Dextrose 5%-NACL

: Dextrose 5%-NACL 0.45%-KCL 20mEq/L 1,000 mL; Status: 0.45%-KCL 20mEq/L 1,000 mL Discontinued; Ordered As Mnemonic: D5 1/2 NS + KCl 20 mEa/L 1.000 mL; Simple Display Line: 40 mL/hr, IV, Stop: 9:28:00 PDT; Ordering Provider: (b) (6) Catalog Code: Dextrose 5% with 0.45% NaCl and KCl 20 m;

Order Dt/Tm: (b) (6) 09:30

Prescription/Discharge Order acetaminophen

: acetaminophen; Status: Ordered; Ordered As Mnemonic: Tylenol Childrens 160 mg/5 mL oral liquid; Simple Display Line: 114 mg, PO, q4hr, 120 mL, PRN: for pain; Ordering Provider: Catalog Code: acetaminophen : Order

Dt/Tm: (10) (10) 09:55

OCT 3 1 2013

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Patient Name:

MRN: DOB:

FIN Nbr:

Admit/Reg Date: Discharge Date:

Outpatient/Clinic Documents

SIGNED BY

06:22 PDT); (b) (6)

12:44 PDT)

n/a

n/a

PATIENT NAME:

MRN: (b) (6)

DATE OF BIRTH: (b) (6)

CLINIC: General Surgery

VISIT DATE: (b) (6)

ATTENDING CLINICIAN: RESIDENT PHYSICIAN:

MD ИD

HISTORY OF PRESENT ILLNESS: (b) (6)

returns to the Pediatric Surgery Clinic at (b) (6)

CaseID: 9661367

Hospital for a follow-up visit after his recent operative reduction of his nonreducible intussusception performed on (b) (c) His postoperative course was complicated in the hospital by methemoglobinemia due to Oraiel poisoning, given erroneously in excess for teething pain by his mother. After being given methylene blue to correct his methemoglobin level, his oxygen saturations on room air returned to 99% to 100%, and by the day of discharge on (6) (6) he was tolerating feeds, had resolution of his abdominal distention and his pain was well controlled.

Since discharge, his mother states that (b) (6) has been gaining weight and has been very active and healthy. He has had a return to normal bowel function, and has been eating solid foods since his discharge. He has had no fevers, does not appear to be in any sort of abdominal distress, and his incision has continued to heal well. The mother has noticed no swelling or redness in the area of the incision.

PHYSICAL EXAMINATION:

VITAL SIGNS: He weighs 9 kg, his temperature is 36.7 degrees Celsius.

GENERAL: He is a well-appearing, healthy child, who is smiling and active during the examination.

ABDOMEN: Revealed a well-healing transverse surgical incision over the medial and right aspect of his mid abdomen.

His abdomen was soft, nontender to palpation, and nondistended.

IMPRESSION AND PLAN: (b) (6) mother was advised that his postoperative course appears to be uncomplicated and (b) (6) appears to be healing quite well. The mother was instructed that should any questions or concerns arise, that she should feel free to call the clinic and schedule a return visit should the need arise; however, at this time there should be no need for any further scheduled visits.

(b) (6)

MD

(on behalf of)

(b) (6)

MD

OCT 3 1 2013

OCT 3 0 2013

(b) (6)

D:

02:04 P

T:

11:57 P

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

Individual Case Safety Report (b) (6)

| Patient Name: | (b) (6) |
|---------------|---------|
| MRN: | |

CaseID: 9661367

DOB: FIN Nbr: Admit/Reg Date: n/a

n/a

| | | | |
|-------------|-------------------|---|------|
| Outpatien | t/Clinic Document | 6 | |
| - Outpution | | | |

Discharge Date:

(b) (6)

l:

12:04 A

Teaching Physician Attestation

I saw and examined the patient and discussed his/her management with the resident/fellow. I reviewed the resident/fellow' s note and agree with the documented findings and plan of care. MD on

Entered by (b) (6)

Electronically signed on

12:44

BS Medical Student

Electronically signed on

06:22

(b) (6)

DSS OCT 3 1 2013

OCT 3 0 2013

Print Date/Time: 12/11/2012 14:26 PST

Report Request ID:

FUKINI FDA 3500A (6/10)

ind manufacturers

| Form A | ^{pp} Case | TOS OF TO | statement on | 12/31/11 reverse. |
|------------------|--------------------|-----------|--------------|----------------------|
| Mfr Report # 549 | 73 | | | |
| UF/Importer Repo | rt# | | | |
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| Y reporting | Ol Alliportor (10) | | | | |
|--|--------------------|-------------|-----------------|--------------------|------------------------------|
| 6 | | | | F | DA Use Only |
| C. SUSPECT PROD | UCT(S) | | | | DA GGG GIII) |
| . Name (Give labeled stree | | | | | |
| #1 HYLAND'S BABY | TEETHING TA | BLETS | | | |
| #2 HYLAND'S TEETH | HING TABLETS | | | | |
| . Dose, Frequency & Rou | | 3 Therar | oy Dates (If it | unknown, gi | ve duration) |
| #1 | | #1 | (Or Dest est | iiiiate) | |
| | | #2 | | | |
| #2 . Diagnosis for Use (India | cation) | ,,,, | 5. Event A | bated After | Use |
| #1 TEMP RELIEF TI | | PAIN | 1 - | ior Dose R s No | educed? |
| #2 TEMP RELIEF TI | | | #1 Ye | s No | Apply |
| #2 1 BM 1 RB 2 2 2 1 | 7. Exp. Date | | #2 🗌 Ye | s 🗌 No | ✓ Doesn's |
| #1UNKNOWN | #1 | | | eappeared | After |
| #2UNKNOWN | #2 | | #1 Ye | duction? | Doesn' |
| NDC# or Unique ID |] | | 1 | | Apply Doesn' |
| 54973-3127-1// | 54973-7504-1 | L | #2 Ye | s No | Apply |
| 0. Concomitant Medical | Products and The | rapy Date | s (Exclude tr | eatment of | event) |
| Brand Name Common Device Name Manufacturer Name, C | | | | | |
| o. Manufacturor Hamo, | , | | | | ` |
| 4. Model # | Lot# | | | _ | or of Device h Profession |
| Catalog # | Expirati | on Date (m | m/dd/yyyy) | | ser/Patient |
| | | | | Other | |
| Serial # | Other# | • | | | |
| 6. If implanted, Give Dat | e (mm/dd/yyyy) | 7. If Ex | planted, Giv | re Date (mn | n/dd/yyyy) |
| 8. is this a Single-use D | aulas that was Bo | 20000000 | and Pausa | d on a Patio | ent? |
| 8. Is this a Single-use D | BAICS FLIST MAS LA | processed | and Rouse | | |
| 9. If Yes to Item No. 8, E | nter Name and Ad | idress of F | leprocesso | r | |
| | | | | | |
| | | | | | _ |
| 10. Device Available for | Evaluation? (Do I | not send to | FDA) | | DS: |
| Yes No | Returned to | | | (mm/ati | EVO A A |
| 11. Concomitant Medica | al Products and T | herapy Dat | es (Exclude | (| of evenly 6 |
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| E. INITIAL REPOR | RTER | | | | |
| 1. Name and Address | | ne# | | | |
| | 01 | 7 ~ | , | | |
| (b) (6) | US | 1/4 | _ | , | |
| | | | . DEC | 0.5 | 2043 |
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| | | | - DECT- | Voltal Barre | enter Alex C |
| 2. Health Professional | 3. Occupation | | UEC 4 | Réport | erter Also So FDA |

NΑ

Yes No Unk

Yes V No

, aye 1 of ⁶ A. PATIENT INFORMATION 4. Weight 3. Sex 2. Age at Time 1. Patient Identifier of Event: (b) (6) Months Female or. or Date Male kgs of Birth: In confidence B. ADVERSE EVENT OR PRODUCT PROBLEM Product Problem (e.g., defects/malfunctions) Adverse Event and/or 2. Outcomes Attributed to Adverse Event (Check all that apply) Disability or Permanent Damage Death: (mm/dd/yyyy) Congenital Anomaly/Birth Defect Life-threatening Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 4. Date of This Report (mm/dd/yyyy) 3. Date of Event (mm/dd/yyyy) 11/21/2013 11/11/2013 Describe Event or Problem ON 11/10/13, CHILD EXPERIENCED LOSS OF APPETITE, LETHARGY AND WEAKNESS AND WAS DIAGNOSED WITH AN EAR INFECTION. ON (b) (6) CHILD BECAME UNRESPONSIVE AND TAKEN TO HOSPITAL AND PUT IN ICU. CHILD IS LETHARGIC AND SLEEPING CONTINUOUSLY. (b) (6) CHILD PLACED ON CHILD HAD CHOKING EPISODE AND FEEDING TUBE. (b)(6) STOPPED BREATHING AND PUT ON BREATHING TUBE. POSSIBLE BLACK BELLADONNA POISONING PER DOCTORS BUT RUNNING TESTS TO DETERMINE OTHER POSSIBLE CAUSES OF SYMPTOMS. PLEASE TYPE OR USE UPDATE: CHILD HAS BEEN DIAGNOSED WITH INFANT BOTULISM. CHILD WILL BE GIVEN ONE DOSE OF MEDICATION WHICH IS COMPOSED OF HUMAN ANTIBODIES. 6. Relevant Tests/Laboratory Data, Including Dates BLOOD, URINE, CHEST X-RAY, SPINAL TAP, CT SCAN, EEG, AND MRI WHICH WAS NORMAL. WAITING ON RESULTS OF TESTS. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) PRESCRIBED ANTIBIOTICS FOR AN EAR INFECTION ON 11/10/13. Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product

caused or contributed to the event.

| User Facility | Imp | | 2. 017 | mporter i | | | |
|--|--|---|--|----------------------------|--------------|--|--|
| . User Facility or Imp | orter Nam | e/Address | | | | | |
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| | | | | | | | |
| I. Contact Person | | | 5 | . Phone I | Number | | |
| | | | | | | | |
| B. Date User Facility of Importer Became | or | 7. Type of | Report | | 8. Da (m | te c | of This Report |
| Aware of Event (mn | n/dd/yyyy) | nitial [| | | | | |
| | | | /-up#_ | | | | |
| Approximate Age of Device | 10. Even | t Problem Co | odes (R | efer to coo | ting ma | nua |) |
| Age of Device | Patient Code | | | _ | |]- | |
| | Device | | 一. | | | i_ | |
| | Code | L | <u> </u> | <u></u> | |] | |
| 11. Report Sent to FD | A? | | | ere Even | t Occur | | utpatient |
| Yes(mm/de | d/yyyy) | - = | Hospital Home | | _ | ם ר | agnostic Facility |
| No ' | | | Nursing | Home | | | mbulatory urgical Facility |
| 13. Report Sent to Ma | anufacture | "I H | Outpatie | nt Treatm | ent | _ | |
| [] V | d/yyyy) | - | Facility | | | | |
| Yes(mm/d | | | Other: _ | | | peci | 64 |
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| _{of} 6 | |
|--|---|
| H. DEVICE MANUFACTURERS ONLY | |
| 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | ☐ Yes ☐ No |
| | _ |
| 6. Evaluation Codes (Refer to coding manual) | |
| Method - | |
| | |
| Results | |
| Conclusions | 7-[|
| | S. Hanne of Pavine |
| T. II (Collection Production of Collection Collection of Collection Collectio | 8. Usage of Device |
| Recall Notification | Reuse |
| Repair Inspection | Unknown |
| Replace Patient Monitoring | 9. If action reported to FDA under |
| Relabeling Modification/ | 21 USC 360I(f), list correction/ removal reporting number: |
| Other: | temoval reporting number. |
| | · |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| 10. Additional Manufacturer Narrative | and, or |
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CaseID: 9747541

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.



CUSTOMER COMPLAINT RECORD



| MADE IN THE USA SIN | CE 1903 | | | | | |
|--|--------------------------|---|---|--------------------|---------------------------------------|--------|
| SECTION I: | COMPLAINT | | COMPLAINT | #: 2527 | | |
| TAKEN BY: | EDYTA FRACKIE | WICZ | DATE OF COMPLAIN | T: <u>11/14/13</u> | | |
| PRODUCT: | BABY TEETHING | TABLETS // TEETHING TABLE | ITEM COD | E: BTET // TEE | <u>T</u> | |
| SIZE: | UNKNOWN | | LOT NO | .: UNKNOWN | | |
| REPORTER: | (b) (6) | | | | | |
| ADDRESS: | | | | | RECE | IVEC |
| | | | | | | |
| CITY: | | | STATE: | | DEC 0 4 | 2013 |
| COUNTRY: | USA | | ZIP CODE: | | | _ |
| PHONE #: | | | | | | R |
| E-MAIL: | | (b) (c) | THE COUNTY TO CHILD EXP | EDIENOED I OCC | OF ADDETITE | |
| NATURE OF COMPLAINT | LETUADO | R POSTED ON ^{(b) (6)} Y AND WEAKNESS. 11/10/13: (| THAT ON NOV. 10 CHILD EXP CHILD DIAGNOSED WITH AN EAR I | NFECTION AND | PRESCRIBED | |
| ANTIBIOTICS. (b) (6) | CHILD BECAME UNRESPO | | TAL AND PUT IN ICU. CHILD IS EX CHILD HAD CHOKING EPISOD | | | |
| PUT ON BREATHING TUE | E. POSSIBLE BELLADON | INA POISONING PER DOCTORS | S, BUT RUNNING TESTS TO DETER | | | - |
| TESTS: BLOOD URINE X- (b) (6) | RAY CHEST, SPINAL TAP, C | T SCAN, EEG, AND MRI WHICH W | AS NORMAL. WAITING FOR RESULT | S OF TESTS. URI | ADDRESS: | |
| (b) (6) | FOR ADDITIONA | AL SPACE PLEASE USE REVER | RSE OR ATTACH A SEPARATE SH | EET | | - |
| | | | | | | |
| PRODUCT RECEIVED FO | R Y | (11) | RODUCT BEING RETURNED FOR | INSPECTION: | Y (N) | |
| INSPECTION: 11/20/13 UPDATE: CHILL | ` | CLE ONE) | DATE REQUESTED PRODUCT BE | DETLIBNED: | (OINOLL ONL) | |
| DIAGNOSED WITH INFAP BOTULISM. CHILD WILL | BE TREATED | | DATE REQUESTED PRODUCT BE | - KETOKNED. | | |
| WITH ONE DOSE OF MEI COMPOSED OF HUMAN | DICATION ANTIBODIES. | | UDG CALL | TAC ISSUED: | Y (N) (CIRCLE ONE) | |
| | | | UPS CALL | TAG ISSUED: | (CIRCLE ONE) | |
| | | | DATE PRODUC | T RECEIVED: | | |
| SECTION IL: | INVESTIGATION | | | | | |
| | | | | | | |
| INVESTIGATION: | PLEASE SEE ATTACH | ED INVESTIGATION REPORT. | | | | |
| | | | | | | |
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| | | | | | | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST | / NURSE FOR EVALUATION ON | 11/14/13 | | | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST | / NURSE FOR EVALUATION BY | EDYTA F | RACKIEWICZ | | |
| SECTION III: | CORRECTIVE ACTION | <u>t:</u> | | | | |
| | ase Safety Re | port | | | | |
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| SECTION IV: | ADVERSE EVENT REPOR | RIIS . | AE #: | 1517 | | |
| ADVERSE EVENT SERIO | ous: | (_Y), _N | | | | |
| ADVERSE EVENT REPO | | 11/14/13 | BY: EDYTA FRACH | CIEWICZ | - Dre | |
| SECTION V: | | ^ | 1 | | UE | 0 5 20 |
| ************************************** | | 00721 | | 11-27 | -13 | |
| REVIEWED BY MANAGE | MENT BY: | _ PWW | DATE: | 11-27 11-27 | | |
| BY: | 941 | 1 Porcie | DATE: | 11-27 | -13 | |
| o1 | QA / QC DIRE | CTOR | | | | • |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

CaseID: 9747541



Serious Adverse Event SAE 134

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum was "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\stackrel{\text{(b)}}{=}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date 1

Individual Case Safety Report

9747541-01-00-04

DS:

DEC 05;





SERIOUS ADVERSE EVENT DATA FORM

| SECTION I: | PATIENT INFORMATION (IF DIFFEREN | IT FROM REPORTER ON FORM VD1) | |
|--|--|--|----|
| NAME: | (b) (6) | | |
| ADDRESS: | | | |
| CITY: | | STATE: | |
| COUNTRY: PHONE #: | USA | ZIP CODE: | |
| E-MAIL: | | | |
| SECTION II: | PACKAGING INFORMATION: | | |
| AFI | FIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| And Contributes Innovative values to surprise of the surprise of surprise of surprise of surprise of the surpr | And the second of the second o | Teething With continue and the continue | |
| | e Safety Report | THE RESIDENCE OF THE PARTY OF T | |
| SECTION III: | CORRECTIVE ACTION: | | |
| CORRECTIVE A | CTION(S) COMPLETED BY: | DATE: | Di |
| SECTION IV: | 01) 11 | | |
| | MANAGEMENT BY: | DATE: 11-27-13 | |





SERIOUS ADVERSE EVENT DATA FORM

| NE #:151 | 7 | COMPLAINT #: 2527 |
|---|--|---|
| ECTION I: | PATIENT INFORMATION (IF DIFF | FERENT FROM REPORTER ON FORM VD1) |
| IAME: | (b) (6) | |
| DDRESS: | | |
| | 44. | |
| CITY: | LICA | STATE: ZIP CODE: |
| OUNTRY: PHONE #: | USA | ZIF CODE. |
| -MAIL: | | |
| | | |
| ECTION II: | PACKAGING INFORMATION: | |
| AF | FFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| united and second and | Continues on the continues of the contin | HOSEOWENEE Teething Tablets Teething Tablets Tabletas para la Dentición - Brumpomaria Robel for Technique a Children Mytanus Technique Children Mytanus Tabletas para la Dentición Tabletas para la Dentición |
| idual Ca | Modern to the Committee of the Committee | Tablets |
| | lise Salety Report | |
| 9747 | 541-01-00-06 | |
| SECTION III: | CORRECTIVE ACTION: | |
| | | |
| CORRECTIVE | ACTION(S) COMPLETED BY: | |
| ECTION IV: | | Di |
| REVIEWED BY | MANAGEMENT BY: | DATE: |
| | | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

y user-facilities, utors and manufacturers ATORY reporting

| CaseID: 97697446 ement on rever |
|---------------------------------|
| Mfr Report# 5973 See once 2 |
| UF/Importer Report # |

31 of ⁵

| FΩΔ | 11 | _ |
|-----|----|---|
| | | |

4. Initial Reporter Also Ser Report to FDA

Yes No Uni

NOV 0 5 2013

| A. PATIENT INFORMATION | | | C. SUSPECT PR | | | |
|---|------------------------------------|----------------|--------------------------|------------------------|--|--|
| 1. Patient Identifier 2. Age at Time (b) (6) of Event: | 3. Sex | 4. Weight | 1. Name (Give labeled | , | | |
| or8 | Months Female | lbs | #1 HILAND'S BA | BY TEETHING TA | /BLEI2 | |
| Date In confidence of Birth: | √ Male | or kgs | #2 | | | |
| B. ADVERSE EVENT OR PRODU | CT PROBLEM | Kgo | 2. Dose, Frequency & | Route Used | Therapy Dates (from/to (or best e | (If unknown, give duratio estimate) |
| | | -medie mel | #12 TABS UNDE | R TONGUE | #1 | , |
| Adverse Event and/or Pro Outcomes Attributed to Adverse Event | oduct Problem (e.g., defects/malfu | inctions) | #2 | | #2 | |
| (Check all that apply) | | | 4. Diagnosis for Use (| Indication) | | Abated After Use |
| Death:(mm/dd/yyyy) | Disability or Permanent Dan | mage | #1 TEMP RELIEF | SX IRRITABILI | TY | ed or Dose Reduced? |
| Life-threatening | Congenital Anomaly/Birth D | efect | #2 | | #¹ L \ | Yes No Doe: |
| Hospitalization - initial or prolonged | Other Serious (Important Me | edical Events) | 6. Lot # | 7. Exp. Date | #2 🔲 \ | Yes No Doe: |
| Required Intervention to Prevent Perm | anent Impairment/Damage (Device | es) | #1B06813 | #1 | 8. Event | Reappeared After |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of This Report (mm/dd/ | | | _ | _ | roduction? |
| 10/09/2013 | 10/16/2013 | | #2 9. NDC# or Unique ID | #2 | #1 📙 \ | Yes No Appl |
| 5. Describe Event or Problem | | | 54973-3127-1 | | #2 \ \ | Yes No Doe: |
| HAD 8 SMALL "SEIZURES" LASTI | ING A COUPLE OF SECON | DS. | 10. Concomitant Medi | cal Products and The | rapy Dates (Exclude | • |
| EYES ROLLED BACK INTO HEAD, | | | To: Consonituate into | zar roudoto ana riio | iapy value (Excuse) | to define the crowny |
| JERKED LEFT AND RIGHT. CHIL THESE TYPES OF SYMPTOMS. | ID HAS NEVER EXPERIENC | CED | | | | |
| | | | | | | |
| | | | | | | |
| | | | D. SUSPECT ME | DICAL DEVICE | | |
| | | | 1. Brand Name | | | |
| 1 | | | 2. Common Device Na | me | | |
| | | | | | | |
| | | | 3. Manufacturer Name | , City and State | | |
| | | | | | | |
| ļ | | | 4. Model # | Lot # | | 5. Operator of Device |
| | | | | | | Health Profession |
| | | | Catalog # | Expiration | n Date (mm/dd/yyyy) | Lay User/Patient |
| | | | Serial # | Other# | | Other: |
| | | | | | | |
| | | 1 | 6. If Implanted, Give D | ate (mm/dd/yyyy) | 7. If Explanted, Given | ve Date (mm/dd/yyyy) |
| 6. Relevant Tests/Laboratory Data, Includin | ng Dates | | 8. Is this a Single-use | Davice that was Penr | rocessed and Pause | d on a Patient? |
| | | | Yes No | Device that was repr | ocessed and Neuse | d on a ratient: |
| | | i | 9. If Yes to Item No. 8, | Enter Name and Add | ress of Reprocesso | r |
| | | | | | | |
| | | | | | | |
| | | | 10. Device Available fo | r Evaluation 2 (Do not | t cond to EDAI | |
| | | | Yes No | | fanufacturer on: | Dee |
| ĺ | | | L res L No | | andiactorer on. | (mm/da/yyy) |
| | | | 11. Concomitant Medic | cal Products and The | rapy Dates (Exclude | MOV 0 6 2013 |
| Other Relevant History, Including Preexists race, pregnancy, smoking and alcohol use, | | lergies, | | | | 0 0 2013 |
| | | | | | | |
| TAKES GENERIC VERSION OF CLA | RITIN LIQUID FOR PET | HAIR | E. INITIAL REPO | RTER | | |
| ALLERGY (AS NEEDED). | | | 1. Name and Address | | #(b) (6) | |
| | | | | | | |
| | | | (b) (6) | | | |
| | | | | | LE | ? / <u>A</u> |
| | | | | | | 9/- |
| | | ſ | | | | |

2. Health Professional? 3. Occupation

Yes V No

| THUL VIGURE | cupe parcel mobers | |
|-------------|--------------------|--|
| | | |

| | 9767 | 440-01-00-02 | |
|---|----------------|--------------------------------------|-------------------------------------|
| User Facility | Impo | rter | |
| 3. User Facility or Imp | orter Name | Address | |
| | | | |
| 4. Contact Person | | 5. Pho | ne Number |
| Date User Facility o Importer Became Aware of Event (mm | - 1 | 7. Type of Report Initial Follow-up# | 8. Date of This Report (mm/dd/yyyy) |
| 9. Approximate Age of Device | 10. Event F | Problem Codes (Refer to | coding manual) |
| | Patient Code | - | -[|
| | Device Code | - | - |
| 11. Report Sent to FDA | \? | 12. Location Where Ex | vent Occurred |
| Yes(mm/dd. | <i>(yyyy</i>) | ☐ Hospital ☐ Home | Outpatient Diagnostic Facility |
| 13. Report Sent to Mar | nufacturer? | ☐ Nursing Home ☐ Outpatient Trea | Ambulatory Surgical Facility |
| Yes(mm/dd, | <i>(yyyy</i>) | Facility | unon |
| | | Other: | (Specify) |
| G. ALL MANUFA | CTURER | 9 | |
| | | and Manufacturing Site | 2. Phone Number |
| for Devices) EDYTA FRACKIE | | (and manufacturing Site | 310-768-0700 3. Report Source |
| HYLAND'S, INC | | | (Check all that apply) Foreign |
| 154 W. 131ST LOS ANGELES, | | 51 | Study |
| | | | Literature |
| | | | Consumer |
| | | | Health Professional User Facility |
| Date Received by Manufacturer (mm/d | d/yyyy) | 5. (A)NDA # | Company |
| 10/09/20 | | IND# | Representative Distributor |
| 6. If IND, Give Protocol | 1# | STN# | Other: |
| 7. Type of Report (Check all that apply) | | PMA/ 510(k) # | |
| 5-day 30-da | у | Combination Ye | es |
| 7-day Period | dic | Pre-1938 Y | es - |
| | v-up # | OTC Product Y | es |
| 9. Manufacturer Report | Number | 8. Adverse Event Tern | n(s) |
| 54973 AE # 151 | .3 | SEIZURES | |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| 5 | |
|--|---|
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| | |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date (mm/yyyy) |
| Not Returned to Manufacturer | ' '''' |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| provide code. | Yes No |
| | |
| 6. Evaluation Codes (Refer to coding manual) | |
| Method - | - |
| | |
| Results - | |
| Conclusions | |
| | |
| 7. If Remedial Action Initiated, Check Type 8. | Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Treatening meanedion | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative and | d / or 11. Corrected Data |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Plocard Drive, Room 400 Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

NOV 0 6 20



CUSTOMER COMPLAINT RECORD



| | | | COMPL | AINT #: 2522 | |
|--|--|--|---|--|-------------------------------------|
| TAKEN BY: | EDYTA FRAC | KIEWICZ | DATE OF COMP | LAINT: 10/10/13 | |
| PRODUCT: | BABY TEETH | ING TABLETS | ITEM | CODE: BTET | T135 |
| SIZE: | 135 TABLETS | 3 | LC | T NO.:B06813 | |
| REPORTER: | (b) (6) | | | | RECEIVED |
| ADDRESS: | | | | | |
| | | | | | NOV 0.5 2013 |
| CITY: | | | STATE: (b) (| 6) | |
| COUNTRY: | USA | | ZIP CODE: | | CDR |
| PHONE #: | (b) (6) | | | | |
| E-MAIL: | | ALLE ALE MOTUED OA | VE 2 TABLETS FOR THE FIRST T | IME LAST NICHT 1 | 0/00/13 AROLIND 7:30 PM |
| ILLNESS. TAKES AN | NG, AND HEAD JERKEI ALLERGY MEDICINE F NJURY. HAS NOT CON CUSTOMER CALLED BA | D LEFT AND RIGHT. CHILD HAS FOR ALLERGY TO PET HAIR (GE ITACTED THE DOCTOR. TOLD ICK TO PROVIDE LOT NUMBER. | SEIZURES" LASTING A COUPLE NEVER EXPERIENCED THESE NERIC FOR CLARITIN LIQUID) – HER NOT TO USE THE TABLETS | TYPES OF SYMPTO BUT DID NOT USE AND TO CONTACT | DMS. NO FEVER, NO LAST NIGHT. NO |
| | FOR ADD | ITIONAL SPACE PLEASE USE I | REVERSE OR ATTACH A SEPARA | ATE SHEET | |
| PRODUCT RECEIVED | | (CIRCLE ONE) | PRODUCT BEING RETURN | | (CIRCLE ONE) |
| ividual Cas | se Safety Re | port | DATE REQUESTED PRO | DUCT BE RETURN | ED: |
| | | | U | S CALL TAG ISSU | ED: (CIRCLE ONE) |
| 97674 | 40-01-00-03 | | DATE | PRODUCT RECEIV | /ED: |
| SECTION II: | INVESTIGATION | | | | |
| | | | | | |
| INVESTIGATION: | PLEASE SEE A | TTACHED INSPECTION REPOR | Τ. | | |
| | | | | | |
| | | | | Nor- | |
| , | | | | | |
| | | | | | |
| ADVERSE EVENT FO | DRWARDED TO PHARM | MACIST / NURSE FOR EVALUAT | ION ON : | 10/10/13 | |
| | | MACIST / NURSE FOR EVALUAT | - | 10/10/13 EDYTA FRACKIEW | ICZ |
| ADVERSE EVENT FO | | MACIST / NURSE FOR EVALUAT | - | | ICZ |
| ADVERSE EVENT FO | DRWARDED TO PHARM | MACIST / NURSE FOR EVALUAT | - | | ICZ |
| ADVERSE EVENT FO | DRWARDED TO PHARM | MACIST / NURSE FOR EVALUAT | - | | ICZ |
| ADVERSE EVENT FO | DRWARDED TO PHARM | MACIST / NURSE FOR EVALUAT | - | | ICZ |
| ADVERSE EVENT FO | CORRECTIVE | MACIST / NURSE FOR EVALUAT ACTION: | - | EDYTA FRACKIEW | ICZ |
| ADVERSE EVENT FO | DRWARDED TO PHARM | MACIST / NURSE FOR EVALUAT ACTION: | - | EDYTA FRACKIEW | |
| ADVERSE EVENT FO | CORRECTIVE | MACIST / NURSE FOR EVALUAT ACTION: | - | EDYTA FRACKIEW | |
| ADVERSE EVENT FO | CORRECTIVE A CO | MACIST / NURSE FOR EVALUAT ACTION: | - | EDYTA FRACKIEW | |
| ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTION SECTION IV: | CORRECTIVE A CO | ACCIST / NURSE FOR EVALUAT ACTION: REPORTS | ION BY: | EDYTA FRACKIEW | |
| ADVERSE EVENT FOR SECTION IV: ADVERSE EVENT SE | CORRECTIVE A CO | REPORTS | BY: EDYT | DATE: AE #:1513 | DS |
| ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT SECTION SECTION IV: | CORRECTIVE A CO | REPORTS | BY: EDYT | DATE: AE #:1513 | DS |
| ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT SECTION SECTION IV: | CORRECTIVE A CO | REPORTS | BY: EDYT | DATE: AE #:1513 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1



SE EVENT DATA FORM



| AE #:1513 | COMPLAINT #: _2522 | |
|--|--|-------------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: ADDRESS: | (b) (6) | |
| CITY: COUNTRY: PHONE #: | USA ZIP CODE: (b) (6) ZIP CODE: | |
| E-MAIL: | | |
| AFF Indications: Impairing a participation of the property and participation of the particip | HONEOPATHIC Teething Tablets Tablets are represented by potential to produce the produce the potential to produce the produce the potential to produce the produce the produce the potential to produce the prod | |
| SECTION III: | CORRECTIVE ACTION: | |
| CORRECTIVE AC | TION(S) COMPLETED BY: DATE: | |
| SECTION IV: REVIEWED BY MA | NAGEMENT BY: DATE: 10-25-13 NOV QUE Ball QA/QC DIRECTOR DATE: 10-22-13 |)SS 0 6 2013 |



CaseID: 9767440

Serious Adverse Event SAE-0048-2013

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot #B06813, are currently in the Standard Homeopathic Co. (SHC) warehouse. All but 7 units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B06813 was manufactured using bulk lot # 120102. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B06813. Additionally, the Baby Teething bulk lot # 121015 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B06813.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B06813.

Manufacture and processing occurred within established procedures to ensure product quality.

10122113

Date

NOV 0 6 201:

Page 1 of 1



or VOLUNTARY reporting of rse events, product use events and

CaseID: 9790085

| Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 |
|--|
| See PRA statement on reverse |

| Adverse Event Reporting Program | | Page | of a | <u> </u> | seque | ence # 3 3 3 | 03 | 8 | |
|--|---|--------------------------|----------|---------------------------------------|------------|--------------------|------------|---|-----------|
| A. PATIENT INFORMATION | | _ | | Oose or Amount | Ь, | Frequency | Route | | |
| Patient Identifier 2. Age at Time of Event or | 3. Sex | 4. Weight | #1 | | —i | riequency | 1 | | ٦ |
| (b) (6) Date of Birth: | Female | 23#10°2 | | 2 tablets | - 11 | on u | byn | north | 1 |
| DoB: | _ | or | #2 | | Ti. | | | | ĭ |
| In confidence | Male | kg | | | [| | | | |
| B. ADVERSE EVENT, PRODUCT PRO | BLEM OR ER | ROR | 3. Da | es of Use (If unknow | n, give d | luration) from/to | | nt Abated After Use | _ |
| Check all that apply: | | | 11 ' | best estimate) 29 - 11/30 | | | 1 | ed or Dose Reduced? | n'4 |
| 1 Adverse Event Product Problem (e.g. | | | H — | 129 - 133 | | | #1 🖸 | Yes No Does Apply | |
| Product Use Error Problem with Differen | t Manutacturer of | Same Medicine | ۰۰ | gnosis or Reason fo | | | #2 | Yes No Does | |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) | | | #1 #1 | gnosis or Reason to | r USe (II | naication) | 8. Eve | nt Reappeared After | |
| Death: Disabil | ity or Permanent I | Damage | II | Teething | | | I | ntroduction? | |
| (mm/dd/yyyy) Life-threatening Conge | nital Anomaly/Birti | n Defect | #2 | Fussiness | | | #1 ∐ | Yes No Does | n't |
| ☐ Hospitalization - initial or prolonged ☑ Other | | | 6. Lot | | 7 Exp | iration Date | #2 | Yes No Does | n't |
| Required Intervention to Prevent Permanent Im | | | #1 | unknum | | kunm | 9 NDC | Apply # or Unique ID | _ |
| | of this Report (m | | #2 | | #2 | | 0.1120 | " or ornique ib | |
| | 114/13 | nodwyyyy) | E. 8 | SUSPECT MEDIC | CALD | EVICE | | | |
| | | | | nd Name | | | | | - |
| Parents gave to 2 teething | tablets ar | d put | | | | | | | |
| himdown for nap. Abnormal during nap - grunting, squ wake for >10min. Eval in | bustonia | +d | 2. Cor | nmon Device Name | | | 26 | . Procode | _ |
| himdness by rup. Monormac | . oracing p | W) (A) | | on borroo manie | | | 20 | DSS | |
| durinas - grunting, squ | irming, who | ldn't | | | | | | | j |
| who for Marin Food in | ED ince | might | 3. Mar | ufacturer Name, City | y and Si | tate | | DEC 3 0 2013 | 3 |
| Wall for Morning to | - Circu | , | | | | | | | |
| Service. | | | 4 14- | 1-14 | 11-4 | 4 | | | _ |
| | | | 4. Mod | 101 # | Lot | # | | 5. Operator of Device | |
| | | | | | | | | Health Professiona | al |
| | | | Cat | alog# | Exp | iration Date (mm | /dd/yyyy | Lay User/Patient | |
| | | | | | | | | Other: | |
| 6. Relevant Tests/Laboratory Data, Including Date | s | | Seri | al# | Unic | que identifier (UD | I) # | 1 | |
| Influenza (neg) RSV (neg) | | | | | | | | | |
| esv (near) | | | 6. If Im | planted, Give Date (| mm/dd/v | (VVV) 7. If Expl | anted. (| Give Date (mm/dd/yyyy) | \exists |
| (3, (3)) | CTL | 9 | | | | | | , | |
| | DEC 9A | 2042 | | is a Single-use Devi Yes ☐ No | ce that | was Reprocessed | I and R | eused on a Patient? | |
| | DEC 30 | 2013 | | s to Item No. 8, Enter | Name an | d Address of Pen | rocesso | - | 4 |
| 7 Other Polyment History I and Jilly Polymer | | | | - 10 11011 1101 0, <u>E</u> 11101 1 | i dillo di | ia Address of Rep | 000330 | • | |
| Other Relevant History, Including Preexisting Mallergies, race, pregnancy, smoking and alcohol use | edical Conditions e, liver/kidney prol | s (e.g., olems, etc.) | | | | | | | 1 |
| 6.1 | 0 1-2 | down | F. 0 | THER (CONCOM | ITANI | T) MEDICAL P | RODI | JCTS | 4 |
| prints event. Diago | Ju 1 | | | t names and therap | | | | | ٦ |
| onic to event Diag | wied with | ear | Tyl | | | | | | |
| to the toloring | | | 1hu | pnfen | | | | | ١ |
| infection that am | | | 0 0 | | | | | | ╛ |
| | | | | PORTER (See c e and Addres:(b) (6) | ontide | entiality sectio | n on b | ack) | 4 |
| C. PRODUCT AVAILABILITY | | | Nam | | | | | | |
| Product Available for Evaluation? (Do not send pro | duct to FDA) | | Addr | ess: | | | | | |
| Yes No Returned to Manufacturer o | n: | dagad | | | | | | | 1 |
| D. SUSPECT PRODUCT(S) | (IIIII) | 7333/ | City: | | | | | | |
| . Name, Strength, Manufacturer (from product label | | | Phone | # | | | | | 1 |
| 1 Name: Hyland's Teething Tablet Strength: | 5 | | | | | | | | |
| Manufacturer: | | | 2. Heal | th Professional? 3. | Occupa | tion | | . Also Reported to: | 4 |
| 2 Name: | | | | | | uan | ⊣ ` | Manufacturer | |
| Strength: | | | | ı do NOT want your id | | | _ | User Facility | |
| Manufacturer: | | | | e manufacturer, place | | | | Distributor/Importer | |

PLEASE TYPE OR USE BLACK INK

t Consumer Report

CaseID: 9820308

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

| UNTARY reporting f | - / | | FDA USE ONLY |
|--|------------|------------------------|--------------|
| ts, product ploble as and oduct use errors | | Triage unit sequence # | 536227 |
| | | | |

| 9020300-01-00-01 | .ts, produ oduct use | uct ploble as and e errors | Triage unit sequence # | 3622 | る |
|--|---------------------------------------|---|---------------------------|-------------------|----------------------|
| Adverse Event Reporting Program | Ottact us | e cirois — | | | |
| A. PATIENT INFORMATION | 44 | 2 Dose or Amount | Frequency | Route | |
| Patient Identifier 2. Age at Time of Event or 3. Sex (6) Date of Birth: | 4. Weight | #1 | | | |
| 5 Months Female | 12 lb | #2 | | | |
| (b) (6) ✓ Male | or kg | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | | |
| In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR I | | 3. Dates of Use (If unkno | wn_give_duration) from | 20 5 Event A | bated After Use |
| s. ADVERSE EVENT, PRODUCT PROBLEM OR I | ERROR | (or best estimate) | with give databolity from | | or Dose Reduced? |
| ✓ Adverse Event Product Problem (e.g., defects/malfu | inctions) | #1 12/02/2013 ~ | | #1 Yes | s No Doesn't |
| Product Use Error Problem with Different Manufacture | r of Same Medicine | #2 | | #2 \ Ye | s No Doesn't |
| Outcomes Attributed to Adverse Event | | 4. Diagnosis or Reason | | | Reappeared After |
| (Check all that apply) (b) (6) | and Damage | #1 Teething pain a | nd uncomfort | | duction? |
| ✓ Death: Disability or Permane | · | #2 | | #1 Ye | s No Doesn't Apply |
| Life-threatening Congenital Anomaly/ | 1 | | 2 Emiliado Basa | #2 Ye | Fig. Decemb |
| Hospitalization - initial or prolonged Other Serious (Import | | 6. Lot# #1 | 7. Expiration Date | , | Apply |
| Required Intervention to Prevent Permanent Impairment/Dam | age (Devices) | #2 | | 9. NDC # 6 | or Unique ID |
| Date of Event (mm/dd/yyyy) 4. Date of this Report | t (mm/dd/yyyy) | | | | |
| 12/02/2013 01/10/2014 | | E. SUSPECT MED | ICAL DEVICE | | <u> </u> |
| Describe Event, Problem or Product Use Error After using Hyland Teething Tablets on my | 5 mo old | Coranio Name | | | |
| grandson for the first time he died in his | s sleep. When | | | | |
| they found him he had a temp of 102 and ca is Accute Cardio Pulminary Arrest I believ | use of death | 2. Common Device Nam | е | CTU | 1 |
| caused by these teething tablets!!!! After | reading the | | | | |
| effects of Belladonna used in these tablet | | 3. Manufacturer Name, 0 | City and State | JAN 1 3 2 | 2014 |
| almost sure there is a link to my grandsor these tablets. SOMEONE NEEDS TO INVESTIGAT | TE THIS!!!!! | | | | :014 |
| | | | | | |
| | | 4. Model # | Lot# | 5 | Operator of Device |
| | | [], | |] [| Health Professional |
| | | Catalog # | Expiration Dat | e (mm/dd/yyyy) | Lay User/Patient |
| | | | | | Other: |
| Relevant Tests/Laboratory Data, Including Dates | 3 46. 3 | Serial # | Other# | |] Other. |
| Autopsy is pending | | Senai # | Other # | | |
| | | | | | |
| | | 6. If Implanted, Give Dat | te (mm/dd/yyyy) 7. | If Explanted, Giv | /e Date (mm/dd/yyyy) |
| | | 8. Is this a Single-use D | evice that was Repro | cessed and Reu | sed on a Patient? |
| | | Yes No | • | | |
| | | 9. If Yes to Item No. 8, En | ter Name and Address | of Reprocessor | |
| Other Relevant History, Including Preexisting Medical Condi | tions (e.g., | 11 | | | |
| allergies, race, pregnancy, smoking and alcohol use, liver/kidney | problems, etc.) | | | 241 884 | 270 |
| Race:White | | F. OTHER (CONC | | | |
| Medical Conditions: | | Product names and the | rapy dates (exclude tr | satment or event) | |
| Allergies: | | | | | |
| Important Information: | | | | | |
| important information: | + | G. REPORTER (Se | e confidentiality : | section on ba | ck) |
| The Principal Association of the Principal As | | 1. Name and Address | | | |
| . PRODUCT AVAILABILITY | | (b) (6) | | | DS |
| roduct Available for Evaluation? (Do not send product to FDA) | į la | | | | DS JAN 18 |
| ✓ Yes No Returned to Manufacturer on: | mm/dd/yyyy) | | | | S I MAL |
| . SUSPECT PRODUCT(S) | | Diam'r. | | | |
| Name, Strength, Manufacturer (from product label) | | Phone # (b) (6) | (b) | mail (6) | |
| 1 Name: Hyland Teething Tablets Strength: | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | |
| Manufacturer: | 1 1 W | 2. Health Professional? | 3. Occupation | 4. | Also Reported to: |
| Name: | | Yes No | | | Manufacturer |
| Strength: | | 5. If you do NOT want yo | | | User Facility |
| Manufacturer: | | to the manufacturer, p | lace an "X" in this box | : 🗀 🔝 📙 | Distributor/Importer |

Health Professional Report

CDER

OLUNTARY reporting of wents, product problems and product use errors

| Form Approve (2818 64 0) 0992466 (0 2/31/2011 See OMB statement on reverse. |
|---|
| |

Triage unit sequence #

| 9924 | R10-01-00-01 | | product us | 1/1 | | |
|--|---|---|---------------------------------|--------------------------------|---|--------------------------------------|
| A. PATIENT IN | NFORMATION | | | 2. Dose or Amount | Frequency | Route |
| 1. Patient Identifier | 2. Age at Time of Eve Date of Birth: | ent or 3. Sex | 4. Weight | #1 3 tabs | QD | Oral |
| (6) | 4 Months | ✓ Female | tb | #2 | | |
| | (b) (6) | ☐ Male | or 7.2 _{kg} | "- | | |
| In confidence | EVENT PRODUC | T PROBLEM OR | ERROR | 3. Dates of Use (If unknown | vn. give duration) fron | n/to 5. Event Abated After Use |
| Check all that apply: | | | | (or best estimate) | | ■topped or Dose Reduced? |
| 1. 🗸 Adverse Even | nt Product Prob | olem (e.g., defects/malfu | nctions) | #1 02/14/2014 - 02 | 722/2014 | #1 Yes No Doesr |
| | | Different Manufacture | r of Same Medicine | #2 4. Diagnosis or Reason f | ing Han (Indication) | #2 Yes No Doesr |
| Outcomes Attrib (Check all that ap | outed to Adverse Even | it | | #1 teething | or use (maicallon) | 8. Event Reappeared After |
| Death: | [| Disability or Permane | ent Damage | | | Reintroduction? |
| Life-threatenin | (mm/dd/yyyy) na [| Congenital Anomaly/ | Birth Defect | #2 | | Apply |
| ✓ Hospitalization | n - initial or prolonged [| Other Serious (Import | tant Medical Events) | 6. Lot# | 7. Expiration Date | #2 Yes No Doesr |
| | | manent Impairment/Dam | - | #1 A 97113 | #1 | 9. NDC # or Unique ID |
| 3. Date of Event (m | nm/dd/yyyy) | 4. Date of this Report | t (mm/dd/yyyy) | #2 | #2 | |
| 02/22/2014 | l | 02/22/2014 | | E. SUSPECT MED | ICAL DEVICE | |
| | Problem or Product U | | and | 1. Brand Name | | |
| | | found flushing a s cause had beer | | | | CTU |
| Teething Ta | | ast week at 3 ta | | 2. Common Device Name | 9 | |
| day. | | | | | | FEB 2 4 2014 |
| | | | | 3. Manufacturer Name, C | ity and State | - e enià |
| | | | | | | |
| | | | | | | |
| | | | | 4. Model # | Lot# | 5. Operator of Device |
| | | | | | ĺ | Health Profession |
| Gay. | | | | Catalog # | Expiration Dat | e (mm/dd/yyyy) Lay User/Patient |
| | | | | | | Other: |
| 6. Relevant Tests/L | Laboratory Data, Inclu | ding Dates | | Serial # | Other# | |
| | | CRP, Abd X-rays | and X- ray | | | |
| differentia | | | | 6. If Implanted, Give Date | e (mm/dd/yyyy) 7. | If Explanted, Give Date (mm/dd/yyyy) |
| | | | | | , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | |
| | | | | 8. Is this a Single-use De | vice that was Repro | cessed and Reused on a Patient? |
| | | | | 9. If Yes to Item No. 8, Ent | er Name and Address | of Reprocessor |
| | | | | | | |
| 7. Other Relevant I allergies, race, pr | History, Including Pred regnancy, smoking and | existing Medical Condi alcohol use, liver/kidney | tions (e.g., problems, etc.) | | | |
| | nt with vaccines s stay in NICU f | current, previo | ously well | F. OTHER (CONC | MITANT) MEDIC | CAL PRODUCTS |
| dreer bhore | bedy in hize i | or ton appar. | | Product names and then | | eatment of event) |
| | | | | Tylenol infant dr | ops | |
| | | | | | | |
| | | | | G. REPORTER (See | e confidentiality s | section on back) |
| C BRODUCT | AVAII ADII ITV | | | 1. Name and Address (b) (6) | | |
| | AVAILABILITY for Evaluation? (Do no | ot send product to FDA) | | | | |
| Yes No | Returned to Mar | | | | | |
| 3 | | (/ | mm/dd/yyyy) | | | DS |
| D. SUSPECT | | | | Phone # | l F. | mail CCD o |
| , , · | , Manufacturer (from production) d's teething tal | , | | (b) (6) | | mail FEB 2 |
| Strength: home | eopathic | | | | | |
| | Hyland's Inc | | | 2. Health Professional? | | 4. Also Reported to: |
| #2 Name: | | | | Yes No | Medical Doctor (Physici | ian) Manufacturer User Facility |

Manufacturer:

to the manufacturer, place an "X" in this box:

Distributor/Importer

et Consumer Report

CaseID: 9998991

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

LUNTARY reporting of .nts, product problems and product use errors

CDER

| Om Abratas | • | | statement | |
|------------|--------|--------|-----------|--|
| | FDA US | E ONLY | , | |

| Adverse Event | Reporting Progra | m | F | | 110 | | | |
|-----------------------------------|--------------------------------|--|------------------|--------------------|--|--------------------|---------------------------------------|--|
| A. PATIENT IN | | | | | Dose or Amount | Frequenc | | |
| | 2. Age at Time of Eve | nt or 3. Sex | 4. Weight | #1 | 2-3 tablets 4 | Four ti | mes Taken by | y mouth |
| (b) (6) | Date of Birth: | √ Female | 13 _{lb} | | times per day | | | |
| | (b) (6) | | or | #2 | | | | |
| In confidence | | Male | kg | | | | | At to d Affection |
| B. ADVERSE | EVENT, PRODUC | T PROBLEM OR E | RROR | 3. Da | ites of Use (If unknown, r best estimate) | , give duration) 1 | Stopped | Abated After Use For Dose Reduced? |
| Check all that apply: | | | | #1 0 | 3/07/2014 - 03/0 | 08/2014 | #1 🗸 Y | es No Doesn' |
| 1. Adverse Ever | | lem (e.g., defects/malfund Different Manufacturer | | #2 | | | | |
| | | | or ourse moureme | 4. Di | agnosis or Reason for | Use (Indication |) <u> </u> | Apply |
| (Check all that ap | outed to Adverse Even oply) | • | | | 7 month old with | | n 8. Event | t Reappeared After roduction? |
| Death: | | Disability or Permanent | Damage | #2 | | | #1 🗸 | es No Doesn' |
| Life-threatenin | (mm/dd/yyyy) | Congenital Anomaly/Bi | rth Defect | "" | | | | Apply |
| | - | Other Serious (Importa | | 6. Lc | ot# | 7. Expiration I | Date #2 | ∕es ☐ No ☐ Doesn' Apply |
| | | nanent Impairment/Dama | | #1 B | 36913 | #1 | 9. NDC | # or Unique ID |
| 3. Date of Event (n | | 4. Date of this Report (| | #2 | | #2 | | -3127-1 |
| 03/07/2014 | | 03/09/2014 | | | SUSPECT MEDIC | AL DEVICE | | |
| 5 Describe Event. | Problem or Product U | se Error | | 1. B | rand Name | | | |
| I nurchased | Huland's Baby ' | Teething Tablets | for my | | | | | |
| seven month | old daughter. | After giving her to cry incessant | two tablets | 2. C | ommon Device Name | | | |
| | e. She spiked a | fever of 101, 10 | minutes | 11 | | | | |
| after recei | ving the tablet | s and refused to eeks that reminde | nurse. She | | | | | |
| chicken pox | She was throw | ing up all her mi | lk, and was |] 3. M | anufacturer Name, Cit | y and State | | |
| grabbing at | her arms and l | egs as if they hu | ırt. I have | Н | | | | |
| | my daughter act | this way, or scr hours in my arms | s screaming, | | | 11 -4 # | | Is One of During |
| and finally | passed out. I | had assumed she w | was sick at | 4. M | lodel# | Lot# | | 5. Operator of Device Health Professions |
| first and i | it | | | | | | | Health Professiona |
| and finally first and i | | | • | 0 | atalog# | Expiration | Date (mm/dd/yyyy) | Lay User/Patient |
| 1 | | | | 11 | | | | Other: |
| 6. Relevant Tests/ | /Laboratory Data, Inclu | ding Dates | | ∖⊢₅ | erial # | Other# | | - |
| NA | | _ | | | | | | |
| NA NA | | | | 1 | Investment of Chica Data | (mm/ddhaaa) | 7 If Evplanted (| Give Date (mm/dd/yyyy) |
| 1 | | CTU | |] ^{6, #} | Implanted, Give Date | (IATIVOCE YYYY) | , , , , , , , , , , , , , , , , , , , | |
| 1 | | | 2014 | 8. Is | s this a Single-use Dev | rice that was Re | processed and R | eused on a Patient? |
| | | MAR 112 | 2 014 | 1.1 | Yes No | | | |
| | | | | 9. H | Yes to Item No. 8, Enter | r Name and Add | ress of Reprocesso | OF . |
| 7. Other Relevant | History, Including Pre | existing Medical Conditi | ons (e.g., | 11 | | | | |
| allergies, race, p Race: White | pregnancy, smoking and | alcohol use, liver/kidney | problems, etc.) | | OTLIEB (CONCO | MIT A NIT - NAC | DICAL BROD | LICTS |
| Race: White | | | | | OTHER (CONCO | | | |
| Medical Co | nditions: NA | | | 11770 | ruuti names anu mera | py water (excite | | |
| Allergies: | NA | | | | | | | |
| Two art ant | Information: DD | ETERM baby born a | t 37 weeks | | | | | · |
| gestation | Intolmacton. PR | Dillin baby born a | 6 | G. | REPORTER (See | confidential | ity section on | back) |
| | | | | | Name and Address | | | |
| | AVAILABILITY | not count product to EDA1 | | - (0 | 7(0) | | | |
| 1 | | ot send product to FDA) | | | | | | DS |
| Yes No | Returned to Ma | nufacturer on:(m | m/dd/yyyy) | | | | | DS WAR 1 |
| D. SUSPECT | PRODUCT(S) | | | | | | E-mail | WAR 1 |
| 1. Name, Strengti | h, Manufacturer (from p | | OF C | (b) | one # (6) | | (b) (6) | |
| 1 | nd's Teething Ta | blets | ()((| | | | | |
| Strength: Doe Manufacturer: | es not say Hyland's, Inc. | Las Angeles, CA | J (C | 2.1 | Health Professional? | 3. Occupation | | 4. Also Reported to: |
| #2 Name: | ngiana of inci | | | 11 | Yes No | | | Manufacturer |
| Strength: | | | | 5. | If you do NOT want you | r identity disclos | ed _ | User Facility |

Manufacturer:

to the manufacturer, place an "X" in this box:

☐ Distributor/Importer

B.5. Describe Event or Problem (continued)

... did not even cross my mind that the tablets could have caused her symptoms. But the next night I gave her two more before bed and she was in tears, fever and rash again. I then thought maybe she could have an allergic reaction to the tablets so looked them up on the internet, what I found was extremely alarming. I have no doubt in my mind that Hyland's Baby Teething Tablets had very negative side effects on my daughter.

Individual Case Safety Report

9998991-01-00-02

DSS MAR 1 1 2

net Consumer Report

CaseID: 9999086

DLUNTARY reporting of rents, product problems and

| form Approved: OMB No. | 0910-0291, Expires: 12/31/2011 See OMB statement on reverse. |
|------------------------|---|
| | 5.001.7 |

Triage unit sequence #

| The FDA Satet | ry intormation and t Reporting Progra | m | product use |)/1 | | |
|--------------------|--|----------------------------|---------------------|-----------------------------------|--|--|
| | | | | 2. Dose or Amount | Frequency | Route |
| A. PATIENT | INFORMATION | nt or 13 Sev | 4. Weight | #1 2 tablets | Four time | es Taken by mouth |
| | 2. Age at Time of Eve | I — | 19 _{lb} | | daily | |
| (6) | 5 Months | Female | ID | #2 | | |
| | (b) (6) | ✓ Male | or kg | 1 1 | - 1 | |
| In confidence | | | DDOB | 3. Dates of Use (If unkn | own, give duration) fro | om/to 5. Event Abated After Use |
| B. ADVERSE | EVENT, PRODUC | T PROBLEM OR E | RRUK | (or best estimate) | | Stopped of Dose Resident |
| heck all that appl | - | | etions) | #1 03/07/2014 - 0 | 3/08/2014 | #1 Yes No Does |
| . 🗸 Adverse Ev | ent Product Prob | lem (e.g., defects/malfur | of Same Medicine | #2 | | #2 Yes No Does |
| _ | e Error Problem with | | Ci Gaine Meanana | 4. Diagnosis or Reason | n for Use (Indication) | Д Аррі |
| Check all that | ributed to Adverse Event | t | 1 | #1 Infant teethir | | 8. Event Reappeared After Reintroduction? |
| Death: | | Disability or Permane | nt Damage | | | #1 Yes No Does |
| | (mm (ddffanns) | Congenital Anomaly/E | | #2 | | Apply |
| Life-threater | | _ | | 6. Lot # | 7. Expiration Da | ate #2 Yes No Does |
| Hospitalizat | tion - initial or prolonged | Other Serious (Import | ant Medical Events) | #1 B43013 | #1 | 9. NDC # or Unique ID |
| Required In | tervention to Prevent Perr | nanent Impairment/Dam | age (Devices) | #2 | #2 | |
| 3. Date of Event | (mm/dd/yyyy) | 4. Date of this Report | (mm/dd/yyyy) | 11 | | |
| 03/07/203 | | 03/08/2014 | | E. SUSPECT ME | DICAL DEVICE | |
| 5 Describe Ever | nt Problem or Product U | se Error | | 1. Brand Name | | |
| We garre of | ur 5 month old Hv | lands Teething t | ablets | | | |
| memited at | ternoon/evening. verywhere. He vom | ited again about | 30 minutes | 2. Common Device Na | ime | |
| 1-to- Wo | did not know it | was the tablets. | The next |]}. | | CN |
| day at no | on we gave him th | e tablets again. | The same | 3. Manufacturer Name | City and State | 040 |
| the Unlan | sued. We then lead ds product and ce | ased dosage. He | is slowiy | 3. Manufacturer Name | , City and State | MAD 7 7 com |
| recovering | g. but certainly | still not feelir | ig well. He | 1 | | MAR I 1 2014 |
| is having | trouble taking f | ull feedings. | | | | 5. Operator of Devi |
| | | | | 4. Model # | Lot# | 5. Operator of Devi |
| | , | | | | | Health Professio |
| | | | | Catalog # | Expiration [| Date (mm/dd/yyyy) Lay User/Patient |
| | | | | | | Other: |
| | | | | | | |
| 6. Relevant Tes | ts/Laboratory Data, Inclu | uding Dates | | Serial # | Other# | |
| | | | | | | |
| | | | | 6. If Implanted, Give | Date (mm/dd/yyyy) | 7. If Explanted, Give Date (mm/dd/yyy |
| | | | | 11 | i | D 11 + 12 |
| | | | | | Device that was Re | processed and Reused on a Patient? |
| | | | | Yes No | - N | age of Danrocessor |
| ĺ | | | | 9. If Yes to Item No. 8, | Enter Name and Addre | ess of Reprocessor |
| | ant History, Including Pro | ovieting Medical Cond | itions (e.g. | 11 | | |
| allergies, race | e, pregnancy, smoking and | d alcohol use, liver/kidne | y problems, etc.) | | | DIGAL BEGBLIGTS |
| Race:Whi | te | | | F. OTHER (CON | COMITANT) ME | DICAL PRODUCTS |
| Medical | - Conditions: N/A | | | Product names and | therapy dates (exclud | ne treatment of event) |
| | - | | | | | |
| Allergie | s: Wheat, Soy | | | 11 | | |
| Importan | - t Information: N/ | 'A | - | | (Company internal of | ity section on back |
| | | | | G. REPORTER 1. Name and Addres | | ity section on back) |
| | OT AVAIL ADULTY | | | 1. Name and Address Name: (b) (6) | | |
| C. PRODUC | CT AVAILABILITY able for Evaluation? (Do | not send product to FDA |) | Address: | | ~ |
| Product Availa | | | , | / (401655) | | State: ZIP: MAR 1 |
| Yes 🗌 | No Returned to M | anufacturer on: | (mm/dd/yyyy) | · | | State: ZIP: MAD - |
| D SUSPEC | CT PRODUCT(S) | | | City: | | E-mail |
| 1. Name. Stren | ngth, Manufacturer (from | product label) | | Phone # | | |
| | lands Teething Ta | | MITI | | | |
| Strength: N | | I | 11/- | 2. Health Profession | nal? 3. Occupation | 4. Also Reported to |
| Manufactur | er: Hylands, Inc. | (| 1 | Yes No | | Manufacturer |
| #2 Name: | | | ~ | | t vene identify displan | User Facility |
| Strength: | | * | | 5. If you do NOT wan | nt your identity discloser, place an "X" in this | box: 🗸 🔲 Distributor/Imp |

Manufacturer:

to the manufacturer, place an "X" in this box:

10023432-02-00-01

FORM FUA 3500A (6/10)

| z | A. PATIENT INF | ORMATION | 1 | | | | | | | |
|----------------------------|---|---|---------------|---|--|------------|--|--|--|--|
| | . Patient Identifier b) (6) | 2. Age at Time of Event: | е | | 3. Sex | 4. Weight | | | | |
| ľ | b) (b) | or | 6 | Months | Female | 17lbs | | | | |
| | | Date | | | ✓ Male | OF too | | | | |
| L | In confidence B. ADVERSE E | of Birth: | PODII | CT PROBLE | M | kgs | | | | |
| Г | | | | | | iunational | | | | |
| 1. | 1. Adverse Ever | | | duct Problem (6 | e.g., derects/mair | unctions) | | | | |
| ľ | Outcomes Attributed to Adverse Event (Check all that apply) | | | | | | | | | |
| ١ | Death: | (mm/dd/yyy) | /) | Disability | or Permanent Da | mage | | | | |
| 1 | Life-threateni | | ′ | Congenita | i Anomaly/Birth I | Defect | | | | |
| ١ | Hospitalizatio | ✓ Hospitalization - initial or prolonged ✓ Other Serious (Important Medical Events) ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices) | | | | | | | | |
| L | | | rent Perm | | | | | | | |
| ١ | 3. Date of Event (m | | /2012 | 4. Date of This | Report (mm/de 12/10/201 | | | | | |
| ŀ | 11/22/2013 5. Describe Event o | | /2013 | | 12/10/201 | | | | | |
| PLEASE LIFE ON USE DEFICIE | CHILD DIAGNOS SEIZURE LIKE (SANDIFER'S S WAS HOSPITAL ACTHAR. | ACTIVITY SYNDROME) IZED ON (b) (6 | RELAT H | ED TO GASTI AS NOT BEEN AND PLACE | ROESOPHAGE | AL REFLUX | | | | |
| | 6. Relevant Tests/L | METABOLIC EEG CON | PEC FIRMED | _ | UNCTURE, M | RI, URINE | | | | |
| | | smoking and al | cohol use | e, hepatic/renal dy | Conditions (e.g., vsfunction, etc.) | allergies, | | | | |
| | CHILD BORN 3 | - 4 WEEK | PREMA | TURE. | | | | | | |
| | (b) (6) | AR INFECT | ION. | GIVEN AUGM | ENTIN. | | | | | |
| | 1 | | | | | | | | | |
| | | | | | | | | | | |
| | 1 | | | | | | | | | |
| | | | | | | | | | | |
| | Submission of | | | | | | | | | |

| facilities | | Report# 5 | 1973 | 5.00 | Page | 2 |
|---|--------------|--------------|--------------------------------|----------------------------|---------------------------|----------|
| nd manufacture Y reporting | | mporter Re | port# | | 100 | |
| 18 B | | | | | | |
| C. SUSPECT PR | ODLICTO | 8) | | | | FDA U |
| Name (Give labeled | | | | | | |
| #1 HYLAND'S BA | BY TEET | HING TA | BLETS | | | |
| #2 | | | | | | |
| Dose, Frequency & | | | | py Dates (o (or best e | (If unknown, estimate) | give du |
| #12-3TABS UP | TO TID | INTERM | #1 | | | |
| #2 I. Diagnosis for Use | (Indication) | | #2 | 5 Event | Abated Aft | er Use |
| #1 TEMP RELIEF | | THING P | AIN | Stopp | ed or Dose | Reduc |
| #2 | | | | #1 ' | Yes No | |
| 6. Lot# | 7. Ex | p. Date | | #2 | Yes No | , 🗆 |
| #1A97113 | #1 | | | | Reappeare roduction? | d After |
| #2 | #2 | | | _ #1 □ | Yes No | · 🗆 |
| 9. NDC# or Unique ID 54973-3127-2 | | | | #2 🗌 | Yes No | , |
| 10. Concomitant Med | | ts and The | rapy Date | s (Exclude | treatment o | f event, |
| | | | | | | |
| 2. Common Device N | lame | | - | | | |
| 3. Manufacturer Nam | e. City and | State | | | | |
| | | | | | | |
| 4. Model # | | Lot# | | | 5. Opera | tor of D |
| Catalog # | | Expiration | n Date (n | nm/dd/yyyy | _ Hea | |
| 0 | | Other # | | | Lay | User/P |
| Serial # | | Other # | | | | |
| 6. If Implanted, Give | Date (mm/d | d/yyyy) | 7. If Ex | planted, G | live Date (m | m/dd/y |
| 8. Is this a Single-us | | at was Rep | rocessed | and Reus | ed on a Par | tient? |
| 9. If Yes to Item No. | | me and Add | dress of i | Reprocess | or | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| 10. Device Available | | • | | - | - | |
| Yes No | D 🗌 R | eturned to | Manufactu | rer on: | (mm/de | |
| | D 🗌 R | eturned to | Manufactu | rer on: | | |
| Yes No | D 🗌 R | eturned to | Manufactu | rer on: | | |
| Yes No | o R | eturned to l | Manufactu erapy Dat | rer on: | | |
| Yes No. | o R | eturned to l | Manufactu | rer on: | | |
| Yes No. | o R | eturned to l | Manufactu erapy Dat | rer on: | de treatment | of eve |
| Yes No. 11. Concomitant Med E. INITIAL REP 1. Name and Address | o R | eturned to l | Manufactu erapy Dat | rer on: | OSS | of ever |
| Yes No. 11. Concomitant Med E. INITIAL REP 1. Name and Address | o R | eturned to l | Manufactu erapy Dat | rer on: | de treatment | of ever |
| Yes No. No. No. No. No. No. No. No. | ORTER | eturned to I | Manufactu erapy Dat | rer on: | OSS B 0 5 2 | of ever |
| Yes No. No. No. No. No. No. No. No. | ORTER | eturned to I | Manufacturerapy Date # (b) (6) | rer on: | OSS B 0 5 2 | O14 |
| Yes No. No. No. No. No. No. No. No. | ORTER | eturned to I | Manufacturerapy Date # (b) (6) | rer on: | OSS B 0 5 2 | O14 |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

10023432-02-00-02

| User Facility | | | 2. UF/I | тропег н | teport l | Nun | ise. |
|--|---|---|---------------------------------------|----------------------------------|-------------------|--|---|
| | | orter | | | | _ | |
| 3. User Facility or Impo | orter Name | e/Address | | | | | |
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| | | | | | | | |
| 4. Contact Person | | | 5 | . Phone N | umber | | |
| • | | | | | | | |
| 6. Date User Facility or Importer Became | • | 7. Type of F | Report | | | | f This Report |
| Aware of Event (mm | /dd/yyyy) | nitial | | | ' | | |
| | | Follow | -up#_ | | | | |
| 9. Approximate | 10. Event | Problem Co | des (Re | efer to cod | ing mar | nual |) |
| Age of Device | Patient | | | | | 1 1 | |
| | Code | | | | | - | |
| | Device | | | | | - | |
| | Code | 140 1 2224 | ion Mr. | ere Event | 00000 | 704 | |
| 11. Report Sent to FD/ | 47 | | ion wn Iospital | ere Event | CCUr | | tpatient |
| Yes(mm/dd | (Ayyy) | - - 🗀 | iospitai iome | | _ | | agnostic Facility |
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| 14. Manufacturer Nam | e/Address | <u> </u> | | | 192 | | ,, |
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| 1. Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, | me/Addre | 5. (A)NDA | \# | | 310 | Portion Core | ort Source ock all that apply) eign dy rature assumer alth Professional er Facility mpany presentative |
| 1. Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, IN: 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm.) | me/Addre EWICZ C. STREET CA 90 | 5. (A)NDA | \#)# | | 310 | Portion Corrections Correction | ort Source ock all that apply) eign dy rature assumer alth Professional er Facility mpany presentative tributor |
| 1. Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm. 12/09/2 | me/Addre EWICZ C. STREET CA 90 | 5. (A)NDA | \# | | 310 | Portion Core | ort Source ock all that apply) eign dy rature assumer alth Professional er Facility mpany presentative tributor |
| 1. Contact Office - Na for Devices) EDYTA FRACKII HYLAND'S, INC 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm/ 12/09/2) 6. If IND, Give Protoc | me/Addre EWICZ C. STREET CA 90 | 5. (A)NDA INC | \#)# !# | | 310 | Portion Corrections Correction | ort Source ock all that apply) eign dy rature assumer alth Professional er Facility mpany presentative tributor |
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The public reporting burden for this collection of information has been estimated to average 68 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| CaseID: 10023432 |
|------------------|
| FDA USE ONLY |

| ! | of 10 | |
|---|---|---|
| | H. DEVICE MANUFACTURERS ONLY | |
| ۱ | Type of Reportable Event | 2. If Follow-up, What Type? |
| | Death | Correction |
| ١ | Serious Injury | Additional Information |
| l | Malfunction | Response to FDA Request |
| l | Other: | Device Evaluation |
| | 3. Device Evaluated by Manufacturer? | Device Manufacture Date (mm/yyyy) |
| l | Not Returned to Manufacturer | |
| | Yes Evaluation Summary Attached | 5 to be defined as the second |
| l | No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| l | piovido dode. | Yes No |
| l | 6. Evaluation Codes (Refer to coding manual) | |
| l | Method | |
| | Results - | |
| ١ | Conclusions |]- |
| 1 | 7. If Remedial Action Initiated, Check Type 8 | . Usage of Device |
| ı | Recall Notification | Initial Use of Device |
| l | Repair Inspection | Reuse |
| ı | Replace Patient Monitoring | Unknown |
| | Relabeling Modification/ Adjustment |). If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| - | Other: | |

Received

and / or

FEB 0 4 2014

CDR

OSS

FEB 04 2017

FEB 0 5 2014

11. Corrected Dat

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

10. Additional Manufacturer Narrative

OMB Statement:
"An agency may not conduct or spo and a person is not required to resp to, a collection of information unless displays a currently valid OMB conti number."



PLAINT RECORD



| 100234 | 32-02-00-03 | COM | IPLAINT#: | 2531 | |
|--|--|--|--|---|--|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF CO | | 12/09/13 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | | EM CODE: | BTETT250 | |
| SIZE: | 250 TABLETS | | LOT NO.: | A97113 | |
| REPORTER: (b) (6) | | | | - | |
| ADDRESS: | | | | | - |
| _ | manage of the State of the Stat | | | | |
| CITY: | | STATE: | (b) (6) | | - |
| COUNTRY: USA | | ZIP CODE: | | | |
| (b) (6) PHONE #: | | | | | |
| E-MAIL: | GIVING CHILD 11/20/13 3 TABLETS AT | OFOTHER AND THEN THE NEXT OF | V. I II I ODANI | CANE A TABLET | A FEMILIANES AND |
| STARTED CRYING AND HAVIREFLEX WHICH WAS COMING HAD THESE EPISODES AND IN OFEVER. 11/25/13: WENT SEIZURE LIKE ACTIVITY RELIENDOSCOPY TO CONFIRM. ING TABLETS DURING THIS TO THE HOSPITAL PEDIATR DIAGNOSIS. CHILD IS ON ZAOTHER DAY AND HAS CONNINEUROLOGIST ABOUT THE THE MOTHER THAT IT FE POSELSE. TOLD HER THAT IF EST. | ABLETS 2 TABLETS ABOUT 3 TIMES THAT DAY, ING SPASMS (SHE DESCRIBES IT AS AN EXAGGE GIN CYCLES. THE CYCLES WOULD LAST MAYB MOM TOOK HIM TO THE ER. AT THE ER THEY FIOT THE PEDIATRICIAN WITH A SICK CALL AND SATED TO GASTROESOPHAGEAL REFLUX (SAND SHE WENT HOME AND CHILD WAS HAVING MOFIME (CARIOUS DOSES). ON (D) (G) MOTHER VICE NEUROLOGIST CAME IN AND THEY DID EEG. NTAC AND ACTHAR (FOR SEIZURES). LAST DOSECTED THE INFANTILE SPASMS WITH THE TEET FEETHING TABLETS. CHILD IS BOTTLE FED. WAS SIBLE HER CHILD COULD BE SENSITIVE OR ALL FECT IS A TRANSIENT HOMEOPATHIC EFFECT: OR THE TEETHING TABLETS AND SHE ACCEPTE FOR ADDITIONAL SPACE PLEASE US | ERATED MORO REFLEX). REACHE E A MINUTE AND HAVING 6 OR 7 E DUND AN EAR INFECTION AND GASHE VIDEOTAPED THE EPISODE AI IFER'S SYNDROME) BUT SHE HAS ECYCLES UP TO 8 PER DAY. MOWENT BACK TO ER, AND THE DOC AND CONFIRMED 'INFANTILE SPASE OF TEETHING TABLETS WAS 12. HING TABLETS. LAST SPASM WAS PREMATURE BY 3 – 4 WEEKS. (6 ERGIC TO THE TEETHING TABLET THEN THE SYMPTOMS SHOULD RID. PAID \$10. | S OUT ARM: PISODES. (I VE HIM AN A: NOT FOLLO THER CONT TOR SAID TI SMS". THIS \$204/13. MO' S ON 12/04/1 DUR PHARM S OR SYMP' ESOLVE AFT | S AND CRYS OUT 10) (6) ANTIBIOTIC (AUGM RSE PRACTITIONER RIVED UP WITH HAV INUED TO GIVE CH HAT THE CHILD W IS RECOGNIZED U THER HEARD ABOU 3. SHE IS GOING IACIST, EDYTA FR TOMS COULD BE I TER PRODUCT IS I | LIKE A STARTLE WOKE UP AND IENTIN). THERE WAS R SAID IT WAS A VING AN HILD MORE TEETH- OULD BE ADMITTED INDER THE EPILEPSY UT THE RECALL THE TO TALK TO THE ACKIEWICZ, TOLD JUE TO SOMETHING |
| | | | | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (N) (CIRCLE ONE) | PRODUCT BEING RETU | RNED FOR | INSPECTION: | Y (CIRCLE ONE) |
| | (* / | DATE REQUESTED P | RODUCT B | E RETURNED: | |
| | | Dà | | . TAG ISSUED: | Y (CIRCLE ONE) |
| SECTION II: IN | IVESTIGATION | D A | ILT NODO | | |
| | | | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION R | EPORT. | | | |
| | RDED TO PHARMACIST / NURSE FOR EVALUA | | 12/09/13 EDYTA F | RACIEWICZ | |
| SECTION III; | CORRECTIVE ACTION: | | | | |
| | | 763 | | | |
| (6) | REFUND REQUEST TOTALING \$ 15.79. 12/27/ | (6) MAILED REFUND CHECK | (#511188] | TOTALING \$ 15.79 | ON ARTICLE # |
| 70081830000486288153. | | | | | |
| CORRECTIVE ACTION(S) | COMPLETED BY: (b) (6) | | DATE: | 12/10/13 & 12/ | 27/13 |
| SECTION IV: | DVERSE EVENT REPORTS | | AE #: | 1521 | ി?ര |
| ADVERSE EVENT SERIOU | s: (Y) N | | | | - OO |
| ADVERSE EVENT REPORT | TED ON: 12/09/13 | BY: ED | YTA FRAÇK | KIEWICZ | FEB 0 5 2014 |
| SECTION V: | Ω . | 11 | FEB 0 | A ALCO | |
| REVIEWED BY MANAGEMI | ENT BY: | | DATE: | 31-7 | 3-14 |
| BY: | The Vicin | | DATÉ: * | 01-2 | 2-13-EJ |
| | QA / QC DIRECTOR | | - | 01-23 | 3-14 for 01-1 |

cc: QA / QC Packaging Production Shippina / Receiving 01-15-14 TON 171-22-14 Form # VD1



10023432-02-00-04



CaseID:17002591322127 201470124170 1834 000486 8153.

December 10, 2013

(b) (6)

Received FEB 0 4 2014 CDR

Dear (b) (6

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$ 14.39. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach

President

Enc: Refund Check - \$ 15.79

DSS FEB 0 5 2014

FEB 04 2014

MPLAINT RECORD

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| 1 | Case nd 1 | 10023432 2)17/13 JNAW Hylands 7001 |
|----|--------------|--|
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| #- | 2521 | 862 |

| 1 1 41 44 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 | 023432-02-00-06 | | | 06 |
|--|--|--|---|---|
| 100 | 023432:02 00:00 | COMPLAINT #: | 2531 | o |
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 12/09/13 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT250 | |
| SIZE: | 250 TABLETS | LOT NO.: | A97113 | |
| REPORTER: | (b) (6) | | | |
| ADDRESS: | - | | | |
| | - | | | |
| CITY: | | STATE: _(b) (6) | | |
| COUNTRY: | USA (b) (6) | ZIP CODE: | | |
| PHONE #: | | | | |
| E-MAJL: | (b) (6) GIVING CHILD 11/20/13 3 TABLETS AT BEDTIME A | | | |
| SEIZURE LIKE AC' ENDOSCOPY TO (ING TABLETS DUF TO THE HOSPITAI DIAGNOSIS. CHIL OTHER DAY AND NEUROLOGIST AF THE MOTHER TH/ ELSE. TOLD HER | ODES AND MOM TOOK HIM TO THE ER. AT THE ER THEY FOUND AN I AT 3. WENT-TO-THE PEDIATRICIAN WITH A SICK GALL AND SHE VIDEO TIVITY RELATED TO GASTROESOPHAGEAL REFLUX (SANDIFER'S SYS CONFIRM. SHE WENT HOME AND CHILD WAS HAVING MORE CYCLES RING THIS TIME (CARIOUS DOSES). ON (D) (6) MOTHER WENT BACK. L. PEDIATRIC NEUROLOGIST CAME IN AND THEY DID EEG AND CONFIRM STATE AND ACTHAR (FOR SEIZURES). LAST DOSE OF TEE HAS CONNECTED THE INFANTILE SPASMS WITH THE TEETHING TAB BOUT THE TEETHING TABLETS. CHILD IS DOTTLE FED. WAS PREMATITED FOR SIBLE HER CHILD COULD BE SENSITIVE OR ALLERGIC TO AT THAT IF EFFECT IS A TRANSIENT HOMEOPATHIC EFFECT THEN THE REFUND FOR THE TEETHING TABLETS AND SHE ACCEPTED. PAID \$1 FOR ADDITIONAL SPACE PLEASE USE REVER. | TAPED THE EPISODE AND THE NUR: NOROME, BUT SHE HAS NOT FOLLO S UP TO B PER DAY. MOTHER CONTI IK TO ER, AND THE DOCTOR SAID TH FIRMED "INFANTILE SPASMS". THIS I: THING TABLETS WAS 12/04/13. MOT LETS. LAST SPASM WAS ON 12/04/13 TURE BY 3 - 4 WEEKS. OUR PHARM! THE TEETHING TABLETS OR SYMPT SYMPTOMS SHOULD RESOLVE AFTI | SE PRACTITIONE MED UP WITH HA NUED TO GIVE CI INT THE CHILD W S RECOGNIZED L HER HEARD ABO S. SHE IS GOING ACIST, EDYTA FR OMS COULD BE I ER PRODUCT IS I | R SAID IT WAS A VING AN HILD MORE TEETH- OULD BE ADMITTED INDER THE EPILEPSY UT THE RECALL THE TO TALK TO THE ACKIEWICZ, TOLD |
| | | | | |
| PRODUCT RECEINSPECTION: | EIVED FOR Y N F | RODUCT BEING RETURNED FOR | INSPECTION: | Y (N) |
| | ,, | DATE REQUESTED PRODUCT BE | PETLIDNED. | (CINOLE ONE) |
| | | | - | $\overline{}$ |
| | | UPS CALL | TAG ISSUED: | Y (CIRCLE ONE) |
| | | | | |
| SECTION III | INDICEPTICATION | DATE PRODUC | TRECEIVED: _ | |
| SECTION II: | INVESTIGATION | | , | |
| INVESTIGATION | N: PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | | | | |
| ADVERSE EVEN | NT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON | 12/00/42 | | |
| | NT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY | | RACIEWICZ | <u></u> |
| SECTION III: | CORRECTIVE ACTION: | · EDITARI | VICIEVICZ | |
| | | | | · . |
| 12/10/13 ^{(b) (6)} P | REPARED REFUND REQUEST TOTALING \$ 15.79. | | | |
| | | | | |
| CORRECTIVE A | ACTION(S) COMPLETED BY: (b) (6) | DATE- | 12/10/13 | |
| | | | 127070 | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: | 1521 | |
| ADVERSE EVE | INT SERIOUS: (Y)/ N | | | Dec |
| ADVERSE EVE | NT REPORTED ON: 12/09/13 | BY: EDYTA FRACKI | EWICZ | -00 |
| SECTION V: | 105 | 200 | | FEB 0 5 2016 |
| RÉVIEWED BY | MANACEMENT BY: | DATE: | 12-17-1 | |
| BY: | 4 MIL Tham | DATE | 12-17 | -13 |
| | OA / OC DIRECTOR | DATE: _ | 1.5 [] | ~ |

FEB 04 2014

CaseID: 10023432





SAE-0056-2013

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot #A97113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All but 7 units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A97113 was manufactured using bulk lot # 120608. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # A97113. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 120608 was tested for total Atropine and Scopolamine and the results were with in specification of $z_{(k)}^{(k)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0692-2013) has been received for Hyland's Baby Teething Tablets lot # A97113. Both complaints were reviewed based on the current information available it does not appear that they are related.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A97113.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

Date

988 FEB 0 5 2014

Page 1 of 1



10023432-02-00-08



CaseID: 10023432

SERIOUS ASTÉRSE EVENT DATA FORM

| AE #: | COMPLAINT #: _2521 |
|--|--|
| SECTION I: PATIENT INFORMATION (IF DIFFE | ERENT FROM REPORTER ON FORM VD1) |
| NAME: (b) (6) | |
| ADDRESS: | , |
| 1 | |
| CITY: | STATE: (b) (6) |
| COUNTRY: USA | ZIP CODE: |
| (b) (6) PHONE #: | ZII GODE. |
| E-MAIL: | |
| | |
| SECTION II: PACKAGING INFORMATION: | |
| AFFIX PACKAGING LABEL HERE | AFFIN CODY OF COMME |
| ALTIAL AGIAGING EABLE NEAL | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY |
| | PANELS) |
| Indications beauth more and a second second warnings to set me wice | Getting Tablets |
| Indications bearen's specific to the property of the control of th | |
| pleasant of the part of the pa | 1250 |
| PROPERTY OF THE PERSON THEOPEN PARTY OF THE PERSON THE | |
| more a mount and a polets areas out a series and a | Feething Tablets Service Servi |
| Finance CLUBA PCINODO BUPE GRADADA PARA (GRA GRADADA PARA (GRADADA PARA PARA PARA PARA PARA PARA PAR | Security from Salarian (Salarian Salarian Salari |
| Aprille (Full file Full fil | The Contract |
| ADMÉS DE LACTION 45 COLONIO A DEL ET S MANAGEMENT DE LACTION DE LA | |
| ERFERING CONTROL | |
| | |
| SECTION III: CORRECTIVE ACTION: | |
| SOURCE IN ACTION. | |
| | |
| | |
| | |
| COPPECTIVE ACTION(C) COMOLETED DV | |
| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: |
| SECTIONING | Dea |
| SECTION IV: | 7200. |
| REVIEWED BY MANAGEMENT BY | DSS DATE: 12-17-13B 0 5 201 |
| 5/110 1 | 6 |
| BY: QA/QC DIRECTOR | 10ML DATE: 12-17-13 |

For the by user-facilities, ers, distributors and manufacturers or MANDATORY reporting

| Casel |): 010024 See | 2521, Expires 12 OMB statement on re |
|----------------------|------------------|---|
| Mfr Report # 549M3 | page | 2 |
| UF/Importer Report # | | |

| | See OMB statement on | | | | |
|----------------------|----------------------|------|--|--|--|
| Mfr Report # 549M3 | page | 98 2 | | | |
| UF/Importer Report # | | | | | |
| | | | | | |

FDA Use

| FURWI FUA 35U | UA (6/1U) | | | , | Page | | | |
|--|----------------------------|-------------|------------------|---------------------------------------|-------------------|--|--|--|
| A. PATIENT INF | ORMATIO | N | | | | | | |
| Patient Identifier (b) (6) | 2. Age at Tim of Event: | 1 | Years | 3. Sex | 4. Weight | | | |
| | or Date | | | Female | or lbs | | | |
| In confidence | of Birth: | (b) (6) | | ✓ Male | kgs | | | |
| B. ADVERSE E | VENT OR F | RODU | CT PROBLE | M | | | | |
| 1. Adverse Event and/or Product Problem (e.g., defects/malfunctions) | | | | | | | | |
| Outcomes Attribu (Check all that app | | e Event | | | | | | |
| Death: | | | Disability | or Permanent Da | mage | | | |
| ✓ Life-threatening | (mm/dd/yyy ng | y) | Congenit | al Anomaly/Birth [| Defect | | | |
| Hospitalizatio | n - initial or pro | longed | Other Ser | ious (Important M | fedical Events) | | | |
| Required Inte | rvention to Pre | vent Perm | | nt/Damage (Devic | | | | |
| 3. Date of Event (mi | | | 4. Date of Thi | s Report (mm/do 01/16/2014 | | | | |
| 5. Describe Event of | 07/2014 | | L | 01/10/201 | , | | | |
| | | | _ | | | | | |
| HAD A SEIZURE EYES ROLLED U | | e nevi | | IS EYES OPE | NED AND LASTED | | | |
| AROUT 2 MINUT | | | | HAD AN EEG | | | | |
| (1) | NO RESULTS | AVAII | ABLE). | | | | | |
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| | | | | | | | | |
| 6. Relevant Tests/L | aboratory Dat | a, Includir | ng Dates | | | | | |
| EEG RESUL | TS PENDIN | G. | | | | | | |
| | | | | | | | | |
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| | | | | | | | | |
| 7. Other Relevant F | listory, Includ | ing Preex | isting Medical (| Conditions (e.g., or sfunction, etc.) | allergies, | | | |
| race, programoy, | y and di | | | | | | | |
| NONE | | | | | | | | |
| 1 | | | | | | | | |
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| 1 | | | | | | | | |

| 1. Name (Give labeled | strength & | mfr/labeler) | n r merc | | | |
|------------------------|-------------|---------------|--------------|------------|---------------------------|---------------|
| #1 HYLAND'S B | ABY TEET | THING TA | ABLETS | | | |
| #2 | Poute He | ad | 3 Thorn | ny Daton | (If unknown, g | nive due |
| 2. Dose, Frequency 8 | | | from/to | o (or best | | are dure |
| #12 TABS HS X | k 1 DOSE | <u> </u> | #1 | | | |
| #2 | | | #2 | | | |
| Diagnosis for Use | | | | | Abated Afte ed or Dose | |
| #1 TEMP RELIE | F TEETHI | ING PAIN | | #1 🔲 | | ✓ A |
| #2 | | | | #2 | Yes No | |
| S. Lot# | 1 | cp. Date | | | Reappeared | After |
| #1B06713 | #1 | | | | roduction? | |
| #2 | #2 | | | #1 🔲 | Yes No | ✓ A |
| 54973-3127- | | | | #2 | Yes No | |
| 0. Concomitant Med | | -4 | P-4 | (Eugland) | ten nim ani -f | |
| 2. Common Device N | | l State | | | | |
| | | | | | | |
| 4. Model # | | Lot# | | | 5. Operato | or of De |
| Catalog # | | Evnication | on Date (mi | m/ddhaaa | | h Profes |
| Anthropia a | | -April acid | (1111 | | Lay | Jser/Pati |
| Serial # | | Other# | | | Other | r: |
| 6. If Implanted, Give | Date (mm/c | id/yyyy) | 7. If Exp | lanted, G | ive Date (mn | n/dd/yyy |
| 8. Is this a Single-us | | at was Rep | rocessed | and Reus | ed on a Patio | ent? |
| | 8 Enter Na | me and Add | drass of D | nrocess | or | |
| 9. If Yes to Item No. | o, enter Na | me and Add | uress of Re | shrocess: | o, | |
| | | | | | Mae | s. |
| 10. Device Available | for Evaluat | tion? (Do no | ot send to F | DA) | USS | <u> </u> |
| Yes N | o | teturned to h | Manufacture | er on: | N 302 | OIA |
| 11. Concomitant Me | | | | | (11111-000- | of event) |
| | | | | | L |)S |
| E. INITIAL REP | ORTER | | | | | |
| Name and Address | | Phon | e #(b) (6) | | | . 0 () |
| (b) (6) | | - | | | | 1 1 1 1 1 1 1 |
| | | | JAN 2 | 9 201 | 4 | |
| 0 HP/ 5 1 | -10 10 0 | | | | Initial Repo | rter Ale |
| 2. Health Profession | | cupation | | " | Report to F | DA |
| Yes ✓ No | NA NA | | | | Yes | No [|

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 5

| | | | .1157) | - 6 | I. DEVICE MAN | UFACTURERS ONL | Υ | |
|---|----------------|------------------------------|---|-----|--------------------|---------------------------|-------------------|---|
| Check One | | 2. UF/Importer R | eport Number | 1. | Type of Reportable | Event | 2. If Follow- | up, What Type? |
| User Facility | Impor | rter | | | Death | | Cor | rrection |
| User Facility or Impo | orter Namel | Address | | | Serious Injury | | □ Adv | ditional Information |
| . User racincy or impo | 0,10, 14411101 | nuuruss | | | Malfunction | | | |
| | | | | | | | | sponse to FDA Reque |
| | | | | | Other: | | Dev | vice Evaluation |
| | | | | 3. | Device Evaluated b | y Manufacturer? | 4. Device M | lanufacture Date |
| | | | | | _ | to Manufacturer | (mm/yyyy | |
| Contact Person | | 5. Phone N | ımher | | | aluation Summary Attached | . | |
| . Contact Person | | J. Priorie iv | umper | | | • | L | for Single Use? |
| | | 7.7 | O Data of This Data of | | No (Attach pa | ge to explain why not) or | S. Labeled | or single use : |
| Date User Facility or importer Became | | 7. Type of Report | 8. Date of This Report (mm/dd/yyyy) | | · | | Ye | s No |
| Aware of Event (mm | n/dd/yyyy) | nitial Initial | | _ | | | <u></u> | |
| | | Follow-up # | | 6. | Evaluation Codes | (Refer to coding manual) | | |
| 9. Approximate | 10. Event F | Problem Codes (Refer to codi | ng manual) | | Metho | od - | - | - |
| Age of Device | D-tit [| | | | | | | |
| | Patient Code | - | - | | Resul | ts - |]- | |
| | Device | | | | | | | |
| | Code _ | | | | Conclusion | ns | | |
| 11. Report Sent to FDA | A? | 12. Location Where Event | Occurred | 7. | If Remedial Action | Initiated, Check Type | 8. Usage of Dev | vice |
| Yes | | Hospital | Outpatient | | Recall | Notification | Initial I | Use of Device |
| (mm/dd | l/yyyy) | Home | Diagnostic Facility | | Repair | Inspection | Reuse | |
| No | | Nursing Home | Ambulatory Surgical Facility | | Replace | Patient Monitoring | Unkno | wn |
| 13. Report Sent to Mar | nuracturerr | Outpatient Treatme | | | | Modification/ | 9. If action repo | orted to FDA under |
| Yes | Manael | Facility | | | Relabeling | Adjustment | 21 USC 360i(| (f), list correction/ orting number: |
| No (mm/dd | ******* | Other: | (Specify) | | Other: | | Tellioval repo | nung number. |
| 14. Manufacturer Nam | 0/A ddr000 | | (Specily) | | | | `] | |
| 14. Wallulacturer Hall | iciAddicaa | | | - | | | | |
| | OT 11055 | | | | | | | |
| G. ALL MANUFA | | | 2. Phone Number | | | | | |
| for Devices) | me/Address | (and Manufacturing Site | 2. Phone Number | | | | | |
| | | | 310-768-0700 | | | | | |
| EDYTA FRACKIE | | | 3. Report Source (Check all that apply) | | | | | |
| HYLAND'S, INC 154 W. 131ST | | | Foreign | | | | | |
| LOS ANGELES, | | 61 | Study | | | | | |
| Los inicales, | | | Literature | | | | | |
| | | | t3 | | | | | |
| | | | Consumer | | | | | |
| | | | Health Professional | | | | | |
| 4. Date Received by | | 5. | User Facility | | | | | |
| Manufacturer (mm/c | | (A)NDA # | Company Representative | | | | | |
| 01/10/2 | 1014 | IND# | Distributor | | | | | |
| 6. If IND, Give Protoco | oi # | | Other: | | | | | |
| | | STN# | | | | | | |
| 7 Type of Penort | | PMA/ | | 11 | | | | |
| Type of Report (Check all that apply | 1) | 510(k) # | | | | | | |
| 5-day 30-d | lay | Combination Product Yes | | | | | | |
| 7-day Perio | - | | | | | | | - |
| ☐ 10-day 🗸 Initia | | Pre-1938 Yes | | | | | | DSS |
| | ow-up # | OTC Product Yes | | | | | | |
| 9. Manufacturer Repo | | 8. Adverse Event Term(s) | 1 | 1. | | | | DSS JAN 802 |
| | | SEIZURE | | | | | | ~ 1/2 |
| 54973 AE # 15 | 120 | | | | | | Tran A | TA GALF |
| | | | | | | | JAN Z | 9 2014 |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

OMB Statement:
"An agency may not conduct or spc and a person is not required to resc to, a collection of information unless displays a currently valid OMB cont number."



OMER COMPLAINT RECORD



| 10024252-01-0 | DO-03 | COMPLAINT #: | 2535 |
|---|--|---|--|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 01/10/2014 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 |
| SIZE: | 135 TABLETS | LOT NO.: | B06713 |
| REPORTÉR:(b) (6 | 6) | | - A - 11 / F A |
| ADDRESS: | | | RECEIVED |
| (b) (6 | 6) | (b) (6) | JAN 2 9 2014 |
| CITY: | | STATE: | JAN & V ZOII |
| COUNTRY: US/ | 6) | ZIP CODE: | CDR |
| PHONE #: E-MAIL: | CELL PHONE | | |
| NATURE OF COMPLAINT: LIKE HIS EYES OPENED A FOLLOWED UP WITH SOI LIVES 6 MONTHS OUT OF | CHILD HAD A SEIZURE ON (b) (6) UNDER THE TONGUE. NO VACCINATI AND EYES ROLLED UP INTO HIS HEAD AND HE W ME TESTS. HAD AN EEG DONE ON (b) (6) BUT F THE YEAR. PAID \$8 PURCHASED IN (U) R ON 011014 FOR US ADDRESS AND LEFT A MESSA HER MESSAGE. ALSO SENT AN E-MAIL TO CUSTOME FOR ADDITIONAL SPACE PLEASE USE F | IONS AROUND THAT TIME. NO FEVER, N /ENT STIFF. LASTED ABOUT 2 MINUTES NO RESULTS AS OF YET. SEIZURE OCC WANTS A REFUND. PRESENTLY FA GE ON CELL PHONE. TRIED CALLING THRE R REQUESTING THAT SHE SEND HER U. S. | NO ILLNESS. SEIZURE LOOKED . WENT TO THE FR AND CHARLED IN (6) WHERE FAMILY AMILY IS LIVING IN (b) (6) ET TIMES ON 01/14/14 BUT THERE WAS ADDRESS FOR A REFUND. |
| PRODUCT RECEIVED FO INSPECTION: | OR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | (CIRCLE ONE) |
| salis e salis en ales ent | | | TAG ISSUED: (CIRCLE ONE) |
| SECTION II: | INVESTIGATION | DATE PRODUC | CT RECEIVED: |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REP | PORT | |
| INVESTIGATION. | PLEASE SEE ATTACHED INVESTIGATION INC. | O(V) | |
| | | | N TO THE RESERVE OF THE PARTY O |
| | | | |
| ADVERSE EVENT FORW | VARDED TO PHARMACIST / NURSE FOR EVALUAT | TON ON : 01/10/20 | 114 |
| ADVERSE EVENT FORW | VARDED TO PHARMACIST / NURSE FOR EVALUAT | ION BY: EDYTA | FRACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | - |
| | | | |
| CORRECTIVE ACTION(S | S) COMPLETED BY: | DATE: | · • |
| SECTION IV: | ADVERSE EVENT REPORTS | AE# | 1525 |
| ADVERSE EVENT SERIO | ous: | | |
| ADVERSE EVENT REPO | | BY: EDYTA FRACI | KIEWICZ PC |
| SECTION V: | | 1.1 | UO |
| REVIEWED BY MANAGE | EMENT BY: | JOHN DATE | 01-20-14 JAN 8 |
| | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | ` | 01-17-14 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

Individual Case Safety Report

10024252-01-00-04



Serious Adverse Event SAE-0002-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B06713, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B06713 was manufactured using bulk lot # 120917. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B06713. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 120917 was tested for total Atropine and Scopolamine and the results were with in specification of \leq (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B06713. One other SAE (130, lot #B06813) has been reported related to the bulk lot (lot # 120917) used to manufacture the lot indicated in this complaint. Both instances indicate similar reactions. Although two complaints of a similar nature have been received for lots manufactured using bulk lot # 120917 these complaints constitute about a (b) (4) pf each lot. We will continue to monitor complaints and if additional complaints are received on this lot or associated bulk lot they will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B06713.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

Date

1/17/14

SSU Soa NAN

Page 1 of 1

CaseID: 10024252



CaseID: 10024252

JUS ADVERSE EVENT DATA FORM

| AE #:152 | 25 | COMPLAINT #: 2535 |
|----------------------|---|---|
| SECTION I: | PATIENT INFORMATION (IF DIFFE | RENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| DDRESS: | | |
| | (b) (6) | (b) (6) |
| CITY: | LIGA | STATE: |
| COUNTRY: PHONE #: | USA (b) (6) | ZIP CODE: |
| E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | |
| | FFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE |
| | THAT ACKNOWN EXPERIENCE | (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| | | |
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| , | | 7667 - 100 ± 100 |
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| | Con an analysis and an analysis | |
| SECTION III: | CORRECTIVE ACTION: | |
| | | • |
| | | |
| | | |
| CORRECTIVE | ACTION(S) COMPLETED BY: | DATE: |
| | | 4 |
| SECTION IV: | | DS DS |
| REVIEWED BY | MANAGEMENT BY: | DATE: 01-20-14AN 8 |
| 3Y: | Peux Main | DATE: 01-17-14 |
| , | QA / QC DIRECTOR | DATE: |

or use by user-facilities distributors and manufactu AANDATORY reporting

FGASSELD OMEOO 237(2)23, Expires 12/: See OMB statement on reporter Report #

Page 1 of 5

4. Initial Reporter Als Report to FDA Yes No

FEB 25 2014

| F | ORM FDA 3500A (6/10) | | , age i | o | |
|---------------|--|---|---------------|-------------------------------------|---------------|
| | A. PATIENT INFORMATION | | | C. SUSPECT PRODUC | |
| | Patient Identifier 2. Age at Time | 3. Sex | 4. Weight | 1. Name (Give labeled strength | |
| (| of Event: 15 | Months Female | Ibs | #1 HYLAND'S BABY TE | ETHING T |
| | Date | ✓ Male | or | #2 | |
| l | In confidence of Birth: | | kgs | 2. Dose, Frequency & Route U | lsed |
| | B. ADVERSE EVENT OR PRODUC | TPROBLEM | | #13 TABLETS 2X ON | 1/28/14 |
| - 1 | 1. 🕢 Adverse Event and/or 🗌 Proc | duct Problem (e.g., defects/malf | ınctions) | | |
| | Outcomes Attributed to Adverse Event (Check all that apply) | | | #2 4. Diagnosis for Use (Indication | n) |
| | Death: | Disability or Permanent Da | mage | #1 TEMP RELIEF TEET | |
| l | (mm/dd/yyyy) / Life-threatening | Congenital Anomaly/Birth I | Defect | | |
| - 1 | Hospitalization - initial or prolonged | Other Serious (Important N | | #2 | 5 . D.t. |
| | Required Intervention to Prevent Perma | anent Impairment/Damage (Devic | es) | -05110 | Exp. Date |
| | 3. Date of Event (mm/dd/yyyy) | 4. Date of This Report (mm/do | | #1B26113 #1 | |
| | 01/28/2014 | 02/03/201 | 1 | #2 #2 | 2 |
| | 5. Describe Event or Problem | | | 9. NDC# or Unique ID | |
| | SON HAD A SEIZURE AT MIDNIGH | T WHEN HE WAS ASLEED | BESIDE | 54973-3127-3 | |
| | HIS MOTHER. IT LASTED 5 MNU | | | 10. Concomitant Medical Prod | ducts and T |
| | AND "IT TOOK A WHILE FOR HIM | TO COME OUT OF IT". | HE | TYLENOL AT 8 PM. | |
| | TURNED PURPLE. PARENT CALLE BROUGHT HIM TO THE HOSPITAL. | D 911 AND AN AMBULAN | ICE I | | |
| ž | bioodiii iiiii 10 iiib iiib iiib | | | | |
| USE BLACK INK | | | 1 | D. SUSPECT MEDICAL | L DEVICE |
| Ä | | | | 1. Brand Name | |
| BI | | | - | 2. Common Device Name | |
| SE | · | | l | 2. Common Device Name | |
| 20 | | | | 3. Manufacturer Name, City a | nd State |
| OR | | | | | |
| PLEASE TYPE | | | 1 | 4. Model # | Lot# |
| F | | | | | <u> </u> |
| SE | | RECEIVE | ED | Catalog # | Expira |
| ΞĀ | | | | Serial # | Other |
| Ы | | FE RAF, CAF | IVEL |) [| |
| | | | | 6. If Implanted, Give Date (mr | m/dd/yyyy) |
| | 6. Relevant Tests/Laboratory Data, Includir | ng Dates | 5 2014 | 8. Is this a Single-use Device | that was R |
| | | STS NEGATIVE | | Yes No | , alat was it |
| | CHILD WAS DIAGNOSED AS HAVI | NG HAD A SETZUE | SENT | 9. If Yes to Item No. 8, Enter | Name and A |
| | HOME TO FOLLOW-UP WITH HIS | | THE CHAIL | | |
| | | | 0007777 | | |
| | HOSPITAL GAVE CHILD IBUPROF | | | 10. Device Available for Eval | uation? (Do |
| | 111111111111111111111111111111111111111 | • | | Yes No | Returned t |
| | · · | | | | |
| | | | | 11. Concomitant Medical Pro | ducts and |
| | Other Relevant History, Including Preexi race, pregnancy, smoking and alcohol use, | isting Medical Conditions (e.g., hepatic/renal dysfunction, etc.) | allergies, | | |
| | CHILD HAD A LOW GRADE FEVER | OF 100.6F. PRIOR T | O THE | | |
| | SEIZURE CHILD WAS GIVEN TYLE BABY TEETHING TABLETS AT 10 | | | E. INITIAL REPORTER | |
| | PRIOR CHILD HAD BEEN RESTLES | | | Name and Address | Ph |
| | | YLENOL FOR THE TEETH | | 1 | √ ∟ |
| | BEFORE WITH NO SYMPTOMS. HIS MONTHS AGO, AND HAE HAD NO | | | (b) (6) | |
| | PRE-EXISTING CONDITIONS. | | | | |
| | | | | | |
| | | | | | |
| | Submission of a report does not co | nstitute an admission the | t medical | 2. Health Professional? 3. 0 | Occupation |

| | | | | | FDA | se |
|---------------------------------|---------------|---------|-----------|---------------|-----------------------------|----------|
| C. SUSPECT PRODU | | | | | | |
| Name (Give labeled strenger) | - | | | | | |
| #1 HYLAND'S BABY | TEETHING | TAB | LETS | | | |
| #2 | | | | | | |
| 2. Dose, Frequency & Rou | te Used | | | | unknown, give de | urai |
| #1 3 TABLETS 2X O | N 1/28/1 | 4 | #1 | (or best es | umate) | |
| | | | | | | _ |
| #2 | -#1 | | #2 | E Event ! | Abated After Use | _ |
| 4. Diagnosis for Use (Indic | • | 12 TAT | | | d or Dose Reduc | |
| #1 TEMP RELIEF TE | ETHING F | AIN | | #1 🗌 Ye | es No 🗸 | Ar |
| #2 | | | | #2 Ye | es No N | Do |
| 6. Lot# | 7. Exp. Dat | e | | | | -Af |
| #1B26113 | #1 | | | | Reappeared Afte duction? | r |
| #2 | #2 | | | #1 🗌 Y | es No 🗸 | VI Dr |
| 9. NDC# or Unique ID | | | | l | | <u></u> |
| 54973-3127-3 | | | | #2 Y | es No | A |
| 10. Concomitant Medical F | Products and | d Ther | apy Dates | (Exclude t | reatment of event |) |
| TYLENOL AT 8 PM. | | | | | | |
| TIBEROD AT 0 PM. | | | | | | |
| | | | | | | |
| | | 0= | | | *** | _ |
| D. SUSPECT MEDIC 1. Brand Name | AL DEVI | CE | | | | |
| 1. prand Name | | | | | | |
| 2. Common Device Name | | | | | | |
| 3. Manufacturer Name, Cl | ty and State | | | | | |
| , | • | | | | | |
| | | | | | E 0 | _ |
| 4. Model # | Lot | # | | | 5. Operator of I | |
| Catalog # | Exp | iration | Date (mi | m/dd/yyyy) | Health Pro | |
| - | | | | | Lay User/F | ati |
| Serial # | Ott | her# | | | Other: | |
| O Klassiania Cha Bata | (mm (dd4 | 4 | 7 H Eve | lanted Ch | ve Date (mm/dd/y | = |
| 6. If Implanted, Give Date | (mm/aa/yyyy | 0 | /. IT EXP | nanted, Gr | re Date (mm/ou/y | yyy |
| 8. Is this a Single-use Dev | rice that was | s Repr | ocessed | and Reuse | d on a Patient? | _ |
| Yes No | | | | | | _ |
| 9. If Yes to Item No. 8, En | ter Name an | d Add | ress of R | eprocesso | r | |
| | | | | | | |
| | | | | | | |
| 10. Device Available for E | valuation? | Do not | send to F | DA) | | _ |
| Yes No | | | anufactur | | | |
| | | | | - (Contout | (mm/dd/yyyy) | |
| 11. Concomitant Medical | Products an | id The | rapy Date | s (EXCIUDE | reaument of eve | nt) |
| | | | | | | |
| | | | | | | |
| E. INITIAL REPORT | ER | | (b) (c) | | | |
| 1. Name and Address | | Phone | # (b) (6) | | DSS FEB 26 20 | |
| | ۱ ۱ | | | | | |
| (b) (6) | | | | , | -EB 2 6 21 | 11 |
| | | | | | U f.(| 115 |

Yes V No

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Page 2 of 5

ly)

| Cas | CaseID: 10027923 | | | | |
|--|--|--|--|--|--|
| | FDA USE ONLY | | | | |
| : 5 | | | | | |
| | | | | | |
| H. DEVICE MANUFACTURERS ONLY | | | | | |
| Type of Reportable Event | 2. If Follow-up, What Type? | | | | |
| Death | Correction | | | | |
| Serious Injury | Additional Information | | | | |
| Malfunction | Response to FDA Reques | | | | |
| Other: | Device Evaluation | | | | |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date | | | | |
| Not Returned to Manufacturer | (mm/yyyy) | | | | |
| Yes Evaluation Summary Attached | | | | | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? | | | | |
| provide code: | ☐ Yes ☐ No | | | | |
| | | | | | |
| 6. Evaluation Codes (Refer to coding manual) | | | | | |
| Method - |]-[| | | | |
| | | | | | |
| Results | | | | | |
| Conclusions | | | | | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device | | | | |
| Recali Notification | Initial Use of Device | | | | |
| Repair Inspection | Reuse | | | | |
| Replace Patient Monitoring | Unknown | | | | |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: | | | | |
| Other: | | | | | |
| | | | | | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Da | | | | |
| | | | | | |
| | | | | | |
| , | | | | | |
| <u>.</u> | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| . Check One | | | 2. UF/In | nporter R | eport Number |
|--|--|---|--|------------------------------|---|
| User Facility | Impo | rter | | | |
| . User Facility or Impo | orter Name | Address | | | |
| . User racinty of impo | orter Harrier | raul 699 | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| . Contact Person | | | 5. | Phone No | ımber |
| | | | | | |
| | | | | | O Detactor: |
| Date User Facility of Importer Became | r [| 7. Type of I | Report | | 8. Date of This Report (mm/dd/yyyy) |
| Aware of Event (mm | n/dd/yyyy) | Initial | | | , |
| • | | | | | |
| | | Follow | -up# | | |
| 9. Approximate | 10. Event | Problem Co | des (Re | fer to codi | ng manual) |
| Age of Device | Patient [| | | | |
| | Code | | - | | - |
| | Device | | = | | |
| | Code | | _ - | |]-[|
| 14 Panert 0 | | 10 1 | tion William | re Event | Occurred |
| 11. Report Sent to FD/ | A. | | | " = FAGU(| |
| Yes | | | lospital | | Outpatient Diagnostic Facility |
| No (mm/do | <i>\(\forall yyyy\)</i> | | lome | | Ambulatory |
| | nufact | ┧ □ ν | Nursing H | lome | Surgical Facility |
| 13. Report Sent to Ma | . ru ideturer | ' = | _ | it Treatme | |
| Yes | | | acility | | |
| (mm/do | 1/уууу) | | Other: | | |
| No | | ⊥ ' ` | | | (Specify) |
| ∐ No | | | | | |
| No 14. Manufacturer Nam | ne/Address | | | | |
| ∐ No | ne/Address | | | | |
| ∐ No | ne/Address | | | | |
| ∐ No | ne/Address | | | | |
| ∐ No | ne/Address | | | | |
| ∐ No | ne/Address | | | | |
| No | | | | | |
| ∐ No | | | | | |
| G. ALL MANUEA | ACTURE | RS | ufacturin | ng Site | 2. Phone Number |
| 14. Manufacturer Nam | ACTURE | RS | ufacturir | ng Site | 2. Phone Number 310-768-0700 |
| G. ALL MANUFA 1. Contact Office - Na for Devices) | ACTURE | RS | ufacturir | ng Site | 310-768-0700 |
| G. ALL MANUFA 1. Contact Office - Na for Devices | ACTURE | RS | ufacturin | ng Site | l . |
| G. ALL MANUFA 1. Contact Office - Na for Devices TUTTI GOULD HYLAND'S, IN | ACTURE | RS ss (and Man | ufacturir | ng Site | 310-768-0700 3. Report Source (Check all that apply) |
| G. ALL MANUFA 1. Contact Office - Na for Devices TUTTI GOULD HYLAND'S, IN 154 W. 131ST | ACTURE ame/Address C. STREET | RS s (and Man | ufacturir | ng Site | 310-768-0700 3. Report Source (Check all that apply) Foreign |
| G. ALL MANUFA 1. Contact Office - Na for Devices TUTTI GOULD HYLAND'S, IN | ACTURE ame/Address C. STREET | RS ss (and Man | ufacturir | ng Site | 310-768-0700 3. Report Source (Check all that apply) |
| G. ALL MANUFA 1. Contact Office - Na for Devices TUTTI GOULD HYLAND'S, IN 154 W. 131ST | ACTURE ame/Address C. STREET | RS s (and Man | ufacturir | ng Site | 310-768-0700 3. Report Source (Check all that apply) Foreign |
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| G. ALL MANUFA 1. Contact Office - Na for Devices) TUTTI GOULD HYLAND'S, IN: 154 W. 131ST LOS ANGELES, | ACTURE ame/Address C. STREET | RS s (and Man | ufacturir | ng Site | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer |
| G. ALL MANUFA 1. Contact Office - Na for Devices TUTTI GOULD HYLAND'S, IN 154 W. 131ST | ACTURE nme/Address C. STREET CA 90 | RS ss (and Man 0 61 | | | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company |
| G. ALL MANUFA 1. Contact Office - Nator Devices TUTTI GOULD HYLAND'S, IN 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm.) | ACTURE Ame/Address C. STREET CA 90 | RS ss (and Man 0 61 | ufacturin | | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative |
| G. ALL MANUFA 1. Contact Office - Na for Devices) TUTTI GOULD HYLAND'S, IN 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm. 02/01/2 | ACTURE Ame/Address C. STREET CA 90 | RS (and Man) | | | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company |
| G. ALL MANUFA 1. Contact Office - Nator Devices TUTTI GOULD HYLAND'S, IN 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm.) | ACTURE Ame/Address C. STREET CA 90 | RS ss (and Man 0 61 5. (A)ND/ | A# | | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative |
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| G. ALL MANUFA 1. Contact Office - Na for Devices) TUTTI GOULD HYLAND'S, IN 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm. 02/01/2 6. If IND, Give Protocome of the contact of the co | ACTURE SE (and Man) 5. (A)ND/ INC STN PMA, 510(k Combi Produc Pre-19 | A # D # N # / () # ination ct 2388 | Yes Yes | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: |
| G. ALL MANUFA 1. Contact Office - Na for Devices) TUTTI GOULD HYLAND'S, IN. 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm. 02/01/2 6. If IND, Give Protoc 7. Type of Report (Check all that appl 5-day 30- 7-day Per 10-day Initia | ACTURE SE (and Man) 5. (A)ND/ INC STN PMA 510(k Combi Produc Pre-19 OTC F | A # D # IN # Ination ct 238 Product | ☐ Yes☐ Yes ☑ Yes ☑ Yes ☑ Yes | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: |
| G. ALL MANUFA 1. Contact Office - Na for Devices) TUTTI GOULD HYLAND'S, IN 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm. 02/01/2 6. If IND, Give Protocome of the contact of the co | ACTURE ame/Address C. STREET CA 90 //dd/yyyy) 2014 col # | SE (and Man) 5. (A)ND/ INC STN PMA 510(k Combi Produc Pre-19 OTC F | A # D # IN # Ination ct 238 Product | ☐ Yes ☐ Yes ☑ Yes | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: |
| G. ALL MANUF/ 1. Contact Office - Na for Devices) TUTTI GOULD HYLAND'S, IN 154 W. 131ST LOS ANGELES, 4. Date Received by Manufacturer (mm. 02/01/2 6. If IND, Give Protoco 7. Type of Report (Check all that appl 5-day 30-7-day Per 10-day Initi | ACTURE ame/Address C. STREET CA 90 //dd/yyyy) 2014 col # | SE (and Man) 5. (A)ND/ INC STN PMA 510(k Combi Produc Pre-19 OTC F | A # D # IN # Ination ct 238 Product | ☐ Yes☐ Yes ☑ Yes ☑ Yes ☑ Yes | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850

OMB Statement:
"An agency may not conduct or spx and a person is not required to rest to, a collection of information unles displays a currently valid OMB continumber."

DSS

FEB 26 2014



MER COMPLAINT RECORD



| 10027923:01 | 1-00-03 | | COM | PLAINT#: | 2536 | |
|---|---|---|--|--|---|--|
| TAKEN BY: | TUTTI GOULD | | DATE OF CO | MPLAINT: | 02/01/2014 | |
| PRODUCT: | HYLAND'S BABY | TEETHING TABLETS | ITE | M CODE: | BTETT40 | |
| SIZE: | 40 TABLETS | | | LOT NO.: | B26113 | |
| REPORTER: (b) (6 | 5) | | | | | |
| ADDRESS: | | | | | | |
| | | | | | | |
| CITY: | | | STATE: | (b) (6) | | A |
| COUNTRY: U | SA | | ZIP CODE: | | | - |
| PHONE #: | (6) | | | | | |
| E-MAIL: | | A SEIZURE AT MIDNIGHT WHEN | | | | - 1110 |
| SENT HOME TO FOLLO TYLENOL AT 8 PM AND PEDIALYTE. 24 HOURS BEFORE WITH NO SYM | T: EYES ROL MBULANCE BROUGHT H W-UP WITH HIS DOCTO 3 TABLETS OF BABY T PRIOR HE HAD BEEN I PTOMS. THE MOTHER RGIES OR PRE-EXISTIN O GIVE HIM AN IV BUT CO | LED BACK, AND "IT TOOK A WHIM TO THE HOSPITAL MEDICA RETORN HE HAD A LOW GRASETHING TABLETS AT 10 AM AN RESTLESS, CRANKY AND CUTT SAID THE ONLY THING THAT WAS CONDITIONS. HIS LAST IMM DULDN'T GET A VEIN. BLOOD TES | ILLE FOR HIM TO COME OF ALCARE: HE WAS DIAGNODE FEVER OF 100.6°F. PIOD AT 5 PM. AT THE HOSSING 3 TEETH. HE HAD BE AS DIFFERENT WAS SHE UNIZATION WAS 3 MONTHERS FOR STREP AND FLUW | JT OF IT. DSED AS H RIOR TO TH PITAL HE V EN GIVEN GAVE HIM HS AGO, AI ERE NEGAT | HE TURNED PURI IAVING HAD A SEI HE SEIZURE HE W VAS GIVEN IBUPR: TYLENOL FOR TH I TEETHING TABLE ND HE HAD NO RE TIVE. | PLE. PARENT ZURE AND WAS IAS GIVEN DIFEN AND E TEETHING ETS TWICE THAT |
| | FOR ADDITIO | NAL SPACE PLEASE USE REV | ERSE OR ATTACH A SEP | ARATE SH | EET | |
| PRODUCT RECEIVED F INSPECTION: FOLLOW-UP CALLS: 0 01/30/14; LEFT MESSA TO CALL 1-800-524-965 NEWS FROM THE DOC | (1/29/14, GE BOTH TIME 59 WITH ANY | CIRCLE ONE) | PRODUCT BEING RETU | | | (CIRCLE ONE) |
| NEWS FROM THE DOC | TOR 5 VISIT. | | | UPS CALI | L TAG ISSUED: | (CIRCLE ONE) |
| | | | DA. | TE PRODU | CT RECEIVED: | |
| SECTION II: | INVESTIGATION | | 27. | , L. NODO | | |
| SECTION II. | MV20110ATTO | | | | | |
| INVESTIGATION: | PLEASE SEE ATT/ | ACHED INVESTIGATION REPOR | Т. | | | |
| | | | | | | |
| - | | (/ | | | | |
| | | | | | | |
| ADVERSE EVENT FOR | WARDED TO PHARMA | CIST / NURSE FOR EVALUATION | ON: | 02/01/14 | 1 | |
| ADVERSE EVENT FOR | WARDED TO PHARMA | CIST / NURSE FOR EVALUATION | BY: | TUTTI G | OULD | |
| SECTION III: | CORRECTIVE AC | TION: | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| CORRECTIVE ACTION | I(S) COMPLETED BY: | | | DATE | : | |
| SECTION IV: | ADVERSE EVENT RE | PORTS | | AE# | 1526 | |
| ADVERSE EVENT SER | SIOLIS: | (), N | | | | n |
| ADVERSE EVENT REF | | 02/01/2014 | BY: TU | TTI GOULI | | |
| SECTION V: | | | 1 0 | | | LER 3 |
| REVIEWED BY MANA | GEMENT BY: | RIN | alt | DATE | 02-0 | 7-14 |
| DETICITED STREET | a. | a Shai | 1 | | A7 -M | 7-14 |
| BY: | CALOR O | TO TOUR | <u> </u> | DATE: | 07-01 | 17 |

cc: QA/QC

Production Shipping / Receiving FEB 25 2011

Individual Case Safety Report

10027923-01-00-04

STANDARD OMEOPATHIC DE IN THE USA SINCE 1903

Serious Adverse Event SAE-0003-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B26113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B26113 was manufactured using bulk lot # 121648. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B26113. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(5)}$ pm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B26113. One other complaint (CC-0886-2013, lot # B25913) has been reported related to the bulk lot (lot # 121648) used to manufacture the lot indicated in this complaint. Both complaints were reviewed and they were not similar. We will continue to monitor complaints and if additional complaints are received on this lot or associated bulk lot they will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B26113.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

Date

02/07/2014

DSS FER 9 c 30

CaseID: 10027923



| CaseID: 10027 | 7923 |
|---------------|------|
| Hyland's | ® |

| | JUS ADVERS | SE EVENT DATA FORM | |
|---|--|---|------|
| AE #:1526 | | COMPLAINT #:2536 | **** |
| SECTION I: PATI | ENT INFORMATION (IF DIFFERI | ENT FROM REPORTER ON FORM VD1) | |
| NAME: (b) (6) ADDRESS: CITY: | | STATE: (b) (6) | |
| COUNTRY: USA (b) (6) PHONE #: E-MAIL: | | ZIP CODE: | |
| | AGING LABEL HERE TO SHAND THE SHAND | AFFIX COPY OF OUTER CARTO (INCLUDE DRUG FACTS AND PRINCE PANELS) Feething Tablets Tablets Tablets Tablets Tablets Tablets | |
| SECTION III: CO | RRECTIVE ACTION: | | |
| CORRECTIVE ACTION(S) | COMPLETED BY: | DATE: | |
| SECTION IV: | | 1 | |

BY:

QA / QC DIRECTOR

DATE: 02-07-14 DSS

DATE: 02-07-14 FEB 26 201

Adverse Event Reporting Program

10040722-01-00-01

 $\mathit{C}_{\mathcal{D}_{\mathcal{Z}_{\mathcal{R}}}}$

DER CaseID: 10040722

umer Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

Y reporting of luct problems and product use errors

| | FDA USE ONLY |
|---------------------------|--------------|
| Triage unit sequence # | 544(0/01 |
| | |

| A. PATIENT INFORMATION | | | 2. D | ose or Amount | | Frequen | ncy R | oute | | \neg |
|--|--------------------------------|------------------|---------------|--|-----------------|------------|--------------|--------------|---------------------------------|--------------|
| Patient Identifier 2. Age at Time of E | Event or 3. Sex | 4. Weight | #1 [| 2 pills | | once | T | aken by mo | outh | \exists |
| Unspecified Date of Birth: (b) (6) | ✓ Female | 17 _{lb} | <u>"</u> [| | | | | | | |
| | □ | or kg | #2 [| | | | | | | |
| In confidence B. ADVERSE EVENT, PRODU | | | 2 Date | es of Use (If unkno | un aba | duration) | from to | E Event Ab | ated After Use | |
| Check all that apply: | CT PROBLEM OR ER | RUK | | best estimate) | wn, give | duration) | | | Dose Reduced? | 7 |
| | oblem (e.g., defects/malfuncti | ions) | #1 03. | /22/2014 - 03 | 3/25/2 | 014 | | #1 🔽 Yes | □ No □ Doe | esn't |
| Product Use Error Problem wi | ith Different Manufacturer of | f Same Medicine | #2 | | | | | #2 TYes | | esn't |
| 2. Outcomes Attributed to Adverse Eve (Check all that apply) | ent | | | nosis or Reason eething pain | for Use | (Indicatio | n) | | Appared After | oly |
| Death: | Disability or Permanent D | Damarie | "'' 1 | eeching pain | | | ľ | Reintrodu | iction? | |
| (mm/dd/yyyy) | | | #2 | | | | ; | #1 Yes | □ No ☑ Doe | esn't ply |
| Life-threatening | Congenital Anomaly/Birth | | 6. Lot | # | 7 5 | xpiration | Date : | #2 Yes | | esn't |
| ☐ Hospitalization - initial or prolonged ☐ Required Intervention to Prevent Pe | | | #1 | | #1 | Apiiauoii | _ | . NDC # or | Unique ID | oly |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (m. | | #2 | | #2 | | [` | , 1100 # 01 | omque io | |
| 03/25/2014 | 03/25/2014 | in baayyyy) | E. S | USPECT MED | ICAL | DEVICE | | | | |
| 5. Describe Event, Problem or Product | | | | nd Name | | | | | | |
| My baby spits up or vomit | s after consuming H | yland | | | | | | | | |
| Teething Tablets. | | | 2. Con | nmon Device Nam | e | | | | CTU | |
| | | | | | | | | | | |
| | | | 2.10- | | Na | 64-4- | | M, | AR 26 20 | 11 |
| | | | 3. Man | ufacturer Name, C | ity and | State | | | # IF LU | 17 |
| | | | | | | | | | | |
| | | | 4. Mod | lel # | L | ot# | | 15.0 | Operator of Dev | ice |
| | | | | | | | | 1_ | Health Profession | |
| | | | <u> </u> | | | | | | | |
| • | | | Cata | alog# | E | xpiration | Date (mm/c | avvvv) 🗀 | Lay User/Patien | it |
| | | , | | | | | | | Other: | |
| 6. Relevant Tests/Laboratory Data, Inci | luding Dates | | Seri | al# | 0 | ther# | | | | |
| | | | | | . | | | | | _ |
| | | | 6. If Im | planted, Give Dat | e (mm/d | d/yyyy) | 7. If Expla | nted, Give I | Date (mm/dd/yy) | ny) |
| | | | å le th | is a Single-use De | vice th | at was De | processed | and Pouss | d on a Dationt? | |
| | | | | Yes No | 541CG (11 | at was no | processeu | and Neuset | a on a radent? | |
| | | | 9. If Ye | s to Item No. 8, Ent | er Name | and Addi | ess of Repr | ocessor | | \neg |
| 7. Other Relevant History, Including Pro | eexisting Medical Condition | s (e.g., | | | | | | | | |
| allergies, race, pregnancy, smoking and Race: White | | | | | | | | | | |
| Race: white | | | | THER (CONC | | | | | S | |
| Medical Conditions: | | | Produc | ct names and ther | apy dat | es (exclud | de treatment | of event) | | |
| Allergies: | | | | | | | | | | |
| Important Information: | | | | | | | | | | |
| | | 9 | G. RI | EPORTER (See | e confi | dentiali | ty section | on back |) | |
| C. PRODUCT AVAILABILITY | | | 1. Nan | e and Address | | | | | | |
| Product Available for Evaluation? (Do) | not send product to FDA) | | I I | ne: (b) (6) | | | | | | D |
| Yes No Returned to Ma | , | | Add | C35. | | | | フ | | |
| | | da/yyyy) | City | | | | 04-4- | 1 | MA | R |
| D. SUSPECT PRODUCT(S) | are duct to be 15 | | City: | | | | E-mail | ZIP: | | |
| 1-Name, Strength, Manufacturer (from p #1 Name: Hylands Teething Tak | | | | | | | L-man | | | |
| Strength: | | | | | | | l | | | |
| Manufacturer: | | | I | th Professional? | 3. Occ ı | pation | | l | o Reported to: | |
| *2 Name: | - / | | | Yes No | | | | | Manufacturer | |
| Strength: Manufacturer: | | | | u do NOT want you e manufacturer, pla | | | | 1 = | User Facility Distributor/Impor | der |
| | | - 1 | 1 | | | | | ı 🗀 | 2.Juneator/impo | |

PLEASE TYPE OR USE BLACK INK



THE FUA Safety Information and

10149861-01-00-01



CaseID: 10149861

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse,

RY reporting of duct problems and product use errors

| | FDA USE ONLY |
|------------------------|--------------|
| Triage unit sequence # | 548761 |
| | |

| Adverse Event Reporting Program | 1/2 | | |
|--|--|------------------------|---|
| A. PATIENT INFORMATION | 2. Dose or Amount | Frequency | Route |
| 1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight (b) (6) Date of Birth; | #1 | <u> </u> | |
| (b) (6) | | | |
| (b) (6) | #2 | | |
| In confidence ——— | 9 | |][|
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR | Dates of Use (If unknown, (or best estimate) | give duration) from/to | 5. Event Abated After Use Stopped or Dose Reduced? |
| Check all that apply: | #1 | | #1 Yes No Doesn't |
| 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medici | ne | | Apply |
| | 4. Diagnosis or Reason for U | Use (Indication) | #2 Yes No Doesn't |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) | #1 Teething | , | 8. Event Reappeared After |
| ☐ Death: ☑ Disability or Permanent Damage | | | Reintroduction? #1 Yes No Doesn't |
| (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect | #2 | | Apply |
| Hospitalization - initial or prolonged Other Serious (Important Medical Event | 6. Lot# | 7. Expiration Date | #2 Yes No Doesn't |
| Required Intervention to Prevent Permanent Impairment/Damage (Devices) | ³' #1 # | #1 ['] | 9. NDC # or Unique ID |
| | | #2 | |
| 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 04/30/2014 | E. SUSPECT MEDICA | | |
| 5. Describe Event, Problem or Product Use Error | 1. Brand Name | | |
| My son did not get his first tooth until almost after | | | |
| a year old. A friend of mine told me about hylands | | | 250 0 il |
| because I do NOT just give my child medication . I thought it was natural and safe. I used it as needed | 2. Common Device Name | | CIU |
| ccasionally over a corse of maybe 5 months. Out of | | | |
| the clear blue I noticed my son staring off and his eye twitching. At first my boyfriend thought he was in | 3. Manufacturer Name, City | and State | MAY - 1 2 |
| deep thought and my mother did too. I'm with my son | | | |
| every day and I rarely miss a thing. Over a corse of a | . | | |
| few days they came more often. The ONLY thing I ever gave my son was hylands teething tablets. He had an | 4. Model # | Lot# | 5. Operator of Device |
| EEG and which came | | | Health Professional |
| <u>K</u> | Cotalog # | Evaluation Data (m | |
| <u> </u> | Catalog # | Expiration Date (m | nm/dd/yyyy) Lay User/Patient |
| | _ | | Other: |
| 6. Relevant Tests/Laboratory Data, Including Dates EEG positive for seizures MRI within Norman limits | Serial # | Other# | |
| S positive for servates and within norman limits | 11 | | |
| EEG positive for seizures.MRI within Norman limits | 6. If Implanted, Give Date (m | m/dd/yyyy) 7. If Ex | xplanted, Give Date (mm/dd/yyyy) |
| 7 | | | |
| | 8. Is this a Single-use Device | e that was Reprocess | sed and Reused on a Patient? |
| | 9. If Yes to Item No. 8, Enter N | ame and Address of P | Anrocassor |
| | J. II Tes to itelli No. 6, Enter N | and and Address of R | epioce330i |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) | | | |
| Race: White | F. OTHER (CONCOMI | TANT) MEDICAL | PRODUCTS |
| Medical Conditions: None | Product names and therapy | · | |
| medical Conditions: None | | | on orony |
| Allergies: None | | | |
| Important Information: | | | |
| | G. REPORTER (See co | onfidentiality sect | tion on back) |
| C. PRODUCT AVAILABILITY | 1. Name and Address (b) (6) | | |
| Product Available for Evaluation? (Do not send product to FDA) | | | D00 |
| Yes No Returned to Manufacturer on: | | | USS |
| (mm/dd/yyyy) | ·] | | |
| D. SUSPECT PRODUCT(S) | Dhara # | 1 | AY 012 |
| 1. Name, Strength, Manufacturer (from product label) | Phone # (b) (6) | E-mail (b) (6) | |
| #1 Name: Teething tablets Strength: Hylands | | (2) | |
| Manufacturer: | 2. Health Professional? 3. C | Occupation | 4. Also Reported to: |
| #2 Name: | Yes No | • | Manufacturer |
| Strength: | 5. If you do NOT want your ide | entity disclosed | User Facility |
| Manufacturer: | to the manufacturer, place a | | Distributor/Importer |

CaseID: 109 49861 60

B.5. Describe Event or Problem (continued)

... back positive for seizures. Which I supspected . We just had an MRI done and it came back clear . There is absolutely NO doubt that this is from hylands teething tablets. I immediately stopped using them. But the damage has been done. My son is senitive to a lot of things, and I believed he was poisoned by these without me knowing.

Individual Case Safety Report

10149861-01-00-02

DSS MAY 01 2014



fessional Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

Y reporting of .uct problems and product use errors

| | FDA USE ONLY | |
|---------------------------|--------------|--|
| Triage unit sequence # | 549451 | |
| | | |

| הוופ רטא סמופנץ וחוסרוחמנוסח and Adverse Event Reporting Program | product u | se errors | sequence # | (17) |
|---|--|---|----------------------------|---|
| A. PATIENT INFORMATION | | 2. Dose or Amount | Frequency | Route |
| 1. Patient Identifier 2. Age at Time of Event of Date of Birth: | _ 10.0 | #1 as directed | PRN/as needed | Oral |
| 1 Years (b) (6) | | #2 | | |
| In confidence | Male or kg | | | |
| B. ADVERSE EVENT, PRODUCT F Check all that apply: | ROBLEM OR ERROR | Dates of Use (If unknown (or best estimate) | vn, give duration) from/to | 5. Event Abated After Use Stopped or Dose Reduced? |
| | (e.g., defects/malfunctions) | #1 09/19/2013 - 09 | /26/2013 | #1 Yes No Doesn' |
| Product Use Error Problem with Diff | erent Manufacturer of Same Medicine | | | #2 Yes No Doesn |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) | | 4. Diagnosis or Reason f #1 teething | or Use (Indication) | 8. Event Reappeared After |
| | isability or Permanent Damage | #2 | | Reintroduction? #1 Yes No Doesn |
| (mm/dd/yyyy) Life-threatening | ongenital Anomaly/Birth Defect | #2 | | Apply |
| Hospitalization - initial or prolonged 🗸 O | | 6. Lot # | 7. Expiration Date #1 | Apply |
| Required Intervention to Prevent Permane | | #2 | #2 | 9. NDC # or Unique ID |
| ,,,,,, | Date of this Report (mm/dd/yyyy) 5/07/2014 | E. SUSPECT MED | | |
| 5. Describe Event, Problem or Product Use I | | 1. Brand Name | | |
| Single seizure: brief staring appearing awake but unrespons | episode at home, ive that lasted seconds, | | | - |
| and then "seemed more out of of loc. No tonic/clonic shaki | it than usual". No report | 2. Common Device Name | 9 | CTU |
| fatigued for an hour after ev | ent. took Hyland's | | | MAY |
| teething tablets prior to eve stopped- has not had another | | 3. Manufacturer Name, C | ity and State | MAY - 8 2014 |
| since. | | | | |
| | | 4. Model# | Lot# | 5. Operator of Device |
| | | | | Health Professiona |
| | | Catalog # | Expiration Date (m | nm/dd/yyyy) |
| | | | | Other: |
| 6. Relevant Tests/Laboratory Data, Including | Dates | Serial # | Other# | |
| EEG nl, cbc/ lytes normal | | | | |
| | | 6. If Implanted, Give Date | e (mm/dd/yyyy) 7. If Ex | planted, Give Date (mm/dd/yyyy) |
| | | 8. Is this a Single-use De | evice that was Reprocess | sed and Reused on a Patient? |
| | | 9. if Yes to Item No. 8, Ent | er Name and Address of R | eprocessor |
| 7. Other Relevant History, Including Preexist | | \parallel | | |
| allergies, race, pregnancy, smoking and alco previously healthy, no preexi | hol use, liver/kidney problems, etc.) | E OTHER (CONTO | NAITA NITA BACOLO-1 | PRODUCTS |
| | , | F. OTHER (CONCO | | |
| | | none | , | • • • • • • • • • • • • • • • • • • • |
| | | G. REPORTER (See | e confidentiality sec | tion on back) |
| C PRODUCT AVAILABILITY | | 1. Name and Address | | |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not se | nd product to FDA) | (b) (6) | | Do |
| Yes No Returned to Manufac | turer on:(mm/dd/yyyy) | | | DS AY 08 |
| D. SUSPECT PRODUCT(S) | (| St | | AY 08 |
| 1. Name, Strength, Manufacturer (from product) | | Phone # (b) (6) | E-mail (b) (6) | |
| #1 Name: Hyland's teething table Strength: | ES | | | |
| Manufacturer: Hyland's | | 2. Health Professional? | • | 4. Also Reported to: |
| *2 Name: Strength: | | Yes No 5. If you do NOT want you | Medical Doctor (Physician) | ☐ Manufacturer ☐ User Facility |
| Manufacturer: | | to the manufacturer, pk | | Distributor/Importer |



CDER

ofessional Report

CaseID: 10162223

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

RY reporting of duct problems and product use errors

| | FDA USE ONLY | |
|---------------------------|--------------|--|
| Triage unit sequence # | 549447 | |
| | | |

| Adverse Event Reporting Prog | | product use | e erro | rs // | sequence # | יייי דים | 1 (|
|--|--|-------------------------------|----------------|---------------------------------------|--|-----------------|--|
| A. PATIENT INFORMATION | Event or 3. Sex | 4. Weight | | Dose or Amount as directed on | Frequency PRN/as | Route | |
| 1. Patient Identifier 2. Age at Time of Date of Birth: 7 Months | 5. Sex | 17.5 _{lb} | | label | needed | | |
| (b) (6) | ☐ Male | or kg | #2 | | | | |
| In confidence B. ADVERSE EVENT, PRODU | JCT PROBLEM OR E | RROR | | tes of Use (If unknown best estimate) | n, give duration) from | | nt Abated After Use ed or Dose Reduced? |
| Check all that apply: 1. Adverse Event Product Produc | roblem (e.g., defects/maifund | ctions) | 1 . | 0/20/2013 - 10/ | 25/2013 | | Yes No Doesn |
| Product Use Error Problem w | | of Same Medicine | #2 | agnosis or Reason fo | - Hea (Indication) | #2 | Yes No Doesn |
| Outcomes Attributed to Adverse Ev (Check all that apply) | rent | | | teething | r use (marcanon) | | nt Reappeared After |
| Death: (mm/dd/yyyy) | Disability or Permanent | | #2 | - 11.11 | | | Yes ☐ No ☑ Doesn Apply |
| ☐ Life-threatening ✓ Hospitalization - initial or prolonged | Congenital Anomaly/Bi | - 1 | 6. Lo | t# | 7. Expiration Dat | #2 🗍 | Yes No Does |
| Required Intervention to Prevent P | | · · · | #1 | | #1 | | # or Unique ID |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (| mm/dd/yyyy) | #2 | | #2 | | |
| 10/25/2013 | 05/07/2014 | | | SUSPECT MEDIC and Name | CAL DEVICE | | |
| Describe Event, Problem or Product a episodes of seizure ac | tivity involving ar | | | | | | |
| all occurring on the same For the 5 days prior to | seizure, patient ha | | 2. Cc | mmon Device Name | | | |
| taking Hyland's teething discontinued on the day | | atient's | | | | • | TU. |
| EEG, MRI were all normal of seizures or any histo. | | | 3. M a | nufacturer Name, Ci | ty and State | MAY | • |
| has not had any seizures since this time. | | | | | | MAT - | 8 2014 |
| ••••• | | | 4. Mc | odel# | Lot# | | 5. Operator of Devic |
| | | | | | | | Health Profession |
| | | | Ca | talog# | Expiration Date | te (mm/dd/yyyy | /) Lay User/Patient |
| | | | | | | | Other: |
| 6. Relevant Tests/Laboratory Data, Inc EEG normal: (b) (6) | Brain MRI (b) (6) | normal, | Se | rial# | Other # | | |
| | | | 6. If | mplanted, Give Date | (mm/dd/vvvv) 7. | If Explanted. | Give Date (mm/dd/yyyy) |
| | | | | this a Single-use Dev | | - | |
| | | | | Yes No | rice that was Repro | cessed and N | euseu on a Padentr |
| | | | 9. If | es to Item No. 8, Ente | r Name and Address | of Reprocesso |)T |
| Other Relevant History, Including P allergies, race, pregnancy, smoking a | reexisting Medical Condition alcohol use, liver/kidney p | ons (e.g., problems, etc.) | | | | | |
| prior 38 week twin, othe preexisting health issue | | | | OTHER (CONCO | | | |
| seizures or neurologic p | roblems | | Proc | uct names and thera | py dates (exclude tr | reatment of eve | ent) |
| | | | | | | | |
| | | | | PEDORTER (See | confidentiality | saction on | haak) |
| O PROBLICE AVAILABLE | | | 1. Na | REPORTER (See ime and Address | connuentianty : | Section on i | Jack) |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do | o not send product to FDA) | | (b) (6 | | | | D.S |
| Yes No Returned to M | Manufacturer on: | m/ddAana) | | | | | DS 47 08 |
| D. SUSPECT PRODUCT(S) | (mn | n/dd/yyyy) | | | 1- | | 7' 08 |
| 1. Name, Strength, Manufacturer (from #1 Name: Hyland's Teething 2 | | | Pho: (b) (6 | | | -mail (6) | |
| strength: unsure | anters | | | allh Duafacalanala | 2 Decumetics | | A Alex Baseded |
| Manufacturer: Hyland #2 Name: | | | | ealth Professional? ○ Yes No M | Occupation ledical Doctor (Physic | | 4. Also Reported to: Manufacturer |
| Strength: | | | 5. If | you do NOT want your | identity disclosed | | User Facility |
| Manufacturer: | | | ii to | the manufacturer, place | ce an "X" in this box | | Distributor/Import |

Yes No Unk.



10234825-01-00-01



| Mfr Report# | 54973 | |
|---------------|----------|--|
| UF/Importer I | Report # | |
| | | |

| | 1023482 | | -0.0501 | |) 1 |
|--|-----------------------|-----------|-----------------|---------------------------------|------------|
| Patient Identifier | 2. Age at Tim | _ | | 3. Sex | 4. Weight |
|) (6) | of Event: | 14 | Months | Female | lbs |
| | or Date | | | ✓ Male | or |
| In confidence | of Birth: | BOBLI | CT DDODL | ت ا | kgs |
| B. ADVERSE E | VENTORF | | | | |
| Adverse Ever | | | oduct Problem | n (e.g., defects/malf | unctions) |
| Outcomes Attribut (Check all that app | | e Event | | | |
| Death: | (mm/dd/yyy | v) | Disabili | ty or Permanent Da | mage |
| Life-threateni | | ,, | | nital Anomaly/Birth I | |
| ✓ Hospitalizatio | | | | Serious (Important N | |
| | | vent Perm | | nent/Damage (Devid | |
| Date of Event (m 05/ | m/dd/yyyy) 21/2014 | | 4. Date of 1 | his Report (mm/de 05/23/2014 | |
| . Describe Event o | | | 1., | | |
| CHILD WITH AI | TERED MEN | ים זהיים | פסת סוודגיו | CDIDED AS | |
| CLUMSINESS, E | | | | | ICE. |
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| | | | | | |
| | | | | (Continue c | n page 3) |
| Relevant Tests/L | aboratory Data | , Includi | ng Dates | | |
| CT SCAN, MRI | , LABS, X- | -RAYS | WERE NORM | MAL. | |
| | , | | | | |
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| | | | | | |
| | | | | | |
| | | | | | |
| | | | | (Continue d | n page 3) |
| 7. Other Relevant H | listory, Includi | na Preex | isting Medica | l Conditions (e.g., | allergies, |
| race, pregnancy, | smoking and ald | conol use | , hepatic/renal | dysfunction, etc.) | - |
| | | | | | |
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| reporting | or importer reports | | | | | | |
|---------------------------------|---------------------|------------------|----------|----------|--------------|------------------------|-----------------------------|
| : 5 | | | | | | | TDA Hara Only |
| C. SUSPECT PRODU | (C) (/S) | | _ | | | F | DA Use Only |
| Name (Give labeled streng | | ler) | | | | | |
| #1 HYLAND'S BABY | EETHING | ABLE | TS | | | | |
| #2 | 4/2 | 1 | | | | | |
| 2. Dose, Frequency & Route | e Used | 3. | Thereb | yates | (If u | nknown, gi | rve duration) |
| #1 2-3 TABS QID | MONTH | 7/4 # | | or best | estir | nate) | |
| | On | — [" | | | | | |
| #2 4. Diagnosis for Use (Indica | tion) | | | 5. Even | nt Ab | ated After | Use |
| #1 TEMP RELIEF TER | | AIN | l | | | or Dose R | educed? |
| #2 | | | | #1 [_] | Yes | ∐ No | Apply |
| | 7. Exp. Date | | | #2 🔲 | Yes | ☐ No | Doesn't Apply |
| #1 | #1 | | ł | | | appeared | After |
| #2 | #2 | | | _ | trod Yes | uction? | Doesn't |
| 9. NDC# or Unique ID | #Z | | | | 163 | | Apply |
| 54973-3127-2 | | | | #2 | Yes | ∏ No | Doesn't Apply |
| 10. Concomitant Medical Pr | roducts and | Therapy | Dates | (Exclud | e tre | atment of e | vent) |
| | | | | | | | |
| | | | | | | | |
| | | | | | (Ca) | atinue on | page 3) |
| D. SUSPECT MEDIC | AL DEVIC | ÈΕ | | | (OO) | idinas on | page 3) |
| 1. Brand Name | | | | | | | |
| 2. Common Device Name | | | | 2b. | Pro | code | |
| | | | | | | | |
| 3. Manufacturer Name, City | and State | | | | | | |
| | | | | | | | |
| 4. Model # | Lot# | | | | 5 | | of Device |
| Catalog # | Expira | tion Dat | e (mm/e | dd/yyyy) | \exists | | Professional ser/Patient |
| | | | | | 4 | Other: | |
| Serial # | Uniqu | e Identifi | ier (UDI |)# | | LI Other. | |
| 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. | If Expl | anted, (| Give | Date (mm/ | /dd/yyyy) |
| | | | . 17 | | | | |
| 8. Is this a Single-use Devi | ce that was | Reproce | ssed a | nd Reu | sed | on a Patie | nt? |
| 9. If Yes to Item No. 8, Ente | er Name and | Address | of Re | process | sor | | |
| | | | | | | D. | SS |
| | | | | | | | |
| 10. Device Available for Ev | aluation? (E | o not ser | nd to FE | DA) | | JUN] | 1 2014 |
| Yes No | Returned | l to Manu | facture | r on: | | 7 | |
| 11. Concomitant Medical P | Products and | Theran | v Dates | (Exclu | de tr | (mm/dd/y eatment of | |
| 11. Concomitant medicar P | Toducts and | inerap | Daves | LAGIC | uo 1 | outmort of | 0.0, |
| | | | | | | | |
| E. INITIAL REPORT | ED | | | | (Co | nanue or | n page 3) |
| 1. Name and Address | -10 | | | | _ | | |
| (b) (6) | | | | | | | |
| | | | | | | | |
| | | | | | | ii iki 🔹 | 0 444 |
| Phone # | | Email A | ddress | | | JOIN I | 0 2014 |
| (b) (6) | | | | | | | |
| | . Occupatio | | | ľ | 4. Ini Re | tial Repor | ter Also Sent |
| Yes No | hysician | | | | Γ | Yes 🔽 | _ |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

CaseID: 10234825



10234825-01-00-02

| 1. Uneck One | | | 14. 01 | maporter | | w1111111111111111111111111111111111111 |
|---|---|---|----------------------|--|--|---|
| User Facility | [] Impo | rter | | • | | |
| 3. User Facility or Imp | orter Name/ | Address | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| 4. Contact Person | | | 1: | 5. Phone N | lumber | |
| | | | | | | |
| 6. Date User Facility o Importer Became | r 7 | . Type of | Report | | | of This Report |
| Aware of Event (mm | ı/dd/yyyy) | nitial | | | ` | ***** |
| | | Follow | -up#_ | _ | | |
| 9. Approximate | 10. Event P | roblem Co | des (R | Refer to cod | ing manu | al) |
| Age of Device | Patient | A-1 | | | | |
| | Code _ | | | | | |
| | Device Code | | | | | - |
| 11. Report Sent to FDA | 4? | 12. Locat | ion Wh | nere Event | Occurre | d |
| Yes | | □н | lospital | | | Outpatient Diagnostic Facility |
| ∏ No (mm/dd | (yyyy) | □н | lome | | | Ambulatory |
| 13. Report Sent to Mar | nufacturer? | 1 – | lursing | | | Surgical Facility |
| | | | otpatie | nt Treatme | ent | |
| I I I Yes | Vyyyy) | П | ther: _ | | | |
| Yes(mm/dd | | | | | (Spe | cify) |
| □ No (mm/dd | a/Addrage | | | | | |
| (mm/da | e/Address | <u></u> | | | | |
| □ No (mm/dd | e/Address | | | | | |
| □ No (mm/dd | e/Address | | | | | |
| □ No (mm/dd | e/Address | | | | | |
| No (mm/dd | | | | | | |
| No (mm/dd | CTURER | | r Dovice | 200 | 2 Pho | one Number |
| No (mm/dd | CTURER | | r Devid | ces) | | one Number 768–0700 |
| No (mm/dd | CTURER Manufactur | | r Devid | ces) | 310- | 768-0700 oort Source |
| No (mm/dd | CTURER Manufactur | | r Devic | ces) | 310- 3. Rej (Ch | 768-0700 port Source eck all that apply) |
| No (mm/dd | CTURER Manufactur | | r Devic | ces) | 310- 3. Reg (Ch | 768-0700 cort Source leck all that apply) creign |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S | CTURER Manufactur ICZ TREET | ing Site fo | r Devid | ces) | 310- 3. Rep (Ch | 768-0700 cort Source eck all that apply) creign udy |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. | CTURER Manufactur ICZ TREET | ing Site fo | r Devic | ces) | 310- 3. Rep (Ch | 768-0700 cort Source leck all that apply) oreign udy lerature |
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| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address STANDARD@HYLAN | CTURER I Manufactur ICZ TREET A 90061 | ring Site fo | r Devic | ces) | 310- 3. Rep (Ch Fo St Liu Co W He | 768-0700 port Source leck all that apply) oreign udy lectature onsumer lealth Professional |
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| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address STANDARD@HYLAN 4. Date Received by | CTURER I Manufactur ICZ TREET A 90061 DS.COM | 5. (A)NDA | # | | 310- 3. Rep (Ch | 768-0700 port Source eek all that apply) preign udy lecrature ponsumer ealth Professional ser Facility propany epresentative |
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| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address STANDARD@HYLAN 4. Date Received by Manufacturer (mm/c) 35/21/2 6. If IND, Give Protoco | CTURER Manufactur ICZ TREET A 90061 DS.COM dd/yyyy) | 5. (A)NDA IND BLA PMA/ | # | | 310- 3. Reg (Chi | 768-0700 port Source leck all that apply) preign udy lecature possumer palth Professional ser Facility propany appresentative stributor |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address STANDARD@HYLAN 4. Date Received by Manufacturer (mm/c) 35/21/2 | ICTURER I Manufactur ICZ TREET A 90061 DS.COM dd/yyyy) 014 | 5. (A)NDA IND BLA PMA/ 510(k) | #### | | 310- 3. Reg (Chi | 768-0700 port Source leck all that apply) preign udy lecature possumer palth Professional ser Facility propany appresentative stributor |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address STANDARD@HYLAN 4. Date Received by Manufacturer (mm/c 5/21/2 6. If IND, Give Protoco 7. Type of Report (Check all that apply 5-day 30-d | CTURER I Manufactur ICZ TREET A 90061 DS.COM dd/yyyy) 014 bl # | 5. (A)NDA IND BLA PMA/ | # # # # # # ation | | 310- 3. Reg (Chi | 768-0700 port Source leck all that apply) preign udy lecature possumer palth Professional ser Facility propany appresentative stributor |
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| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address STANDARD@HYLAN 4. Date Received by Manufacturer (mm/c 05/21/2 6. If IND, Give Protoco 7. Type of Report (Check all that apply, | CTURER I Manufactur ICZ TREET A 90061 DS.COM dd/yyyy) 014 bl # | 5. (A)NDA IND BLA PMA/ 510(k) Combin Product Pre-193 OTC Pr | # # # # ation | Yes Yes | 310-3. Reg (Ch | 768-0700 port Source leck all that apply) preign udy lecature possumer palth Professional ser Facility propany appresentative stributor |
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | FDA USE ONLY | |
|---|---|--|
| 5 | , | |
| H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event | 2. If Follow-up, What Type? | |
| | Correction | |
| Death Serious Injury | Additional Information | |
| Malfunction | Response to FDA Request | |
| i wandi ciron | Device Evaluation | |
| | | |
| 3. Device Evaluated by Manufacturer? | Device Manufacture Date (mm/yyyy) | |
| Not Returned to Manufacturer | , , , , , , , , , , , , , , , , , , , | |
| Yes Evaluation Summary Attached | | |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? | |
| provide design. | Yes No | |
| 6. Event Problem and Evaluation Codes (Refer to | coding manual) | |
| Patient Code |]- | |
| Device | | |
| Code | | |
| Method - | ————— | |
| Results - | | |
| Conclusions | | |
| '. If Remedial Action Initiated, Check Type | 8. Usage of Device | |
| Recall Notification | Initial Use of Device | |
| Repair Inspection | Reuse | |
| Replace Patient Monitoring | Unknown | |
| Relabeling Modification/ | 9. If action reported to FDA under | |
| Adjustment | 21 USC 360i(f), list correction/ removal reporting number: | |
| Other: | | |
| | | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data | |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

ECORD



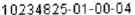
| | 10234825-01-00-03 | COMPLAINT#: | 2547 | |
|--|---|---|---|---------------|
| IAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 05/21/2014 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTET | |
| SIZE: | DID NOT HAVE BOTTLE | LOT NO.: | DID NOT HAVE BOTTLE | |
| REPORTER: _(b) (6) | | | | |
| ADDRESS: _ | | | | |
| - | | (b) (6) | | |
| CITY: | | STATE: (b) (6) | | |
| COUNTRY: USA (b) (6) | | ZIP CODE: | | |
| PHONE #: | | | | |
| E-MAIL: N/A | MOM HAS BEEN GIVING HYLAND'S BABY TEE | THING TABLETS DOSSIBLE LID T | 22_3 TARS FOLIR TIMES A DAY | |
| ABOUT HYLAND'S BABY TER CHILD HOSPITALIZED. TOLI | FOR 1 MONTH. CHILD PRESENTS WITH ALTE POLICY OF THE PROPERTY WITH ALTE POLICY OF THE PROPERTY | ERED MENTAL STATUS DESCRIBE VT IN THE HOME. DOCTOR REQU IAL. TOLD HIM THAT I WOULD FIL R LONGER THAN RECOMMENDED | D AS CLUMSINESS, FALLING ESTED MORE INFORMATION E A REPORT WITH THE FDA SINCE DURATION COULD CAUSE A | |
| | FOR ADDITIONAL SPACE PLEASE USE REVERS | SE OR ATTACH A SEPARATE SHE | ET | |
| | | | | |
| PRODUCT RECEIVED FOR INSPECTION: | (CIRCLE ONE) | RODUCT BEING RETURNED FOR | (CIRCLE ONE) | |
| | | DATE REQUESTED PRODUCT BE | RETURNED: | |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) | |
| | | DATE PRODUC | T RECEIVED: | |
| SECTION II: INV | ESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| INVESTIGATION. | TELAGE GLE ATTACHED INVESTIGATION REPORT. | | | |
| | | | | |
| AND THE STATE STAT | | | | |
| | | | | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION ON: | 05/21/201 | 4 | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDYTA F | RACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | |
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| CORRECTIVE ACTION(S) CO | MPLETED BY: | DATE: | | 200 1120 |
| | MPLETED BY: ERSE EVENT REPORTS | DATE: | JUN | |
| SECTION IV: ADV | ERSE EVENT REPORTS | | JUN | |
| SECTION IV: ADV ADVERSE EVENT SERIOUS: | ERSE EVENT REPORTS Y / N | AE #: | JUN 1 (1537 | 1120 |
| SECTION IV: ADV ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTE | ERSE EVENT REPORTS Y / N | | JUN 1 (1537 | 1120 |
| SECTION IV: ADV ADVERSE EVENT SERIOUS: | ERSE EVENT REPORTS Y / N | AE #: BY: <u>EDYTA FRACK</u> I | JUN 1537 TUN 1 0 | 1120 |
| SECTION IV: ADV ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTE | ERSE EVENT REPORTS O ON: 05/21/2014 | AE #: BY: <u>EDYTA FRACK</u> I | JUN 1 (1537 | 11 20 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

CaseID: 10234825







erse Event SAE-0014-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible.

The customer complaint system was reviewed and it did reveal that in the last twelve months that there have been seventy-two Adverse Event (AE) which also included eleven Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum was "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of \$(4) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

5/29/14

USS JUN 11 2014

JUN 1 0 2014

CaseID: 10234825

DATA FORM

| AE #:153 | 37 | COMPLAINT | #: _2547 | |
|--|--|--|--|------------------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFER | RENT FROM REPORTER ON FOR | M VD1) | |
| NAME: | UNKNOWN | | A A A A A A A A A A A A A A A A A A A | |
| ADDRESS: | | | | |
| CITY: | | STATE: | (b) (6) | |
| COUNTRY: PHONE #: | USA | ZIP CODE | | |
| E-MAIL: | | | | |
| SECTION II: | PACKAGING INFORMATION: | | | |
| AF | FIX PACKAGING LABEL HERE | (INCLUDE DRUG FACT | OUTER CARTON HERE S AND PRINCIPAL DISPLAY (NELS) | |
| Author Ingrafilante Colorros Planylorus SI FP LS, Devroville SI FP LS, Orber Coulds SI FP LS, Mattern FP LS, Orbe Coulds SI FP LS, Mattern FP LS, Orbe Coulds SI FP LS, Mattern FP LS, Mat | Teething Tablets Tablets Tablets Tablets The LEF OF PAN AND TRATTELEF OF PAN AND TRATTABLET FROM TETHING TABLETS TABLETS TABLETS TO GUICK-OSSOLVING TO GUICK- | Technical Baby By these offer grands from the product of the party ONE STARTS ONING THATS ON | With a contage of commons of the common of t | |
| SECTION III: | CORRECTIVE ACTION: | | .4 | |
| | | | | — DSS — JUN 11 2014 |
| CORRECTIVE A | CTION(S) COMPLETED BY: | | DATE: | |
| SECTION IV: | T). | 11 | | JUN 1 0 2014 |
| REVIEWED BY I | MANAGEMENT BY: | Nolt- | DATE: 06-02- | 14 |
| BY: | QA/QC DIRECTOR | | DATE: 06-0244 | |



| A. PATIENT INF | ORMATIO | N | | | |
|--|-----------------------------------|-------------------------|---------------------------------------|--------------------------------------|-------------|
| 1. Patient Identifier | 2. Age at Tim | iė | | 3. Sex | 4. Weight |
| (b) (6) | of Event: | 10 | Months | ✓ Female | lbs |
| | Date | | | | or |
| in confidence | of Birth: | | | Male | kgs |
| B. ADVERSE E | VENT OR P | RODU | CT PROBLE | M | |
| 1. 🗸 Adverse Even | t and/or | Pro | duct Problem (e | .g., defects/malf | unctions) |
| 2. Outcomes Attribut | | Event | | | |
| Death: | y) | | ☐ Disability of | r Permanent Da | mage |
| Life-threatenin | (mm/dd/yyy | у) | Congenital | Anomaly/Birth [| Defect |
| ✓ Hospitalization | - | onaed | | ous (Important M | |
| | | - | anent Impairment | | |
| 3. Date of Event (mr. | n/dd/yyyy) | | 4. Date of This | Report (mm/do | Vyyyy) |
| 04/30/2014 | 05/11-12 | /2014 | | 05/16/2014 | |
| 5. Describe Event or | Problem | | | | |
| CHILD HAD 1 O | R 2 DASES | RANDO | MLY OF TEF | THING TARE | ETS. |
| MAYBE 4 TABS | | | | HE WAS FIN | |
| COUPLE WEEKS | | | ED TO DO TH | | |
| DIAGNOSED ON | b) (6) | | PNEUMONIA. | THE EVENT | |
| SHE STOPPED B | | AND TU (b) (6) | RNED BLUE | | |
| AGAIN ON MOTH THE HOSPITAL. | | | HER UP TO A | | ENT TO |
| SHE WAS HAVIN | | | | | R MRI |
| | | | /ERNIGHT AN | | |
| TAKING KEPPRA FOR A COUPLE | | | | TEETHING T SEIZURE. | MOTHER |
| READ ON INTER | | | | | 110 211 211 |
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| 1 | | | 11 161 4 | n (6 anti nue o | n page 3) |
| 6. Relevant Tests/La | boratory Data | , Includin | g Dates | U.5014 | ,g/ |
| (b) (6) | | | | | |
| MR | I WAS CLE | AK | يا ك | 111 | |
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| Other Relevant Hi race, pregnancy, s | story, Includir moking and alc | ng Preexis ohol use, | sting Medical Co hepatic/renal dys | nditions (e.g., & function, etc.) | allergies, |
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| | | | | (Continue o | n page 3) |
| Submission of a personnel, user fa | report does | not co | nstitute an ad | mission that | medical |

caused or contributed to the event.

Approved: OMB No. 0910-0291, Expl res: 6/30/2015 See OMB statement on reverse. ser-facilities, 54973 rs and manufacturers ORY reporting UF/Importer Report # of 5 F DA Use Only C. SUSPECT PRODUCT(S) Name (Give labeled strength & mfr/labeler) #1 HYLAND'S BABY TEETHING TABLETS Therapy Dates (If unknown, give duration) from/to (or best estimate) 2. Dose, Frequency & Route Used #12 TABLETS AS NEEDED #1 #2 4. Diagnosis for Use (Indication) 5. Event Abated After Use Stopped or Dose Reduced? #1 TEMP RELIEF TEETHING PAIN Doesn's #1 Yes No #2 Doesn' Apply #2 Yes No 6. Lot # Exp. Date #1113749 8. Event Reappeared After Reintroduction? Doesn't #2 #1 Yes No #2 9. NDC# or Unique ID Doesn' #2 Yes No Apply 54973-3127-2 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) D. SUSPECT MEDICAL DEVICE 1. Brand Name 2b. Procode 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Operator of Device Health Professional Expiration Date (mm/dd/yyyy) Catalog # Lay User/Patient Other: Unique Identifier (UDI) # Serial # 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor DSS JUN 1 1 2014 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) E. INITIAL REPORTER 1. Name and Address JUN 1 0 2014 Email Address (b) (6) # Initial Reporter Also Sent Report to FDA 2. Health Professional? 3. Occupation NA Yes ✓ No Yes No V Unk

CaseID: 10234831

duct

CaseID: 10234831



| 10234831-01-00-02 | | | | | | |
|--|--|---|---|--|--|--|
| User Facility | ∐ Im po | orter | | | | |
| 3. User Facility or Imp | orter Name | Address | | | | |
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| | | | | | | |
| 4. Contact Person | | 5. Phone N | lumber | | | |
| | | ĺ | | | | |
| Date User Facility o Importer Became | r | 7. Type of Report | 8. Date of This Report (mm/dd/yyyy) | | | |
| Aware of Event (mn | r/dd/yyyy) | Initial | | | | |
| | | Follow-up# | | | | |
| 9. Approximate Age of Device | 10. Event | Problem Codes (Refer to code | ing manual) | | | |
| | Patient Code | - | - | | | |
| | Device [| _ | | | | |
| 11. Report Sent to FDA | Code L | 12. Location Where Event | Occurred | | | |
| l _ | 71 | Hospital | Outpatient | | | |
| Yes(mm/dd | Ууууу) | Home | ☐ Diagnostic Facility ☐ Ambulatory | | | |
| 13. Report Sent to Mar | nufacturer | | Surgical Facility | | | |
| Yes | | Outpatient Treatment Facility | nt | | | |
| No (mm/dd/yyyy) Other: | | | (Specify) | | | |
| (mm/dd | | (Specify) | | | | |
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| No (mm/dd | e/Address | 1 | (Зреспу) | | | |
| No (mm/dd | | | (Specify) | | | |
| No (mm/dd | CTUREF | | | | | |
| No (mm/dd | CTUREF | | 2. Phone Number 310-768-0700 | | | |
| No (mm/dd 14. Manufacturer Nam G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK | CTUREF | | 2. Phone Number 310-768-0700 3. Report Source | | | |
| No (mm/dd 14. Manufacturer Nam G. ALL MANUFA 1. Contact Office (and Name | CTUREF | | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) | | | |
| In No (mm/dd) 14. Manufacturer Nam G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. | CTURE: Manufactu | | 2. Phone Number 310-768-0700 3. Report Source | | | |
| No (mm/dd 14. Manufacturer Nam G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address | CTURES Manufactu | ring Site for Devices) | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. | CTURES Manufactu | ring Site for Devices) | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address | CTURES Manufactu TREET A 9006 | ring Site for Devices) | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address | CTURES Manufactu TREET A 9006 | thiclaboratories. | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ | CTURES Manufactu TREET A 9006 | thiclaboratories. (A)NDA# | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ | CTURES Manufactu TREET A 9006 homeopa | thiclaboratories. | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) | CTURES Manufactu TREET A 9006 homeopa | thiclaboratories. 9 5. (A)NDA# IND# BLA# | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeake 4. Date Received by Manufacturer (mm/c) 6. If IND, Give Protocol | CTURE: Manufactu TREET A 9006 home opa | thiclaboratories. | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) 6. If IND, Give Protocol | TREET A 9006 homeopa | thiclaboratories. of S. (A)NDA # IND # BLA # PMA/ | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) 6. If IND, Give Protoco | TREET A 9006 homeopa | thiclaboratories. of 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day 30-day 7-day Perio 10-day Initial | TREET A 9006 homeopa | thiclaboratories. 9 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Product Yes | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) Manufacturer (mm/c) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day | CTURES Manufactu TREET A 9006 homeopa dd/yyyy) si # | thiclaboratories. 9 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Product Yes OTC Product Yes | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day | CTURE; Manufactu TREET A 9006 homeopa dd/yyyy) bi # | thiclaboratories. 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Product Yes Pre-1938 Yes | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: | | | |
| G. ALL MANUFA 1. Contact Office (and Name ALISON MC PEAK Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, C. Email Address alison.mcpeak@ 4. Date Received by Manufacturer (mm/c) Manufacturer (mm/c) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day | CTURE; Manufactu TREET A 9006 homeopa dd/yyyy) bi # | thiclaboratories. 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Product Yes Pre-1938 Yes OTC Product Yes | 2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: | | | |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | FDA USE ONLY |
|---|---|
| .5 | |
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | ☐ Yes ☐ No |
| | |
| 6. Event Problem and Evaluation Codes (Refer to | coding manual) |
| Patient Code | - |
| Device | |
| Code | |
| Method - | - - |
| | |
| Results | |
| Conclusions - |]-[|
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| | 9. If action reported to FDA under |
| Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | |
| - AAAA AAAA AAAA | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual case safety Report

FRECORD



| | 10234831-01-00-03 | | COMPLAINT #: | 2546 | |
|--|---|---|---|--|---|
| TAKEN BY: | ALISON MC PEAK | DATE | OF COMPLAINT: | 05/15/2014 | |
| PRODUCT: | HYLAND'S BABY TEETHING | TABLETS | ITEM CODE: | BTETT250 | |
| SIZE: | 250 TABLETS | | LOT NO.: | 113749 | |
| REPORTER: | (b) (6) | | | | |
| ADDRESS: | 10 000000000000000000000000000000000000 | | | , | |
| | | | (b) (6) | | |
| CITY: | (b) (6) | S1 | TATE: | | |
| COUNTRY: | USA (b) (6) | ZIP | CODE | | |
| PHONE #: | (b) (6) | | | | |
| E-MAIL: | CHILD HAD 1 OR 2 DO | SES RANDOMLY OF TEETHING TABLE | TS. MAYBE 4 TABL | ETS A DAY A FE | W WEEKS AGO. |
| TURNED BLUE KEP MACHINE AND SAW TAKING KEPPRA. S | | COUPLE WEEKS THEN SHE STARTED (b) (6) WITH PNEUMONIA. THE EV AY, MONDAY, (b) (6) THEY WENT TO RES IN 1 DAY. HER MRI WAS CLEAR. | TO DO THIS WEIR ENTS WHERE SHE THE HOSPITAL. T THEY KEPT HER (| D THING AND TU STOPPED BREA HEY HOOKED HE OVERNIGHT AND | RNED BLUE. THING AND ER UP TO A SHE IS NOW |
| | FOR ADDITIONAL SPACE | PLEASE USE REVERSE OR ATTACH | A SEPARATE SHE | ET | |
| | _ | | | | _ |
| PRODUCT RECEIVE INSPECTION: 05/15/14 AMP: HER TEETHING TABLET | (CIRCLE ONE) | , | RETURNED FOR I | | Y (CIRCLE ONE) |
| PART OF RECALL. | | | | _ | |
| | | | UPS CALL 1 | TAG ISSUED: | (CIRCLE ONE) |
| | | | DATE PRODUC | T RECEIVED: | |
| SECTION II: | INVESTIGATION | | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVES | TIGATION REPORT | | | |
| INVESTIGATION. | PERSE SEE AT INCHED INVES | TIGATION REPORT. | | | |
| | | | | | - |
| | | | | | _ |
| | | | | | |
| | ORWARDED TO PHARMACIST / NURSE | | 05/15/14 | | |
| - | ORWARDED TO PHARMACIST / NURSE | FOR EVALUATION BY: | ALISON M | IC PEAK | 15.1.12.110004 |
| SECTION III: | CORRECTIVE ACTION: | | | , | |
| | | | | | |
| | | | | | |
| | | | | | Dss |
| CORRECTIVE ACTIO | ON(S) COMPLETED BY: | | DATE: | | JUN 1 1 2014 |
| SECTION IV: | ADVERSE EVENT REPORTS | | AE #: | 1536 | |
| ADVERSE EVENT S | ERIOUS: | N | | | |
| ADVERSE EVENT R | EPORTED ON: 05/15/14 | | ALISON MC PEA | AK | |
| SECTION V: | _ | $\rightarrow 11$ | | | JUN 1 0 2014 |
| REVIEWED BY MAN | AGEMENT BY: | Kwalt | DATE: | 05-29 | 3-14 |
| BY: | QA / QC DIRECTOR | u ' | DATE: _ | 05-27 | -14 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

CaseID: 10234831





e Ever

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # 113749, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # 113749 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # 113749. The lot was also submitted for microbial testing and all results were within specifications. Additionally, the Baby Teething bulk lot # 113749 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # 113749. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # 113749.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

512311

Date

DSS JUN 11 2014

JUN 1 0 2014

CaseID: 10234831

10234831-01-00-05

VENT DATA FORM

| AE #: | 1536 | | COMPLAINT # | #: 2546 | |
|--|--|--|--|--|--------------|
| SECTION | N 1: | PATIENT INFORMATION (IF DIF | FERENT FROM REPORTER ON FORM | A VD1) | |
| NAME: | | (b) (6) | | | |
| ADDRES | SS: | | | | |
| CITY: | | (b) (6) | STATE: | (b) (6) | |
| COUNTR | RY: | USA | ZIP CODE: | | |
| PHONE | | (b) (6) | | | |
| E-MAIL: | | | | | |
| SECTIO | <u>N II:</u> | PACKAGING INFORMATION: | | | |
| | AF | FIX PACKAGING LABEL HERE | (INCLUDE DRUG FACTS | OUTER CARTON HERE S AND PRINCIPAL DISPLAY (NELS) | |
| 127-PFS, DLIZO chained. Bear longers of of single model weaking that in which we have a substitute of the single of the financial of a new wises of device of your along it may be a worsen long of any financial of the part of worders. | IFUS, Overcomin St. 46 ST IFUS. Behadone IEEE STEELS Behadone IEEE STEELS Behadone IEEE STEELS BEHADON STEELS BEHAD | POC 64973-3327-2 40746 OPAT HICK THE MARK OF THE CONTROL OF THE C | Technic Charge C | With a monthly growth of the control | |
| SECTIO | ON III: | CORRECTIVE ACTION: | | 4. | |
| | | | | | — DSS |
| CORRE | ECTIVE A | CTION(S) COMPLETED BY: | | DATE: | JUN 1 1 2014 |
| SECTION | ON IV: | | | | 1 0 2017 |
| REVIE | WED BY | MANAGEMENT BY: | KWOW | DATE: 05-29 | 8-14 |
| BY: | | Que 18 | cui_ | DATE: 05-27 | -14 |



Form Approved: OMB No. 0910-0291, Expires: 12/31/2011

CaseID: 10257359 See OMB statement on reverse.

THE FUA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

ž

BLACK

TYPE OR

EASE

F

| RY reporting of |
|--------------------|
| Juct problems and |
| product use errors |

| ict problems and | Triage unit | Triage unit sequence # 554682 | | |
|--|------------------|-------------------------------|------------|--|
| eerrors | | | n ces | <i>_</i> |
| 2. Dose or Amount | Frequ | ency | Route | |
| #1 2 to 3 table | | times | | |
| #2 | | У . | <u> </u> | |
| "" | | | | |
| Dates of Use (If unkl (or best estimate) | | on) from/to | | t Abated After Use d or Dose Reduced? |
| #1 03/10/2014 - | 05/20/2014 | | #1 🔽 ` | Yes No Does |
| #2 | | | #2 [] | Yes No Does |
| 4. Diagnosis or Reaso #1 Teething - I v better than or | was told it w | | 8. Even | Apply t Reappeared After troduction? |
| #2 | | | - #1 🔲 Y | |
| 6. Lot# | 7. Expiration | n Data | #2 🗀 🗎 | Yes No Does |
| #1 | #1 | in Date | | # or Unique ID |
| #2 | #2 | | -1 | -3127-3 |
| E. SUSPECT ME | DICAL DEVI | CE | | |
| 1. Brand Name | | | | |
| | | | _ | |
| 2. Common Device Na | me | | CTU | |
| • • • • • • • • • • • • • • • • • • | | | | |
| | | JUN | 232 | O1A |
| 3. Manufacturer Name | City and State | - W - O 1 1 | 200 | .014 |
| | | | | |
| | | | | |
| 4. Model # | Lot# | | | 5. Operator of Device |
| | 1 | | | Health Profession |
| Catalog # | Evnication | n Data (m | m/dd/naad | Lay User/Patient |
| outding # | CAPITALI | in Date (iiii | redaryyyy) | Lay Osen/Patient |
| | | | | Other: |
| Serial # | Other# | | | Ì |
| | | | | |
| 5. If Implanted, Give Da | ate (mm/dd/yyyy) | 7. If Ex | planted, G | ive Date (mm/dd/yyyy) |
| O la Abia a Cianta anno I | N | | | |
| 8. Is this a Single-use I | Device that was | Reprocess | ed and Re | used on a Patient? |
| 9. If Yes to Item No. 8, Er | ter Name and Ad | dress of Re | processor | |
| | | | | |
| | | | | |
| F. OTHER (CONC | OMITANT) M | EDICAL | PRODU | ICTS |
| Product names and the | | | | |
| | | | | DSS |
| | | | | JUN 23 20 |
| | | | | |
| G. REPORTER (Se | ee confidentia | lity secti | on on ba | ack) |
| 1. Name and Address b) (6) | | | | |
| | | | | |
| | | | | |
| | | | | |
| Phone # | | E | | |
| b) (6) | | E-mail (b) (6) | | |
| | | | | |
| 2. Health Professional? | 3. Occupation | | 4. | Also Reported to: |
| Yes No | | | | Manufacturer |
| | 1 | | , | |

1. Patient Identifier | 2. Age at Time of Event or 4. Weight Date of Birth: (b) (6) 21_{lb} Female 9 Months (b) (6) ✓ Male In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply: 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Check all that apply) ___ Death: Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 05/21/2014 06/22/2014 5. Describe Event, Problem or Product Use Error I started giving my son hylands teething tablets, 2 pills at a time up to 4 dose's daily never more than twice in a hour. He started "Jerking" and I thought it was add excitement jerks or something. one day he started doing it a lot more than ever before so I took him to (b) (6) hospital er and got him checked out. They say it was the form of a seizure but that it was not because he was still focusing her was just "jerking" taking his head to his shoulder and locking up his muscles for 2-7 sec. So we went home he continues to jerk for a week longer as I am still giving him the ... 6. Relevant Tests/Laboratory Data, Including Dates none 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Race: White For additional information see B7 below. C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label) #1 Name: Hylands teething tablet Strength: Manufacturer #2 Name: Strength: 5. If you do NOT want your identity disclosed User Facility Manufacturer: to the manufacturer, place an "X" in this box: ☐ Distributor/Importer FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID/1025Z359

B.5. Describe Event or Problem (continued)

teething tablets for teething and then I came across a recall for his tablets. I then made a apt with his dr at (b)(6) which tells me the teething tablets have belladonna and that it causes toxicity and to immediately quit giving these tablets to my son. So I threw away all 3 box's I had and even took and threw away the ones at his daycare I gave them. With in 1 week of not having any teething tablets my son has quit "jerking" and is acting completely normal again.

Individual Case Safety Report

10257359-01-00-02

DSS JUN 2 3 2014 B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions: none

Allergies: none

Important Information: none

RX Meds: none

OTC Meds: none

Individual Case Safety Report



10257359-01-00-03

DSS JUN 23 2014

tors and manufacturers DATORY reporting

CaseID: 10267562

Form Approved: OMB No. 0910-0291, Exp-ires: 6/30/2015

| | | | Jee CIVID | statement of revers | - |
|----------------|---------|-----|-----------|---------------------|---|
| Mfr Report# | 4973 | see | 24 | Page | |
| UF/Importer Re | eport # | | | 1 3 | |
| | | | | | - |

| M FDA | 3500A (2/13) | Page 1 |
|-------|--------------|--------|

| FORM FDA 350 | 0A (2/13) | | | Page |
|--|---|--|--------------------------------------|------------------|
| A. PATIENT INF | ORMATION | | | |
| 1. Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight |
| (b) (6) | of Event: 18 | Months | | |
| | Date | | Male | or |
| In confidence | of Birth: | OT DEADLE | | k |
| B. ADVERSE E | VENT OR PRODUC |) I PROBLE | VI | |
| 1. Adverse Even | | duct Problem (e. | .g., defects/malfu | unctions) |
| Outcomes Attribut (Check all that appl | ted to Adverse Event | | | |
| Death: | | Disability o | r Permanent Dar | mage |
| Life-threatenin | (mm/dd/yyyy) ng | Congenital | Anomaly/Birth D | Defect |
| Hospitalization | n - initial or prolonged | Other Serio | ous (Important M | edical Event |
| Required Inter | vention to Prevent Perma | anent Impairment | /Damage (Devic | es) |
| 3. Date of Event (mn | n/dd/yyyy) | 4. Date of This | Report (mm/dd | Vyyyy) |
| 09/01/2013 | 06/06/2014 | | 06/12/2014 | |
| Describe Event or | Problem | | | |
| | REATH, PASSING SHE WILL BITE D | CEIV | WILL START | ILD |
| | 6 | CDR | | |
| | | | (Continue or | page 3) |
| 6. Relevant Tests/Lat | boratory Data, Including | g Dates | · | , , , |
| | | | | |
| | | | | |
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| | | | | |
| | | | | |
| 7. Other Delever III | | | (Continue or | |
| race, pregnancy, sn | story, Including Preexis noking and alcohol use, h | ting Medical Col nepatic/renal dysf | nditions (e.g., al unction, etc.) | iergies, |
| ALLERGIC TO MI | ILK, EGGS, PEANU | ITS | | |
| | | | | |
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| | | | | |
| | | | (Continue or | nage 21 |

caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

| L | (Continue on page 5) | |
|---|---|--|
| S | ubmission of a report does not constitute an admission that medical | |
| p | ersonnel, user facility, importer, distributor, manufacturer or product | |

of 5 FDA Use Only C. SUSPECT PRODUCT(S) Name (Give labeled strength & mfr/labeler) #1 HYLAND'S BABY TEETHING TABLETS Therapy Dates (If unknown, gree duration) from/to (or best estimate) 2. Dose, Frequency & Route Used #1 4 TABS QD PRN X 9 MOS #2 5. Event Abated After Use 4. Diagnosis for Use (Indication) Stopped or Dose Reduced? #1 TEMP RELIEF TEETHING PAIN Doesn't #1 ✓ Yes No #2 Doesn't #2 Yes No Apply 6. Lot # 7. Exp. Date 8. Event Reappeared After Reintroduction? #1 Yes No Doesr #2 #2 Doesn't 9. NDC# or Unique ID Doesn #2 Yes No 54973-3127-1 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) D. SUSPECT MEDICAL DEVICE 1. Brand Name 2b Procode 2. Common Device Name 3. Manufacturer Name, City and State 4. Model# Lot # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: Serial # Unique Identifier (UDI) # 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor JUN **2** 5 2014 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) E. INITIAL REPORTER 1. Name and Address JUN 2 4 2014 MD Phone # Email Address (b) (6) Initial Reporter Also Sent Report to FDA 2. Health Professional? 3. Occupation

NA

Yes No V Unk

Yes No

Individual Case Safety Report

10267562-01-00-02

Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

Approximate Age of Device

Yes

Yes

No

Name

Address

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Device

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

06/06/2014

30-day

✓ Initial

15-day Follow-up # 9. Manufacturer Report Number

54973 AE # 1542

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

7. Type of Report

5-day

7-day

10-day

EDYTA FRACKIEWICZ

HYLAND'S, INC. 154 W. 131ST STREET

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Facility

Other: _

Outpatient Treatment

Home

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Literature ✓ Consumer

User Facility

Company

Distributor

Other:

Study

Report Source (Check all that apply)

Health Professional

Representative

(mm/dd/yyyy)

e 2 o

| | | FDA USE ONLY |
|---|---------------------------|--|
| f <u>5</u> | | |
| H. DEVICE MANUFACTUR | ERS ONLY | |
| 1. Type of Reportable Event Death Serious Injury Malfunction | | If Follow-up, What Type? Correction Additional Information Response to FDA Request |
| | | Device Evaluation |
| Device Evaluated by Manufactur Not Returned to Manufacture Yes Evaluation Summ | er nary Attached | 4. Device Manufacture Date (mm/yyyy) 5. Labeled for Single Use? |
| No (Attach page to explain v | ony non a | Yes No |
| 6. Event Problem and Evaluation C | odes (Refer to | coding manual) |
| Patient Code Device Code Method Results Conclusions | - | - |
| 7. If Remedial Action Initiated, Che | | 8. Usage of Device |
| Recall Notificat Repair Inspectic Replace Patient Modificat Relabeling Modificat Adjustm | on Monitoring tion/ | Initial Use of Device Reuse Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| 10. Additional Manufacturer Na | errative | and / or 11. Corrected Data |
| | | DSS JUN 2 5 2014 |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Pre-1938

Combination

OTC Product

8. Adverse Event Term(s) SEIZURES, SPEECH DELAY

Yes

Yes

√ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Please DO NOT RETURN this form to the above PRA Staff email address.

CaseID: 10267562

OMPLAINT RECORD

COMPLAINT #: 2552

Hylands # 1008 1830 QQQY 1#: 2552 8628 8627

| TAKEN BY: | EDYTA FR | ACKIEWICZ | DATE O | F COMPLAINT: | 06/06/14 | |
|--|---|--|---|--|---|--|
| PRODUCT: | BABY TEE | THING TABLETS | | ITEM CODE: | BTETT135 | |
| SIZE: | 135 TABLE | TS | | LOT NO.: | THREW BOTTI | E AWAY |
| REPORTER: | (b) (6) | | | | ., | |
| ADDRESS: | | | | | | |
| | | | | | | |
| CITY; | | | STAT | TE: (b) (6) | | |
| COUNTRY: | USA | | ZIP CO | DE: | | |
| PHONE #: | (b) (6) | | | | | |
| E-MAIL: | | | | | | |
| WHICH SHE ATTRIB SPEECH. THREW B TEETH HURT. DESC SEIZURES GOING O SEIZURES. NO TES SEIZURES ONCE A I | AINT: REC HAS USED PRODUCT UTES TO THE HYLAN ABY TEETHING TABL CRIBES SEIZURES AS IN SINCE SHE WAS 9 TS FOR SEIZURES AI | CE MAIL MESSAGE: MOTHER ENTLY STARTED HAVING SEIZE FOR 6 – 8 MONTHS. SPOKE 100'S TEETHING TABLETS BECAUTH FOR 100 MOTHER BREAT MONTHS OLD SO FOR ABOUT DMINISTERED BY DOCTOR AT HAVING THEM FRIDAY AFTERIA | ZURE ACTIVITY. DOCTOR TO WITH MOTHER 06/11/14: MO AUSE SEIZURE ACTIVITY SLO 4. WAS GIVING CHILD 4 TAE H, PASSING OUT, LEGS WILL 9 MONTHS. DOCTOR SAID THIS TIME. MOTHER STOPP | OLD HER TO NO THER RECENTI DWS THE BRAIN BLETS EVERY D . START SHAKIN THAT TEETHIN PED THE TABLE | OT TO USE BABY Y NOTICED SOM A ACTIVITY AND (PAY FOR 9 MONTI NG AND SHE WILL G TABLETS WER ETS ON FRIDAY. | TEETHING IE SPEECH DELAY CAUSES DELAYS IN HS WHEN HER L BITE DOWN. E CAUSING THE CHILD HAS THE |
| | | | | | | |
| | FOR AL | DDITIONAL SPACE PLEASE US | E REVERSE OR ATTACH A | SEPARATE SHE | ET | |
| PRODUCT RECEIVE INSPECTION: | D FOR | Y (CIRCLE ONE) | PRODUCT BEING R | | | Y (CIRCLE ONE) |
| | | | DATE REQUESTE | D PRODUCT BE | E RETURNED: | |
| | | | | UPS CALL | TAG ISSUED: | Y (N) (CIRCLE ONE) |
| | | | | DATE PRODUC | T RECEIVED: _ | |
| SECTION II: | INVESTIGATION | ! | | | | |
| INVESTIGATION: | PLEASE SEE | ATTACHED INVESTIGATION R | EPORT | | | |
| | | | | | | |
| ADVERSE EVENT FO | DRWARDED TO PHAR | RMACIST / NURSE FOR EVALU | ATION ON: | 06/06/14 | | |
| ADVERSE EVENT FO | DRWARDED TO PHAR | RMACIST / NURSE FOR EVALU | ATION BY: | EDYTA F | RACKIEWICZ | |
| SECTION III: | CORRECTIVE | ACTION: | | | | |
| | | | | | | |
| | | | | | | DSS |
| | | # 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | |
| CORRECTIVE ACTIO | N(S) COMPLETED BY | /: | | DATE: | | JUN 2 5 2014 |
| SECTION IV: | ADVERSE EVENT | REPORTS | | AE #: | 1542 | |
| | | | | | | |
| ADVERSE EVENT SE | | (Y) / N | | | | |
| ADVERSE EVENT RE | EPORTED ON: | 06/06/14 | BY: | EDYTA FRACK | IEWICZ | |
| SECTION V: | | V | · \ | | | |
| REVIEWED BY MANA | AGEMENT BY: | | Want | DATE: | 06-17- | 14 |
| BY: | man Q | C DIRECTOR | | DATE: (| 06-17- 06-16- | 14 |

cc: QA / QC Packaging Production Shipping / Receiving

Individual Case Safety Report

10267562-01-00-04



Serious Adverse Event SAE-0019-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been sixty-three Adverse Events (AE) which also included nine Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

6/17/14

JUN 2 5 2014

CaseID: 10267562



CaseID: 10267562

EVENT DATA FORM

| AE #: | 1542 | COMPLAINT #: 2552 |
|--|--|--|
| SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: ADDRESS | i | (b) (6) |
| CITY: COUNTRY PHONE #: E-MAIL: | | USA ZIP CODE: |
| SECTION | <u>II:</u> | PACKAGING INFORMATION: |
| Landborn of Length miles (place) on miles and claims. Disconfidence in the broad of borner. In which de sound through the broad miles of disconfidence miles of disconfidence miles of disconfidence miles of disconfidence miles of disconfidence per 200 per file. The company for miles of file. The file of the state the miles of the file. The file of the state the miles of the file. The file of the state the miles of the state the miles of the state the miles of the state the state the miles of the state the br>the state the state the state the state the state the state the state the state the the state the state the state the state the state the state the state the state the the state the state the state the the state the state the state the state the state the the the state the state | integrativa in our me, in antimatory produce, in the many produced and string water fields and antimation of the string and the string of the string and the string of the string and the string of the string and the string of the string and the string of the string and the string of the string and the string of the string of the string of the string of the string of the string of the string of the string of the string of the string of the string of the string of string br>string | Teething Tablets Teething Tablets Teething Tablets Toething Tablets |
| SECTION | <u>III:</u> | CORRECTIVE ACTION: |
| | | DSS JUN 2 5 2014 |
| CORRECT | IVE AC | TION(S) COMPLETED BY: DATE: |
| SECTION REVIEWE | | ANAGEMENT BY: PWWH DATE: OC-17-14 |
| BY: | راه | manical. DATE: 06-16-14 |

mer Report

CaseID: 10272692

| No.\09 | 910 -02 91, | Expires: | 12/ | 31/2011 |
|--------|------------------------|----------|-----|----------|
| S | ee OMB s | tatement | on | reverse. |

| No. | (091 | 0 -02 91 | , Expires: | 12/ | 31/2011 |
|-----|------|---------------------|------------|-----|----------|
| | See | OMB | statement | on | reverse. |

| 10272692-01-0 | 0-01 | Y reporting of act problems and | Triage unit sequence # 55 | SE SE CO |
|--|---|------------------------------------|----------------------------|--|
| ne i DA Galety imoliniauon anu | product | use errors 12 | sequence# | 10007 |
| dverse Event Reporting Program | | 115 | | |
| A. PATIENT INFORMATION | | 2. Dose or Amount | Frequency Four times | Route Taken under the tongue |
| A. PATIENT INFORMATION Patient Identifier 2. Age at Time of Event or Date of Birth: | 3. Sex 4. Weight | 2-3 Cablecs | daily | Taken under the tongue |
| 18 Months | Female 25 | lb #2 | | |
| (b) (6) | ☐ Male or | kg | | |
| In confidence B. ADVERSE EVENT, PRODUCT PRODU | DORLEM OR EPPOR | 3. Dates of Use (If unknow | vn. give duration) from/to | 5. Event Abated After Use |
| B. ADVERSE EVENT, PRODUCT Process all that apply: | ROBLEM OR ERROR | (or best estimate) | | Stopped or Dose Reduced? #1 Yes No Doesn't |
| | (e.g., defects/malfunctions) | #1 06/05/2014 - 06 | /23/2014 | #1 V Yes No Apply |
| Product Use Error Problem with Diffe | rent Manufacturer of Same Medic | tine #2 | 11 - (1 - # - # - # - *) | #2 Yes No Doesn't |
| Outcomes Attributed to Adverse Event | | 4. Diagnosis or Reason f | with sore gumbs. | 8. Event Reappeared After |
| (Check all that apply) | sability or Permanent Damage | | | Reintroduction? |
| (mm/dd/ssss/) | | #2 | | #1 Yes No Doesn't |
| | ongenital Anomaly/Birth Defect | 6. Lot# | 7. Expiration Date | #2 Yes No Doesn't |
| Hospitalization - initial or prolonged Ot | | #1 B32713 | #1 | 9. NDC # or Unique ID |
| Required Intervention to Prevent Permane | | #2 | #2 | |
| . Date of Lyone (minday)))) | Date of this Report (mm/dd/yyyy) | E. SUSPECT MED | ICAL DEVICE | |
| 00,21,2021 | 6/27/2014 | 1. Brand Name | | |
| Describe Event, Problem or Product Use E My 18 month old daughter has b | been using the hylands | | | |
| teething tablets for 3 weeks weeks she has had a horrible | now. In the last two | ar 2 Common Device Nam | e | |
| to the looks of ring worm, but | t all over her body it | 11 | | CTU |
| would stay for 12-24 hours the | en disappear for a day (| or | | |
| two. When this rash would pop use her nebulizer to help wit | h her breathing. I | 3. Manufacturer Name, 0 | City and State | JUN 3 0 2014 |
| brought her to the doctors ve- | sterday 06/26/14. They | · | | 2014 9 0 5014 |
| have referred her to an aller out what causes it, that appo | gist hoping to maybe in intment is 07/21/14. | | Lot# | 5. Operator of Device |
| out what causes it, that appe | | 4. Model # | Lot# | Health Professional |
| | | | | |
| | | Catalog # | Expiration Date (| (mm/dd/yyyy) Lay User/Patient |
| | | · | | Other: |
| 6. Relevant Tests/Laboratory Data, Including | Dates | Serial # | Other# | |
| My 18 month old | | | | |
| | | 6. If Implanted, Give Da | te (mm/dd/vvvv) 7. lf | Explanted, Give Date (mm/dd/yyyy) |
| | | | | |
| | | | evice that was Reproce | essed and Reused on a Patient? |
| | | Yes No | the Name and Address of | (Reprocessor |
| | | 9. If Yes to Item No. 8, En | ILET NATHE AND ADDRESS OF | Reprocessor |
| 7. Other Relevant History, Including Preexist | ting Medical Conditions (e.g., | | | |
| Other Relevant History, Including Preexist allergies, race, pregnancy, smoking and alco Race: White | hol use, liver/kidney problems, etc.) | F. OTHER (CONC | OMITANT) MEDIC | AL PRODUCTS |
| | | Product names and the | erapy dates (exclude trea | atment of event) |
| For additional information se | ae B7 below. | , rough names and the | | <i>'</i> |
| | | | • | |
| | | | | |
| | | G. REPORTER (Se | ee confidentiality se | ection on back) |
| a propust avall appliety | | 1, Name and Address (b) (6) | | ne |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not see | end product to FDA) | | | DS Jun 30 |
| | | | | JUN 2 A |
| Yes No Returned to Manufa | (mm/dd/yyyy) | | | 5011 00 |
| D. SUSPECT PRODUCT(S) | | Phone # | E-m | nail |
| 1. Name, Strength, Manufacturer (from produ | | (b) (6) | (b) (6 | 5) |
| #1 Name: Hylands Teething Tablet Strength: | :5 | | | |
| Manufacturer: Hylands Inc. | | 2. Health Professional | ? 3. Occupation | 4. Also Reported to: |
| #2 Name: | | Yes No | | Manufacturer User Facility |
| | | 5. If you do NOT want v | our identity disclosed | User Facility |

Strength:

Manufacturer:

5. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

☐ Distributor/Importer

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

... daughter will have to undergo a 2 1/2 -3 hour allergy test to try and help figure out the problem.

Individual Case Safety Report

10272692-01-00-02

DSS JUN 30 2014

5505690519272692

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions: Asthma

Allergies: N/A

Important Information: N/A

DV Made: W/A

RX Meds: N/A -----OTC Meds: N/A

Individual Case Safety Report



10272692-01-00-03

DSS JUN **3 0** 2014

sumer Report

CaseID: 10272885

-9910-0291, Expires: 12/31/2011 See OMB statement on reverse.

| ne | FUA | oarety | miorina | JUH AHU |
|-----|------|---------|-----------|-----------|
| ١d٧ | erse | Event i | Reporting | g Program |

RY reporting of duct problems and

| | FDA USE ONLY | |
|------------------------|--------------|--|
| Triage unit sequence # | 555606 | |
| | , | |

| ine FDA Sarety information and Adverse Event Reporting Program | product us | e errors // 2 | sequence # | 0009 |
|--|--|---|------------------------------|--|
| A. PATIENT INFORMATION 1. Patient Identifier 2. Age at Time of Event or Date of Birth: | | 2. Dose or Amount | Frequency | Route |
| 7 Months (b) (6) | Female 20 lb Male or kg | #2 | | |
| B. ADVERSE EVENT, PRODUCT PROCeck all that apply: 1. Adverse Event Product Problem (e.g. | | 3. Dates of Use (If unkr (or best estimate) #1 10/01/2012 - 0 | nown, give duration) from/to | 5. Event Abated After Use Stopped or Dose Reduced? #1 Ves No Doesn't |
| Product Use Error Problem with Differe | | #2 4. Diagnosis or Reason | n for Use (Indication) | #2 Yes No Doesn't Apply |
| Outcomes Attributed to Adverse Event (Check all that apply) Death: Desath: | pility or Permanent Damage | #1 Teething purpo | , , | 8. Event Reappeared After Reintroduction? #1 Yes No Doesn't |
| | genital Anomaly/Birth Defect | #2 | 7. Expiration Date | #2 Yes No Doesn't |
| ✓ Hospitalization - initial or prolonged ☐ Other ☐ Required Intervention to Prevent Permanent I | | 6. Lot# | #1 | 9. NDC # or Unique ID |
| , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | e of this Report (mm/dd/yyyy) | #2 | #2 | |
| 5. Describe Event, Problem or Product Use Erro Hello, my name is (b) (6) the Hylands Teething Tablets in | My son was taking Oct 2012 I don't know | E. SUSPECT ME 1. Brand Name | DICAE DEVICE | |
| there was a recall on them. In started having seizures back to they thought it was from fever h | back for no reason but it was most of the | 2. Common Device Na | | JUN 3 0 2014 |
| time there was no fever n he's of for the seizures and the doctor can't find a link to why he are has a speech delay he was doing until he started having the sei: | still doesn't know or having them . He also fine with his speech | 3. Manufacturer Name | , City and State | 0 0 2014 |
| taking medicine for seizures twi | | 4. Model # | Lot# | 5. Operator of Device Health Professional |
| they thought it was from fever they thought it was from fever time there was no fever n he's for the seizures and the doctor can't find a link to why he are has a speech delay he was doing until he started having the seizures taking medicine for seizures twispeech twice a | | Catalog # | Expiration Date (m | mm/dd/yyyyy) |
| 6. Relevant Tests/Laboratory Data, Including Da EKG, (b) (6) | tes | Serial # | Other# | |
| | | 6. If Implanted, Give D | ate (mm/dd/yyyy) 7. If Ex | xplanted, Give Date (mm/dd/yyyy) |
| | | 8. Is this a Single-use | Device that was Reprocess | sed and Reused on a Patient? |
| | | 9. If Yes to Item No. 8, E | nter Name and Address of R | leprocessor |
| 7. Other Relevant History, Including Preexisting allergies, race, pregnancy, smoking and alcohol Race:Black/African American | Medical Conditions (e.g., use, liver/kidney problems, etc.) | F. OTHER (CONC | COMITANT) MEDICAL | _ PRODUCTS |
| For additional information see | B7 below. | Product names and th | erapy dates (exclude treatm | nent of event) |
| C. DRODUCT AVAILABILITY | | 1. Name and Address | ee confidentiality sec | tion on back) |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send portion) Yes V No Returned to Manufacture | er on: | (b) (6) | | DS |
| D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product la. | (mm/dd/yyyy) | Phone # (b) (6) | E-mail (b) (6) | DSS JUN 3 0 |
| #1 Name: Hylands Strength: Teething Tablets Manufacturer: | | 2. Health Professional | | 4. Also Reported to: |
| #2 Name: Strength: | | Yes No | | Manufacturer User Facility |
| Manufacturer: | | to the manufacturer, | place an "X" in this box: | Distributor/Importer |

B.5. Describe Event or Problem (continued)

... week. I need some answers I also recently gave my 9 month old the same tablets n he have been to the er for having seizures lucky I stopped the tablets and he haven't had another one. Can you please contact me ASAP I have a case that needs to be claimed thank you for your time I look forward to hearing from someone soon. (b)(6)

Individual Case Safety Report

10272885-01-00-02

DSS JUN 3 0 2014

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions: Seizures and speech delay

Allergies: Pollen

Important Information: None

RX Meds: Keppra 3.0 twice a day

OTC Meds: None

Individual Case Safety Report



10272885-01-00-03

DSS JUN 3 0 2014



mer Report

CaseID: 10275530

OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

| 1027.5530-01-00-01 | | Y reporting of .uct problems and | Triage unit | DA USE ONLY |
|---|-----------------------|--|-------------------------|---|
| ine FDA Sarety Information and Adverse Event Reporting Program | product us | se errors 1/2 | sequence # 50 | 2420 |
| A. PATIENT INFORMATION | | 2. Dose or Amount | Frequency | |
| 1. Patient Identifier 2. Age at Time of Event or 3. Sex Date of Birth: | 4. Weight | #1 #1 | | Route |
| 1 Years Femal | le 23 _{lb} | L | | |
| (b) (6) Male | or | #2 | | |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR | kg | L | · | |
| Check all that apply: | ERRUR | Dates of Use (If unknow (or best estimate) | | Event Abated After Use Stopped or Dose Reduced? |
| . Adverse Event Product Problem (e.g., defects/mail | functions) | #1 09/01/2013 - 06/ | 18/2014 | #1 Yes No Does |
| Product Use Error Problem with Different Manufactur | er of Same Medicine | #2 | | #2 Yes No Does |
| 2. Outcomes Attributed to Adverse Event (Check all that apply) | | 4. Diagnosis or Reason for #1 Cutting teeth and | r Use (Indication) | 8. Event Reappeared After |
| Death: Disability or Perman | ent Damage | avoid pain meds. | - Power 1 dates to | Reintroduction? |
| ☐ Life-threatening ☐ Congenital Anomaly | /Birth Defect | #2 | | #1 Yes No Doesr |
| ☐ Hospitalization - initial or prolonged ✓ Other Serious (Impo | rtant Medical Events) | 6. Lot# | 7. Expiration Date | #2 Yes No Doesr |
| Required Intervention to Prevent Permanent Impairment/Dan | nage (Devices) | #1 | #1 | 9. NDC # or Unique ID |
| 3. Date of Event (mm/dd/yyyy) 4. Date of this Report | t (mm/dd/yyyy) | #2 | #2 | - |
| 06/07/2014 06/27/2014 Describe Event, Problem or Product Use Error | | E. SUSPECT MEDIC | AL DEVICE | |
| My 14 mon. old daughter was taking hyland | teething | . prand Name | | |
| tablets she had a seizure, has had breaproblems and extremely fatigue! I'm curiou | athing | | | CTU |
| will cause long time effects and what can | be done? | 2. Common Device Name | | |
| | , | | | JUN 3 0 2014 |
| | 1 | 3. Manufacturer Name, City | and State | |
| | | | | |
| | | 4. Model # | Lot# | |
| | | | 1201# | 5. Operator of Device Health Professional |
| | | Catalog # | Euricetic - Dut. (| |
| | . [] | | Expiration Date (mn | Lay User/Patient |
| Relevant Tests/Laboratory Data, Including Dates | | Serial # | 1000 | Other: |
| My doctor has | | . Jenai w | Other # | |
| | - 11 | 6 If Implement of City But (| | |
| | . [] | 6. If Implanted, Give Date (r | nm/dd/yyyy) 7. If Exp | lanted, Give Date (mm/dd/yyyy) |
| | . [] | 8. Is this a Single-use Device | e that was Reprocesse | d and Reused on a Patient? |
| · · |]} | Yes No 9. If Yes to Item No. 8, Enter N | Jame and Address of Box | |
| Other Relevant History, Including Preexisting Medical Condition | | | and Address of Rep | 10049901 |
| allergies, race, pregnancy, smoking and alcohol use, liver/kidney Race: White | problems, etc.) | • | | , |
| | | F. OTHER (CONCOM | TANT) MEDICAL I | PRODUCTS |
| For additional information see B7 below. | | Product names and therapy | dates (exclude treatmen | nt of event) |
| | [] | | | |
| | - 11 | | | , |
| | | G. REPORTER (See co | onfidentiality sectio | n on back) |
| PRODUCT AVAILABILITY | | 1. Name and Address (b) (6) | | |
| oduct Available for Evaluation? (Do not send product to FDA) | | | | |
| Yes ✓ No ☐ Returned to Manufacturer on: | m/dd/yyyy) | | | DS Jun 8 (|
| SUSPECT PRODUCT(S) | (Julyyyy) | | | |
| lame, Strength, Manufacturer (from product label) | | Phone # | E-mail | |
| Name: teething tablets and teething ge Swength: hylands teething tablets and gel | | | } | |
| Manufacturer: | 112 | 2. Health Professional? 3. C | ccupation | 4. Also Reported to: |
| Name: | | Yes No | | Manufacturer |
| Strength: Manufacturer: | 1 5 | . If you do NOT want your ide | ntity disclosed | User Facility |
| RM FDA 3500 (1/09) Submission of a report does no | - 11 | to the manufacturer, place a | n "Y" in this have | ☐ Distributor/Importer |

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

5535elDr.210275530

... records of the fatigue and breathing problems and she was taking by ambulance to the ER for a siezure just recently.

Individual Case Safety Report

10275530-01-00-02

DSS JUN **3 0** 2014 B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions:

Allergies:

Important Information:

RX Meds: Amoxicillan antibiotic for ear infection

OTC Meds: Tylenol. clartin. orajel.

Individual Case Safety Report



10275530-01-00-03

DSS JUN 3 0 2014

Sisser 140283615

REPORT INFORMATION

1/7

177283

CDER

Report Profile

Report Version FPSR.FDA.DSR.V.V1

Report Category Voluntary Dietary Supplements Report

Submitted 2014-06-20 01:06:26 EST

FDA ICSR ID 1035209

Report Key for Followup 38BEF829-163F02F2-AEBE2280-8829111D-98858ECF-8329673E-2A8FAC1B-46A682C1

Report Identifying Information

CTU

Please enter a title to help you identify

this report.

Hyland's Teething Tablets

JUL - 3 2014

What type of report are you submitting? Adverse event (an adverse health-related event associated with the product)

Regulatory Status Voluntary

CAERS 06/20/2014

USS Jul 032014



Contact Information- Your Contact Information

Do you wish to remain anonymous to the First name Last name Email Confirm email Phone Country United States Street adddress line 1 Street address line 2 <blank> City/Town State Mail/ZIP code Have you reported the event to any of the <blank>

Relevant Details

Patient/Consumer identifier

Are you a healthcare professional? No

Gender Male

Age at time of event, <i>if unknown, please enter Date of birth below</i>

Select unit of measure Month(s)

following?

Date of birth

Weight 13

Select unit of measure Pound(s)

Height 25

Select unit of measure Inch(inches)

DSS

JUL 0 3 2014

Problem Details

If other, please describe symptoms like spasms

Please describe the event or problem

After I gave my son Hyland's Teething Tablets, either his legs, arms or body would look like he was having spasms. After I saw a post on Facebook, I did some research. I am taking my son to his pediatrician first thing tomorrow morning.

Date of event 04/22/2014

Duration of adverse event 2

Select unit of measure minute

Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):

Do you have any relevant tests/laboratory data information to No report?

Individual Case Safety Report



10283615-01-00-03

Adverse Event Terms

Adverse event term Hyland's Teething Tablets

If other, please describe Hyland's Teething Tablets

Relevant Tests/Laboratory Data

Product Information

Select full name of product as it appears

on the package label

Full name of product as it appears on the

package label

Homeopathic Hyland's Baby Teething Table

Product manufacturer, packer, distributor Hyland's, Inc.

Product strength <blank>

Select unit of measure <blank>

Barcode identifier <blank>

Select identifier type <blank>

If other, please describe

Diagnosis or reason for use (indication): Relief due to teething.

Lot number A24314

Expiration/use-by date 06/30/2014

Is the product available for evaluation by

the FDA?

Unknown

DSS

JUL 0 3 2014

000003

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:

04/22/2014

End: 06/19/2014

Duration of product use 2

Select unit of measure month(s)

Frequency of consumption <blank>

> Select unit of measure <blank>

Amount consumed per serving <blank>

> Select unit of measure <blank>

Administration route <blank>

Relatedness Details

Did the event stop when product use

stopped or amount consumed was

reduced?

Did the event reoccur when product use

resumed?

Not Applicable

Please provide any notes describing the

product's usage.

<blank>

Ingredient Details

Ingredient name

Belladonna 12X HPUS

If other, please describe Beliadonna 12X HPUS

Ingredient amount <blank>

Select unit of measure

DSS JUL 0 3 2014

Ingredient Details

Ingredient name Calcarea Phosophorica 6X HPUS

If other, please describe Calcarea Phosophorica 6X HPUS



CaseID: 10283615

556115

Ingredient Details

Ingredient name Chamomilla 6X HPUS

If other, please describe Chamomilla 6X HPUS

Ingredient amount <blank>

Select unit of measure <blank>

Ingredient Details

Ingredient name Coffea Cruda 6X HPUS

If other, please describe Coffea Cruda 6X HPUS

Ingredient amount <blank>

Select unit of measure <blank>

Ingredient Details

Ingredient name Arcacia Gum

If other, please describe Arcacia Gum

Ingredient amount <blank>

Select unit of measure <blank>

Ingredient Details

Ingredient name Lactose N.F.

If other, please describe Lactose N.F.

Ingredient amount <blank>

Select unit of measure <blank>

Product Relevant Details

000005

DSS

JUL 0 3 2014

CaseID: 10283615

556115

Concomitant Product Information



10283615-01-00-06

Concomitant Product Relevant Details

HL7 Batch Information

HL7 Batch Control Information

Submitting Organization Id

(b) (6)

HL7 Batch Sender Information

Sender Id GuestAccount

HL7 Batch Receiver Information

Batch Receiver (Root) USFDA

Batch Receiver (Extension) US Food and Drug Administration

D88

JUL 0 3 2014

HL7 Message Information

HL7 Message Control Information



HL7 Message Sender Information

Unique Sender Identifier ID-NOTGIVEN

Organization Name UNKNOWN

Title Voluntary Dietary Supplement Submitter

HL7 Message Receiver Information

Message Receiver Id USFDA

Attached Files

FILENAME 100_1327.JPG

Description of Attachment Bottle of Homeopathic Hyland's Baby Teething Tablets.

Attachment Type Labeling Materials

FILENAME 100_1326.JPG

Description of Attachment Bottle of Homeopathic Hyland's Baby Teething Tablets.

Attachment Type Labeling Materials

FILENAME 100_1324.JPG

Description of Attachment Bottle of Homeopathic Hyland's Baby Teething Tablets.

Attachment Type Labeling Materials

DSS JUL 0 3 2014



FURINI DE VOUVILLE ...,

| A. PATIENT INF | ORMATION | | | | |
|---|--|--|---------------------------------|-----------|--|
| 1. Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight | |
| (b) (6) | of Event: 1.5 | Years | [Famala | lbs | |
| } | or | | ✓ Female | or | |
| In confidence | of Birth: | | Male | kgs | |
| B. ADVERSE E | VENT OR PRODUC | CT PROBLE | М | | |
| 1. Adverse Even | t and/or Pro | duct Problem (e | .g., defects/malf | unctions) | |
| 2. Outcomes Attribut (Check all that appli | ted to Adverse Event | | | | |
| Death: | y) | ☐ Disability o | r Permanent Da | mane | |
| | (mm/dd/yyyy) | | | Ü | |
| ✓ Life-threatenin | rg n - initial or prolonged | | Anomaly/Birth Dous (Important M | | |
| . — | vention to Prevent Perma | _ | | | |
| 3. Date of Event (mn | | 4. Date of This | | | |
| | 00/2013 | I | 05/23/2014 | | |
| 5. Describe Event or | Problem | l | | | |
| ENMURR COLLEGE | MONIBERT TO THE | * * * * * * * * * * * * * * * * * * * | | | |
| | WONDERING IF H A YEAR AGO COUL | | | | |
| TEETHING TABLE | | TO THE HOS | | | |
| TESTS WERE NO | | OULD NOT D | | | |
| | SEIZURE CHILD | | | | |
| | CRYING. FATHER NED AND COME BA | | | | |
| | UT HOSE INCIDENT | | | | |
| SEIZURE. | | | 011000 | | |
| CETZUDE CVMDE | OMC. IDDE NOM | ave conv. a | | | |
| SEIZURE SYMPTO | OMS: LEFT ARM I LWAYS ABLE TO B | AND BODY SI | | ME FOAM | |
| | PONSIVE TO HER I | | | E. | |
| PRIOR TO, AND | ED TO TAKE THE I FOR A YEAR AFTI DENT OF THE SEI | ER THE SIE | | | |
| | | JONE! | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| 6 D | | | (Continue on | page 3) | |
| Neievant Tests/Lat | ooratory Data, Including | Dates | | | |
| lama | REPEATED EVERY | | | : BRAIN | |
| SPECIALIST: N | NEUROLOGY | | | | |
| ALL TESTS WERE NORMAL. | | | | | |
| | | | | | |
| | | | | | |
| | | | (Continue on | | |
| Other Relevant His race, pregnancy sm | tory, Including Preexist toking and alcohol use, he | ing Medical Con | nditions (e.g., all | ergies, | |
| | | , | , | | |
| | SEIZURE CHILD W | | | TER | |
| CONSTREDED WITH A HOSE, A | ND WAS CRYING. THER SHE HAD "D | FATHER SA | ID THEY | T EDOM | |
| TOO MUCH WATER POSSIBLE CAUSE | . EMT'S RULED | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | (Continue on | page 3) | |

| | $\mathcal{T}C_{\text{ext}}$ | n Annroved: | | | 028532. (páres: 6/30/201 |
|--------------------------------------|-----------------------------|--------------|--------------|-----------------------|-----------------------------|
| er-facilities, U | Mir Report# | | Se | e OMB state | ment on reverse |
| s and manufacturers ORY reporting | UF/Importer Re | | ૧૧૧૯ ટ | <u> </u> | |
| of 5 | | | - 1, | | |
| C: SUSPECT PROD | UCT(S) | | <u> </u> | | FDA Use Only |
| 1. Name (Give labeled stre | ngth & mfr/labeler) | | | | |
| #1 HYLAND'S BABY | TEETHING TA | ABLETS | | | |
| #2 2. Dose, Frequency & Rot | ite Used | 3 Thera | ny Dates / | If unknown | g we duration) |
| #1 1-2 TABS Q4H | ate vseu | from/to | o (or best e | estimate) | g#e ouranon, |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (India | cation) | J | | Abated Afte | |
| #1 TEMP | EPHING PAIN | | | es No | Doesn't Apply |
| #2 6. Lot # | 7. Exp. Date | | #2 🗀 Y | ′es ∏ No | Doesn't |
| #1 JUL | 0.2 2014 | | | Reappeared | Apply After |
| #2 | #2 | | | oduction? ′es ✓ No | ☐ Doesn't |
| 9. NDC# or Unique ID | DR | | | | Apply Doesn't |
| 54973-3127-1 | | | | es No | □ Арріу |
| 10. Concomitant Medical I TYLENOL | rroducts and Ther | rapy Dates | (Exclude | ueaument of | event) |
| | | | | | |
| | | | (0 | | |
| D. SUSPECT MEDIC | CAL DEVICE | | (C | ontinue o | n page 3) |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 2b. P | rocode | |
| 3. Manufacturer Name, Cit | y and State | | | | |
| | | | | | |
| 4. Model # | Lot# | | | 5. Operato | r of Device |
| Catalog # | Expiration | Date (mm/ | dd/yyyy) | | Professional |
| Serial # | Unique Ide | ntifier (UDI |)# | Other | |
| | | , | | | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Expla | anted, Giv | e Date (mm | (dd/yyyy) |
| 8. Is this a Single-use Dev | ice that was Repre | ocessed a | nd Reuse | d on a Patie | nt? |
| Yes No 9. If Yes to Item No. 8, Ent | er Name and Addr | ress of Re | processor | | |
| | | | | | |
| | | | | | 220 |
| 10. Device Available for Ev | aluation? (Do not | send to FD |)A) | | |
| Yes No | Returned to Ma | anufacturer | on: | (mm/ss) | 4,,032 0 |
| 11. Concomitant Medical P | roducts and Ther | apy Dates | (Exclude | treatment of | event) |
| | | | | | |
| E. INITIAL REPORTI | EP. | | (C | ontinue or | page 3) |
| 1. Name and Address | _1\ | | | | |
| (b) (6) | | | | | |
| | · | | 40 0 | | nnes. |
| | | | JU | L 02 | WP . |
| Phone # (b) (6) | Email | Address | | | |
| 2. Health Professional? 3 | Occupation | | 4. 1 | nitial Report | ter Also Sent |
| Yes No | NA . | | [| Yes | |
| | | | | | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

CaseID: 10285322

| Individual Ca: | se Safety Repo | rt | | | FDA USE ONLY |
|---|--|---|--|---|--|
| | | | 2 of 5 H. DEVICE MAN | IUFACTURERS ONL | Y |
| 102853 | 322-01-00-02 | | Type of Reportable | | 2. If Follow-up, What Type? |
| User Facility or Importer Namel | | | ☐ Death ☐ Serious Injury ☐ Malfunction | | Correction Additional Information Response to FDA Request Device Evaluation |
| | | | 3. Device Evaluated b | • | Device Manufacture Date (mm/yyyy) |
| 4. Contact Person | 5. Phone N | umber | Yes Ev | to Manufacturer valuation Summary Attached age to explain why not) or | |
| 6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) | . Type of Report | 8. Date of This Report (mm/dd/yyyy) | provide code: | | Yes No |
| | Follow-up # | | 6. Event Problem and | d Evaluation Codes (Refer | to coding manual) |
| Age of Device Patient Code | roblem Codes (Refer to codi | ng manual) | Code Devic Code | ce | |
| Device Code | - | - | Metho | nd - | |
| 11. Report Sent to FDA? | 12. Location Where Event | Occurred Outpatient Diagnostic Facility | Result | ts |]-[|
| No (mm/dd/yyyy) | Home | ☐ Ambulatory | Conclusion | is | |
| 13. Report Sent to Manufacturer? | Nursing Home Outpatient Treatmer | Surgical Facility | 7. If Remedial Action | Initiated, Check Type | 8. Usage of Device |
| Yes(mm/dd/yyyy) | Facility | | Recall | Notification | Initial Use of Device |
| No (material) | Other: | (Specify) | Repair Replace | Inspection Patient Monitoring | Reuse |
| 14. Manufacturer Name/Address | | | Relabeling Other: | Modification/ Adjustment | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| G. ALL MANUFACTURERS 1. Contact Office (and Manufacturi | | 2. Phone Number | 10. Additional Ma | nufacturer Narrative | and / or 11. Corrected Data |
| Name | ang one for bettees, | 310-768-0700 | | | |
| EDYTA FRACKIEWICZ Address | | Report Source (Check all that apply) | | | j |
| HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061 | | Foreign Study Literature Consumer | | | |
| Email Address STANDARD@HYLANDS.COM | | Health Professional | | | |
| 4. Date Received by Manufacturer (mm/dd/yyyy) 36/20/2014 | 5. (A)NDA # | User Facility Company Representative | | | DSS |
| 6. if IND, Give Protocol# | BLA# | Distributor Other: | | | DSS JUL 0 3 2014 |
| 7. Type of Report (Check all that apply) 5-day 30-day 7-day Periodic 10-day Initial 15-day Follow-up# | PMA/ 510(k) # Combination Product Yes Pre-1938 Yes OTC Product Yyes | | | <i>y</i> ** | |
| 9. Manufacturer Report Number 54973 AE # 1544 | 8. Adverse Event Term(s) SEIZURE | | | | JUL 02 2014 |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff

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PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff email address.

information unless it displays a currently valid OMB control number."



CUSTOMER COMPLAINT RECORD



| SECTION I: | COMPLAINT | | COMPLAINT #: | 2554 | |
|-------------------------------------|---|---|---|--|-----------------|
| TAKEN BY: | TUTTI G | OULD | DATE OF COMPLAINT: | | |
| PRODUCT: | | 'S BABY TEETHING TABLETS | | BTETT135 | |
| SIZE: | 135 TAB | | LOT NO.: | | |
| REPORTER: | (b) (6) | | | | |
| ADDRESS: | | | | | |
| | | | | | |
| CITY: | (b) (6) | | STATE: (b) (6) | | - |
| COUNTRY: | USA | | ZIP CODE: | | |
| PHONE #: | (b) (6) | | | | |
| E-MAIL: | | THER CALLED WONDERING IF HIS 2 Y | FAD OLD DALIGUEERIN OF TUBE FRO | NA VEAR AGO COMES HAVE BEE | |
| "DROWNED AND CO ALWAYS ABLE TO B | AINT: CA MINE CAUSE. CHIL BEEN PLAYING IN T DME BACK" FROM T BREATHE, EYES GL | LUSED BY BABY TEETHING TABLETS. D WAS IMMUNIZED 6 MONTHS PRIOR, THE WATER WITH HOSE, AND WAS CRIOD MUCH WATER. SEIZURE SYMPTOI AZED, STARING, UNRESPONSIVE TO HIS SONLY ONE INCIDENT OF THE SEIZUR | SHE WENT TO THE HOSPITAL AND AL HAD TAKEN TYLENOL THE NIGHT BE (ING, FATHER SAID THEY CONSIDER MS: LEFT ARM AND BODY SHAKING, ER NAME, LASTED 1 MINUTE. CHILD | LL TESTS WERE NORMAL. DOCTO FORE. JUST PRIOR TO THE ED WHETHER SHE MAY HAVE SOME FOAM FROM MOUTH, | |
| | FOR | ADDITIONAL SPACE PLEASE USE REV | ERSE OR ATTACH A SEPARATE SHE | ΕŤ | |
| PRODUCT RECEIVE INSPECTION: | D FOR | Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: Y N | |
| Individual | Case Safet | y Report | DATE REQUESTED PRODUCT BE | RETURNED: | |
| | | | UPS CALL | TAG ISSUED: Y N |) |
| 102 | 285322-01-0 | 0-03 | DATE PRODUC | T RECEIVED: | - |
| OCCITORIA. | | | | | |
| INVESTIGATION: | PLEASE SE | E ATTACHED INVESTIGATION REPORT | | The state of the s | |
| | | | | | |
| | | | | | |
| | | | | | |
| ADVERSE EVENT FO | DRWARDED TO PH | ARMACIST / NURSE FOR EVALUATION | ON: 06/20/14 | | |
| ADVERSE EVENT FO | DRWARDED TO PHA | ARMACIST / NURSE FOR EVALUATION ! | BY: TUTTI GO | DULD | |
| SECTION III: | CORRECTIV | /E ACTION: | | | |
| | | | | | |
| | | | | | |
| | | | | | DSS |
| CORRECTIVE ACTIO | W(C) COMPLETED | 27. | | | IUL 0 3 201 |
| CORRECTIVE ACTIO | IN(S) COMPLETED I | 3Y: | DATE: | | |
| SECTION IV: | ADVERSE EVE | NT REPORTS | AE #: | 1544 | |
| ADVERSE EVENT SE | RIOUS: | (y) N | | | |
| ADVERSE EVENT RE | PORTED ON: | 06/20/14 | BY: TUTTI GOULD | | |
| SECTION V: | | | | JUL O | 2 2014 |
| REVIEWED BY MANA | AGEMENT BY: | * KNU | DATE: | 06-25-14 | |
| BY: | My | o Pallu | _ DATE: _ | 06-25-14 | |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

CaseID: 10285322





Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been sixty-four Adverse Events (AE) which also included ten Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

JUL 0 3 2014

JUL 02 2014

Hylands **

EVENT DATA FORM

| AE #: 1544 | 4 | COMPLAINT # | 2554 | |
|---|--|--|--|-------------------------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFER | ENT FROM REPORTER ON FORM | VD1) | |
| NAME: | (b) (6) | | | |
| ADDRESS: | | | | - |
| | -(b) (6) | | | |
| CITY: | (0) | STATE: | (b) (6) | _ |
| COUNTRY: | USA (b) (6) | ZIP CODE: | | - |
| PHONE #: | - | annuale made of the least of the total and t | | |
| E-MAIL: | VIII. III. III. III. III. III. III. III | , | | _ |
| SECTION II: | PACKAGING INFORMATION: | | | |
| AFI | FIX PACKAGING LABEL HERE | (INCLUDE DRUG FACTS | TER CARTON HERE AND PRINCIPAL DISPLAY IELS) | |
| Indications: Vingons and court proteins of ingress entoneous and court in the proteins of the court of the court of the court of the court of the court of the court of the court of the court of the court of the man of the court of the part of the court of the court of the court of the court of the part of the court of the court of the court of the court of the part of the court of the court of the court of the court of the part of the court of the court of the court of the court of the part of the court of the court of the court of the court of the part of the court of the part of the court of the court of the court of the court of the court of the court of th | Addition of the their fact the addition of the their fact the addition of the their fact the addition of the their fact the addition of the their fact the addition of the add | The second of th | Teething Tablets Baby Teething Tablets Teething Tablets Teething Tablets | |
| SECTION III: | CORRECTIVE ACTION: | | | : |
| | | | | - . |
| CORRECTIVE AC | CTION(S) COMPLETED BY: | | DATE: | - DSS - JUL 0 3 201 |
| SECTION IV: | | 1 | | |
| REVIEWED BY M | MANAGEMENT BY: | alt | DATE: 06-24-14 | _ |

DATE: 06 23 14



| rukm | FDA 3500A (6/10) |
|-------|-------------------|
| A. PA | TIENT INFORMATION |

| osc |
|---------------------|
| er-tavilities, |
| s and manufacturers |
|)RY reporting |

Form Approved: OMB No. 09 10-029 1, Expaires 12/31/11

CaseID: 10285323

Initial Reporter Also Sent Report to FDA

Yes No

| | | | See OMB | statement on revers |
|---------------|---------------------|---|---------|---------------------|
| Mfr Report # | Report # 54073 Page | | 2 | |
| UF/Importer R | | , | | |
| | | | | |

|)RY reporting | UF/Importer Re | eport# | | | |
|--|-------------------|------------------|--|----------------|--|
| of <u>5</u> | | | F | DA Use Oni | |
| C. SUSPECT PRO | DUCT(S) | | · | DA OSE OII | |
| 1. Name (Give labeled stre | | | | | |
| #1 HYLAND'S BABY | ABLETS | | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Ro | ute Used | | tes (If unknown, gi est estimate) | ive duration) | |
| #1 1 TAB SL PRN; | UP TO 4X/DY | #1 | est estimate) | | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Ind | ication) | | vent Abated After | | |
| #1 TEMP RELIEF T | EETHING PAIN | 1 , | Stopped or Dose Re duced? #1 ✓ Yes No Does | | |
| #2 | | | | Apply | |
| 6. Lot # | 7. Exp. Date | #2 | Yes No | Apply | |
| #1B27313 | #1 | | vent Reappeared eintroduction? | After | |
| #2 | #2 | #1 [| #1 Yes No Does | | |
| 9. NDC# or Unique ID | | #2 [| Yes No | Doesn | |
| 54973-3127-3 | Products The | | | Apply | |
| 10. Concomitant Medical | 1 roducts and The | rupy Dates (EXC | ade realment of e | • • (1) | |
| | | | | | |
| | | | | | |
| | | | | | |
| D. SUSPECT MEDICAL DEVICE | | | | | |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | | | |
| 3. Manufacturer Name, City and State | | | | | |
| | | | | | |
| 4. Model # | Lot# | | 5. Operator | of Device | |
| Catalog # | Evoiratio | n Date (mm/dd/y | | Professional | |
| Juliang " | Expiratio | | Lay UserfPa | | |
| Serial # | Other # | | Other: | | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/d | d(yyyy) | |
| | | | | 1. | |
| 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No | | | | | |
| 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor | | | | | |
| | | | | | |
| | | | e- | 300 | |
| 10. Device Available for Evaluation? (Do not send to FDA) | | | | | |
| Yes No Returned to Manufacturer on: (mm | | | | | |
| 11. Concomitant Medical | Denducte and The | rany Datos /Fire | (mrtolia) | 1 3 C | |
| consonnent meulcar | outous and The | .upj Daies (EXC | u saunoni ui c | will) . | |
| | | | | | |
| E ANTIAL DEDOD | | | 1 | | |
| E. INITIAL REPORT 1. Name and Address | | #(b) (6) | | | |
| und nadioss | riiolie | | | | |
| (b) (6) | | | | | |
| | | | | | |
| | | | | | |
| | | | JUL 02 | 201E | |
| i | | | | _ /!!!!! | |

2. Health Professional? 3. Occupation

NΑ

√ No

Yes

1. Patient Identifier 2. Age at Time of Event: 3 Sex 4. Weight of Event: 3 1\2 Months Female or Male In confidence of Birth: kgs B. ADVERSE EVENT OR PRODUCT PROBLEM Adverse Event and/or Product Problem (e.g., defects/malfunctions) 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 05/00/2014 -- 06/17/2014 06/20/2014 5. Describe Event or Problem REPORTER STATES HER SON WOULD HAVE A DRY MOUTH AFTER GIVING THE TEETHING TABLTS TO HIM AND THAT HIS BODY INCLUDING LIMBS WOULD SHAKE ALL OVER AND KEEP SHAKING. REPORTS SAYS THIS WOULD OCCUR RIGHT AFTER GIVING THE TABLETS TO HER SON, AND THAT SYMPTOMS (DRY MOUTH AND SHAKING) WOULD LAST 10 - 15 MINUTES BEFORE STOPPING. 6. Relevant Tests/Laboratory Data, Including Dates NONE Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) CHILD HAS A HOLE IN HIS HEART. NO MEDICATIONS OR TREATMENTS, HAVE TO TAKE HIM TO A HEART DOCTOR IN THE FUTURE.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. Individual Case Safety Report

F. FUK USE BY USEK FACIENTIM

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

> Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ HYLAND'S, INC.

 Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)

10-day 📝 Initial

54973 AE # 1543

| 15-day | Follow-up # ___
| 9. Manufacturer Report Number

5-day

7-day

06/10/2014

30-day

Periodic

154 W. 131ST STREET LOS ANGELES, CA 90061

1. Contact Office - Name/Address (and Manufacturing Site



10285323-01-00-02

Importer

Page 2 of 5

2. UF/Importer Report Number

5 Phone Number

12. Location Where Event Occurred

Outpatient Treatment Facility

Hospital

Home

Other:

Nursing Home

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number
310-768-0700
3. Report Source
(Check all that apply)

Foreign

Company Representative

Distributor

Other:

Study
Literature
Consumer
Health Professional
User Facility

(mm/dd/yyyy)

7. Type of Report

| Initial | Initial | Follow-up # _____ | 10. Event Problem Codes (Refer to coding manual)

| | FDA USE ONLY |
|--|--|
| 5 | |
| H. DEVICE MANUFACTURERS ONLY | · |
| 1. DEVICE MANUFACTURERS ONLY | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| Other: | Device Evaluation |
| Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | Yes No |
| 6. Evaluation Codes (Refer to coding manual) | |
| | |
| Method | |
| Results | |
| Conclusions - | |
| | 8. Usage of Device |
| | Initial Use of Device |
| Recall Notification Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
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| | JUL 02 2014 |
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA #

IND#

STN#

510(k) # __ Combination

Product

Pre-1938

OTC Product Yes

8. Adverse Event Term(s)
DRY MOUTH AND SHAKING

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville MD 20850 OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 10285323



CUSTOMER COMPLAINT RECORD



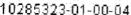
| SECTION I: | COMPLAINT | COMPLAINT #: | 2553 |
|---|---|---|---|
| TAKEN BY: | (b) (6) | DATE OF COMPLAINT: | 06/19/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT40 |
| SIZE: | 40 TABLETS | LOT NO.; | |
| REPORTER: (b) | (6) | | RECEIVED |
| ADDRESS: | | | |
| | | | JUL 0 2 2014 |
| CITY: | | STATE: (b) (6) | on D |
| | SA | ZIP CODE: | CUR |
| PHONE #: |) (6) | | |
| E-MAIL: NATURE OF COMPLAIN THAT SHE NOTICED HE | IT: CAUSING SEIZURES IN CHILDREN ER SON WOULD HAVE A DRY MOUTH AFTER GI | ETHING ON FACEBOOK ABOUT THE PRODU WANTED INFORMATION. AFTER PROVIDI WING THE TECHTING TABLETS OF HIM AND WORLD DESCRIPTION TO THE | THAT HIS BODY INCLUDING LIMBS |
| WOULD SHAKE ALL OV SYMPTOMS (DRY MOU SHE GAVE THE CHILD | ER SON WOULD HAVE A DRY MOUTH AFTER GI ER AND KEEP SHAKING. REPORTER SAYS THI TH AND SHAKING) WOULD LAST 10 – 15 MINUTI THE PRODUCT, UP TO FOUR TIMES PER DAY W IT NUMBER OF TIMES THE CHILD EXPERIENCEI PING THE PRODUCT A FEW DAYS AGO. ADVISI | S WOOLD OCCUR RIGHT AT THE CHILD THE STATES WHEN DOSING THE PRODUCT, UNTIL SHE DID THEORY STATES OF THE CHILD HAS NOT | S THIS OCCURRED EVERY TIME SCONTINUED THE PRODUCT. HAD A DRY MOUTH OR ANY |
| O. W. C. | | | |
| | FOR ADDITIONAL SPACE PLEASE U | SE REVERSE OR ATTACH A SEPARATE SH | |
| PRODUCT RECEIVED FINSPECTION: | FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: Y (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT B | É RETURNED: |
| Individua | l Case Safety Report | | Y (N) |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| | E 18 | DATE PRODUC | CT RECEIVED: |
| 1 | 0285323-01-00-03 | | |
| | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION | REPORT. | |
| | | | |
| | | | |
| | | | |
| | WARDED TO PHARMACIST / NURSE FOR EVAL | (h) (6) | |
| ADVERSE EVENT FOR | WARDED TO PHARMACIST / NURSE FOR EVAL | UATION BY: | |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | nec |
| | | | DSS |
| | | | 13UL 0 8 2014 |
| CORRECTIVE ACTION | VS) COMPLETED BY | DATE | · · |
| CORRECTIVE ACTION | (G) COM LETED BY. | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE # | 1543 |
| ADVERSE EVENT SER | RIOUS: (Y)/ N | | |
| ADVERSE EVENT REF | | BY: EDYTA FRAC | KIEWICZ |
| SECTION V: | | n 1 | Print and |
| | (1) | AH DATE | 06-24- JUL 02 2014 |
| REVIEWED BY MANAG | GEMENT BY: | DATE | 06-23-14 |
| BY: | QA / QC DIRECTOR | DATE: | 06-23-17 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

CaseID: 10285323







Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B27313, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B27313 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B27313. The Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # B27313, however a each of lots manufactured using the same bulk lot (121648) did reveal seven complaints (CC-0886-2013, CC-0059-2014, CC-0066-2014, CC-0122-2014, CC-0123-2014, CC-0200-2014 & CC-0239-2014). The complaints were reviewed and although there was one that was similar and also reported as an SAE (CC-0066-2014) there does not appear to be a trend related to this bulk lot. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B27313.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/23/2014

Date

DSS JUL 0 3 2014

JUL 02 2014



CaseID: 10285323

ENT DATA FORM 10285323-01-00-05

| AE #: | 1543 | COMPLAINT #: 2553 |
|------------------|------------|--|
| SECTION | i | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | | (b) (6) |
| ADDRESS | : | |
| CITY | | STATE: (b) (6) |
| CITY: COUNTRY | : | USA ZIP CODE: |
| PHONE #: | | (b) (6) |
| E-MAIL: | | |
| SECTION I | <u>l:</u> | PACKAGING INFORMATION: |
| | AFF | AND THE PARTY OF T |
| SECTION I | <u>II:</u> | CORRECTIVE ACTION: |
| | | |
| | | DSS |
| CORRECT | IVE AC | TION(S) COMPLETED BY: DATE: |
| SECTION I | | DATE: 06-24-14 02 2014 DATE: 06-24-14 02 2014 DATE: 06-23-14 EJB 06-23-14 |

e by user-facilities ibutoes and margifacturers DATORY reporting

| Form Approved: OMB 6 286 | B statement on reverse. |
|--------------------------|-------------------------|
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|----------------------|------|
| Mfr Report # 54973 | |
| UF/Importer Report # | |
| | |

| FORM FDA 350 | 0A (2/13) | | | ⊬age |
|--|---|---------------------------------------|-------------------------------------|--------------|
| A. PATIENT INF | ORMATION | | | |
| 1. Patient Identifier (b) (6) | 2. Age at Time of Event: | _ | 3. Sex | 4. Weight |
| (2) (2) | or | Months | Female | lbs |
| In confidence | Date of Birth: | | ✓ Male | or kgs |
| | VENT OR PRODUC | T PROBLE | И | |
| 1. Adverse Even | | duct Problem (e | | unctions) |
| 2. Outcomes Attribut | | duct i tobioni (o | | |
| (Check all that appl | | | . D | |
| Death: | (mm/dd/yyyy) | | r Permanent Da | - |
| Life-threatenin | _ | | Anomaly/Birth Dous (Important M | |
| · | n - initial or prolonged vention to Prevent Perma | <u></u> | | |
| 3. Date of Event (mn | | | Report (mm/do | |
| | 24/2014 | l | 06/26/2014 | |
| 5. Describe Event or | | | | |
| | IZURE LIKE ACTI ETS WERE DISCON | | RESOLVED W | HEN BABY |
| | Recoi | 2014 | | |
| | CD | R | | |
| | | | | |
| 6 Polovant Tests/I al | boratory Data, Including | n Dates | (Continue or | n page 3) |
| | ests conducted | | AN; RESULT | S WERE |
| | | | (Continue or | |
| 7. Other Relevant His race, pregnancy, sn | story, Including Preexis noking and alcohol use, I | ting Medical Co nepatic/renal dysi | nditions (e.g., a unction, etc.) | llergies, |
| 1 | | | (Continue or | n page 3) |

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| . e | | | *** |
|-------------------------------------|---|---|--|
| 5 | | | FD ≜ Us |
| C. SUSPECT P | | | |
| , | d strength & mfr/labele ABY TEETHING | | |
| #1 11122112 | noi iooi | 11.02 | |
| #2 | | | |
| 2. Dose, Frequency | | | y Dates (If unknown, give dura (or best estimate) |
| #1 UNKNOWN DO | SE X 6 MONTHS | _ #1 | |
| #2 | | #2 | |
| 4. Diagnosis for Use | (Indication) | 1 | Event Abated After Use Stopped or Dose Reduced |
| #1 TEMP RELIE | F OF TEETHING | PAIN | #1 Yes No PA |
| #2 6. Lot # | 7. Exp. Date | | #2 Yes No |
| #1B27213 | #1 | } | 8. Event Reappeared After |
| | I | | Reintroduction? |
| #2 9. NDC# or Unique II | #2 | | #1 Yes No A |
| 54973-3127- | | | #2 Yes No A |
| | | herapy Dates | (Exclude treatment of event) |
| io. Concomitant me | and it | | ,, |
| | | | ! |
| | | | |
| | | | (Continue on page |
| D. SUSPECT M | EDICAL DEVICE | | |
| 1. Brand Name | | | |
| 2. Common Device | lama | | 2b. Procode |
| 2. Common Device | saine | | 22.1100000 |
| | | | ls a da |
| 4. Model# | Lot # | | 5. Operator of Dev |
| Catalog # | Expiration | on Date (mm/o | |
| Serial # | Unique | Identifier (UDI) | ; |
| oci iai ii | | | , |
| 6. If Implanted, Give | Date (mm/dd/yyyy) | 7. If Expla | anted, Give Date (mm/dd/yyyy |
| 8. Is this a Single-us | e Device that was Re | eprocessed an | nd Reused on a Patient? |
| Yes N | | | |
| 9. If Yes to Item No. | 8, Enter Name and A | ddress of Rep | processor |
| | | | |
| | | | |
| 10. Device Available | for Evaluation? (Do | not send to FD | A) |
| ☐ Yes ☐ N | | | . 7 |
| | Returned to | | on: |
| 11. Concomitant Me | | Manufacturer | (mm/dd/yyyy) |
| | | Manufacturer | on:(mm/dd/yyyy) (Exclude treatment of event) |
| | | Manufacturer | (mm/dd/yyyy) |
| | | Manufacturer | (mm/dd/yyyy) (Exclude treatment of event) |
| E. INITIAL REP | dical Products and Ti | Manufacturer | (mm/dd/yyyy) |
| E. INITIAL REP | dical Products and Ti | Manufacturer | (mm/dd/yyyy) (Exclude treatment of event) (Continue on page |
| | dical Products and Ti | Manufacturer | (mm/dd/yyyy) (Exclude treatment of event) |
| 1. Name and Addres | dical Products and Ti | Manufacturer | (mm/dd/yyyy) (Exclude treatment of event) (Continue on page |
| 1. Name and Addres | ORTER s | o Manufacturer herapy Dates | (Exclude treatment of event) (Continue on page |
| 1. Name and Addres (b) (6) Phone # | ORTER s Ei | Manufacturer herapy Dates LSC mail Address | (Exclude treatment of event) (Continue on page DSS JUL 10 |
| 1. Name and Addres (b) (6) | ORTER S El (b) | Manufacturer herapy Dates LSC mail Address | (Exclude treatment of event) (Continue on page |

| | | | | |) af 5 | | | FDA USE ONLY | ieiD; 103023 |
|--|------------------------------------|--|--------------------|--|--------|--|--|---|--------------------------------|
| 10 | 302300 | 5-01-00-02 |) Taning panjar | age 2 | | | ACTURERS ONL | Y | What Type? |
| User Facility or Impo | Impo | orter | , amportor | upur muunu | | e of Reportable Ev Death Serious Injury Malfunction | ent | Correct Additio | |
| Contact Person Date User Facility or Importer Became Aware of Event (mm) | | 7. Type of Repor | 5. Phone No | 8. Date of This Report (mm/dd/yyyy) | | No (Attach page provide code: | Manufacturer ation Summary Attached to explain why not) or | 5. Labeled for | |
| 9. Approximate Age of Device 11. Report Sent to FDA | 10. Event Patient Code Device Code | Follow-up # Problem Codes (| Refer to codir | - - | 6. Eve | Patient Code Device Code Method Results | raluation Codes (Refer | to coding manual) | - |
| Yes(mm/dd | (yyyy) | ☐ Hospita | al | Outpatient Diagnostic Facility Ambulatory Surgical Facility | - | Conclusions | Hated Chark Time | | - |
| 13. Report Sent to Mar Yes | | | ient Treatmen | • | l I | Remedial Action Ini Recall Repair Replace | Notification Inspection Patient Monitoring | Initial Use | i |
| 14. Manufacturer Nam | e/Address | | | | 10. | Relabeling [Other: | Modification/ Adjustment | 9. If action reporte 21 USC 360i(f), removal reporting and / or 11. | list correction/ ng number: |
| G. ALL MANUFA | | | ia-a) | 2. Phone Number | | _ | | | ! |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S' | ICZ | iring Site for Dev | ica) | 310-768-0700 3. Report Source (Check all that apply) Foreign Study | | | | | |
| LOS ANGELES, C. Email Address STANDARD@HYLAN 4. Date Received by | A 9006 DS.COM | 5. | | Literature Consumer Health Professional User Facility | | | | | |
| Manufacturer (mm/c 36/24/2 6. If IND, Give Protoco | 014 | (A)NDA # IND # BLA # PMA/ | | Company Representative Distributor Other: | | | | | · . |
| 7. Type of Report (Check all that apply, 5-day 30-d 7-day Peric 10-day Initia | lay odic | 510(k) # Combination Product Pre-1938 | Yes | | | | | | ÷ |
| | ow-up # | OTC Product 8. Adverse E | | | | | | | D\$S JUL 1 0 201 |
| 54973 AE # 15 | | SEIZURE | | | | | | | JUL 1 0 201 |
| | | | | | ـــا ك | | | 014D 04-4 | . Il An augment to accomme |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Individual Case Safety Report

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff information unless it dis PRAStaff@fda.hhs.gov valid OMB control number Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 10302306

3: 10302306 COMPLAINT #: 2559 1.0302306-01-00-03 DATE OF COMPLAINT: 06/24/14 ITEM CODE: BTET---T40 HYLAND'S BABY TEETHING TABLETS PRODUCT: LOT NO.: B27213 SIZE 40 TABLETS (b) (6) REPORTER ADDRESS: STATE: CITY: ZIP CODE: USA COUNTRY: PHONE #: (b) (6) CUSTOMER SENT E-MAIL THAT HER CHILD HAD SEIZURE LIKE ACTIVITY WHILE USING HYLAND'S BABY NATURE OF COMPLAINT: AFTER BABY TEETHING TABLETS. TAKEN TO A NEUROLOGIST AND TESTS WERE NORMAL. SEIZURE ACTIVITY STOPPED AFTER BABY TEETHING TABLETS WERE DISCONTINUED. CUSTOMER SENT E-MAIL THAT LOT # IS B27213 AND CHILD BEGAN USING THE TABLETS WHEN HE WAS ABOUT 4 MONTHS. IS NOW 10 MONTHS. HAS NOT CONTACTED HYLAND'S BY PHONE FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT BEING RETURNED FOR INSPECTION: PRODUCT RECEIVED FOR (CIRCLE ON (CIRCLE ONE INSPECTION: DATE REQUESTED PRODUCT BE RETURNED: (CIRCLE ONE UPS CALL TAG ISSUED: DATE PRODUCT RECEIVED: INVESTIGATION SECTION II: PLEASE SEE ATTACHED INVESTIGATION REPORT. INVESTIGATION:

SECTION V:

REVIEWED BY MANAGEMENT BY:

ADVERSE EVENT REPORTED ON:

ADVERSE EVENT SERIOUS:

BY:

cc: QA / QC Packaging Production Shipping / Receiving 06/24/2014

_

EDYTA FRACKIEWICZ

BY:

DATE: 07 ALIII

DATE: 07-01-14

DSS

JUL 1 0 2014

Form # VD1

Individual Case Safety Report

10302306-01-00-04



s Adverse Event SAE-0026-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B27213, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B27213 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B27213. The Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(a) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured three other customer complaints (CC-0123-2014, CC-0239-2014 & CC-0409-2014) have been received for Hyland's Baby Teething Tablets lot # B27213. The complaints were reviewed and there does not appear to be a trend related to this lot. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B27213.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

Date

6/26/2014

DSS JUL 1 0 2014

CaseID: 10302306



SE EVENT DATA FORM

| Hylands ID: 1030230 |
|---------------------|
|---------------------|

| AE #: | 1549 COMPLAINT #: 2559 | <u>.</u> |
|---------------------|--|---------------------|
| SECTION I | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | - |
| ADDRESS | | - |
| CITY: | STATE: | |
| COUNTRY | USA ZIP CODE: | - |
| PHONE #: E-MAIL: | (b) (6) | - |
| SECTION | PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| SECTION | : CORRECTIVE ACTION: | - |
| | | <u> </u> |
| CORRECT | /E ACTION(S) COMPLETED BY: DATE: | - ! |
| SECTION REVIEWE | BY MANAGEMENT BY: BY MANAGEMENT BY: DATE: 07-01-14 DATE: 07-01-14 | DSS JUL 1 0 2014 |

DISTRIBUTION: FDA ADVERSE EVENT FI

JUL 09 2014



| FUKM | FUA | JOUUA (| 4/13 |) | |
|-------------|-----|---------|------|---|--|

A. PATIENT INFORMATION

| by user-facilities, |
|--------------------------|
| butors and manufacturers |
| DATORY reporting |

. age 1

| Form Approved | OMB No. 0910-0291, Expres. 6/30/2015 See OMB statement on reverse. | |
|---------------|---|--|
| | | |

| | Form Approved | : OMB No. 0910-0291, Expres: 6/30/20 See OMB statement on rever |
|--------|---------------|--|
| report | # 54973 | |

| Mfr Report# 54973 | |
|----------------------|------|
| UF/Importer Report # | |
| | |

| s and manufacturers DRY reporting | UF/Importer R | eport# | | | • |
|---|---------------------|---------------|------------|---------------------------|----------------------------|
| of ⁵ | | | - | | |
| | DUCT/C) | | | | FDA Use Only |
| C. SUSPECT PRO 1. Name (Give labeled str | | | | | <u> </u> |
| #1 HYLAND'S BAB | , | | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Ro | oute Used | 3 Thera | ny Dates | (Hunknown | give duration) |
| #1 1 TAB SL QD X | | from/to | o (or best | estimate) | gi no dui adonj |
| | . 4 PIONITIS | #1 | | | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Ind #1 TEMP RELIEF T | • | | | Abated Afte ed or Dose | |
| | EEIHING PAIN | | #1 🔲 | Yes 📝 No | Doesn't Apply |
| #2 | | | #2 🗍 | Yes □ No | Doesn't |
| 6. Lot# | 7. Exp. Date | i | | | Apply |
| #1B50413 | #1 | | | Reappeared roduction? | After |
| #2 | #2 | | #1 🔲 ` | res 🗌 No | Doesn't Apply |
| 9. NDC# or Unique ID | | | #2 🗆 | res No | Doesn't |
| 54973-3127-1 10. Concomitant Medical | Products and The | any Date | | | Apply |
| 10. Conconneant medical | rioducis and The | apy Dates | (Exclude | ureaument or | event) |
| | | | | | Ī |
| | | | | | - 1 |
| | | | (C | ontinue or | page 3) |
| D. SUSPECT MEDI | CAL DEVICE | | | | |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 2b. P | rocode | |
| 3. Manufacturer Name, Ci | ity and State | | | | |
| wandracturer Harrie, Ci | y and State | | | | 1 |
| 4.4.4.4 | | | | | |
| 4. Model# | Lot# | | | 5. Operator | |
| Catalog # | Expiration (| Date (mm/d | d/yyyy) | | Professional |
| | | | | | en/Patient |
| Serial # | Unique Iden | itifier (UDI) | # | Other: | j |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Expla | nted, Giv | e Date (mm/d | ddlyyyy) |
| | | | | | |
| 8. Is this a Single-use Dev | rice that was Repro | cessed an | d Reusec | i on a Patien | t? |
| 9. If Yes to Item No. 8, Ent | er Name and Addre | ss of Rep | rocessor | | |
| | | | | | |
| | | | | | |
| 10. Device Available for Ev | (aluation? (Po act) | and to ED | | | |
| | Returned to Ma | | | | |
| | | | | (mm/dd/yy) | |
| 11. Concomitant Medical F | roducts and Thera | py Dates (| Exclude t | reatment of e | vent) |
| | | | | | |
| | | | (Co | ntinue on | page 3) |
| E. INITIAL REPORT | ER . | | | | |
| l. Name and Address b) (6) | | | | | 1 0 201 |
| | | | | .H n | 1 0 20. |
| | | | | JUL | 4 W 2014 |
| | | | | | |
| Phone # o) (6) | Email | Address | | | |
| . Health Professional? 3. | Occupation | | 4. In | itial Reporte | r Also Sent |
| | | | | | |
| ☐ Yes ☑ No N | IA | | Re | Port to FDA | |

1. Patient Identifier 2. Age at Time 3. Sex 4. Weight of Event: Months Female Date or ✓ Male In confidence of Birth: kgs B. ADVERSE EVENT OR PRODUCT PROBLEM ✓ Adverse Event and/or Product Problem (e.g., defects/malfunctions) Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 02/00/2014 - PRESENT 06/24/2014 5. Describe Event or Problem CHLD HAS BEEN EXPERIENCING SEIZURES FOR THE PAST 4 MONTHS. DESCRIBED AS CHILD STARTS SHAKING AND EYES ROLL BACK IN HIS HEAD. PLEASE TYPE OR USE BLACK INK Received JUL 0 9 2014 COR (Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates (Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 06/24/14: MOTHER SAID SHE STOPPED BABY TEETHING TABLETS ON 06/18/14 AND CHILD HAD A SEIZURE ON 06/24/14 THAT LASTED 10 SECONDS. (Continue on page 3) Submission of a report does not constitute an admission that medical

personnel, user facility, importer, distributor, manufacturer or product

caused or contributed to the event.

| | | | | | | | | Case FDA USE ONLY | ID: 1030233 |
|---|----------------|-----------------------------|-----------------------|--|-------------------|-------------------------------|-----------------------------|---|---|
| | | | | | | | | FDA OSE ONLY | |
| 1 | 030233 | 34-01-00-0 | i.) Ar i nai an ca | ilicia i laci | ge 2 of 5 | _ | | | |
| | | | _ | | | | FACTURERS ONL | | |
| 1. Cneck One User Facility | ☐ Imp | i i | r/importer | report number | | e of Reportable E | Event . | 2. If Follow-up | |
| 3. User Facility or Imp | | | | | | Death Serious Injury | | Corre | |
| | | | | | 1.1 = | Malfunction | | 1 = | onal Information onse to FDA Request |
| | | | | | 11 - | | | | e Evaluation |
| Ĭ | | | | | 3. Dev | ice Evaluated by | Manufacturer? | 4. Device Man | ufacture Date |
| | | | | | 1 1 - | Not Returned to | | (mm/yyyy) | uracidie Date |
| 4. Contact Person | | | 5. Phone I | Number | 7 7 | Yes Evalu | ation Summary Attached | , | · [|
| 6 Detailles Facilities | | | | 1 | | No (Attach page provide code: | to explain why not) or | 5. Labeled for | Single Use? |
| Date User Facility of Importer Became Aware of Event (mn) | , | 7. Type of Repor | τ | 8. Date of This Report (mm/dd/yyyy) | | provide dadg. | | Yes | ☐ No |
| Andre or Event (mir | #GG/yyyy/ | Initial | | | 6. Ever | nt Problem and E | valuation Codes (Refer | io codina manual) | |
| 9. Approximate | 10 Event | Problem Codes (# | Pafar ta acc | line manual) | | Patient | | | |
| Age of Device | Patient [| Problem codes (/ | Terer 10 cod | ing manual) | _ | Code Device | | | |
| | Code | | · | | _ | Code | - | | |
| | Device Code |]- | | - | 7 | Method | _ | | |
| 11. Report Sent to FDA | | 12. Location W | here Event | Occurred | - | | | | |
| ☐ Yes | | Hospital | | Outpatient | | Results | | | |
| No (mm/dd/ | (УУУУ) | Home | | ☐ Diagnostic Facility ☐ Ambulatory | ′ | Conclusions | - | | |
| 13. Report Sent to Man | ufacturer? | | Home ant Treatme | Surgical Facility | 7. If Re | medial Action Ini | tiated, Check Type | 8. Usage of Device | |
| Yes(mm/dd/ | /www) | Facility | ant treatme | nt. | | Recall | Notification | Initial Use | of Device |
| No (minute) | 11111 | Other: | | (Specify) | - | Repair [| Inspection | Reuse | l |
| 14. Manufacturer Name | e/Address | | | (1) | | Replace [| Patient Monitoring | Unknown | |
| | | | | | | Relabeling | Modification/ Adjustment | If action reported 21 USC 360i(f), if removal reporting | st correction/ |
| | | | | | | Other: | | removarreportii | ig number. |
| | | | | | | | | | |
| | | | | | 10. | Additional Manu | facturer Narrative | and/or 11. | Corrected Data |
| G. ALL MANUFAC | | | | 2. Phone Number | | | | | |
| Name | mandiactur | ing site for bevio | | 310-768-0700 | | | | | |
| EDYTA FRACKIEWI | CZ | | | 3. Report Source (Check all that apply) | \dashv \vdash | | | | |
| Address | | | | (Check all that apply) | | | | | 1 |
| HYLAND'S, INC. 154 W. 131ST ST | REET | | | Study | 11 | | | | i 1 |
| LOS ANGELES, CA | | | | Literature | | | | | 1 1 |
| Email Address | | | | Consumer | | | | | |
| STANDARD@HYLAND | S.COM | | | Health Professional | | | | | 1 |
| Date Received by Manufacturer (mm/dd | t/vvvv) | 5. | | User Facility Company | | | | | İ |
| 06/19/20 | | (A)NDA # | | Representative | | | | | ĺ |
| 6. If IND, Give Protocol | # | IND# | | Distributor Other: | | | | | |
| | | BLA# | | | | | | | |
| 7. Type of Report | | PMA/ 510(k) # | | | - | | | | |
| (Check all that apply) 5-day 30-day | , | Combination | | | - | | | | ľ |
| 7-day Periodi | | Product Pre-1938 | Yes Yes | | _ | | | | |
| 10-day 📝 Initial | | 0700 | ☐ Yes | | | | | | Dee |
| 15-day Follow- | | | | |] | | | | DSS JUL 1 0 201 |
| Manufacturer Report | | 8. Adverse Even SEIZURES | nt Term(s) | | | | | | JUL 1 0 201 |
| 54973 AE # 1540 | 6 | | | | | | | | - 0 201 |
| | | | | | J L | | | | |
| This section applies | only to req | uirements of the l | Paperwork | Reduction Act of 1995. | Departme | nt of Health and H | uman Services | OMB Statement: "/ | Nn aganau atau aat |

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

dividual case safeth Kebolt

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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PRA Staff email address.

CaseID: 10302334

Individual Case Safety Report 10302334 COMPLAINT #: 2556 10302334-01-00-03 DATE OF COMPLAINT: __06/19/14 ITEM CODE: BTET----T135 HYLANU'S BABY TEETHING TABLE IS PRODUCT: LOT NO.: B50413 135 TABLETS SIZE: (b) (6) REPORTER: ADDRESS: (b) (6) STATE: CITY: ZIP CODE: USA COUNTRY: (b) (6) PHONE #: E-MAIL: MALE CHILD IS 7 MONTHS OLD. WAS GIVING THE TEETHING TABLETS 1 TABLET EVERY DAY X 4 MONTHS. STARTED HAVING SEIZURES SINCE HE WAS 2 OR 3 MONTHS OLD. STOPPED USING THE TEETHING TABLETS YESTERDAY WHEN SHE SAW A FACEBOOK POST. CHILD STARTS SHAKING AND EYES ROLL BACK IN HIS HEAD. IS GOING TO CONTACT AN ATTORNEY. TOLD HER THAT SHE WAS USING TABLETS FOR LONGER THAN RECOMMENDED. PROVIDED INFORMATION ABOUT BABY TEETHING TABLETS AND INGREDIENTS IN THE TEETHING TABLETS. TOLD HER THAT THERE IS NO CURRENT RECALL ON BABY TEETHING TABLETS. ATTEMPTED TO CALL CUSTOMER FOR FOLLOW-UP ON 06/22 AND 06/23 BUT NO ANSWER SO LEFT A MESSAGE.

106/24/14 FOLLOW-UP: CONTACTED THE CUSTOMER FOR FOLLOW-UP INFORMATION AND SHE TOLD ME SHE HAD STOPPED BABY TEETHING TABLETS ON NATURE OF COMPLAINT: 06/18/14 AND THAT CHILD HAD A SEIZURE ON 06/24/14 THAT LASTED 10 SECONDS. FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT BEING RETURNED FOR INSPECTION: Ν PRODUCT RECEIVED FOR (CIRCLE ONE (CIRCLE ONE) INSPECTION: 06/22/14: ATTEMPTED TO CALL DATE REQUESTED PRODUCT BE RETURNED: CUSTOMER FOR FOLLOW-UP; NO ANSWER; LEFT A MESSAGE. 06/23/14: ATTEMPTED TO CALL Ν CUSTOMER FOR FOLLOW-UP; NO (CIRCLE ON UPS CALL TAG ISSUED: ANSWER: LEFT A MESSAGE. DATE PRODUCT RECEIVED: INVESTIGATION SECTION II: PLEASE SEE ATTACHED INVESTIGATION REPORT INVESTIGATION: 06/19/14 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: EDYTA FRACKIEWICZ ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: SECTION III: DATE: CORRECTIVE ACTION(S) COMPLETED BY: ADVERSE EVENT REPORTS AE #: 1546 SECTION IV: ADVERSE EVENT SERIOUS: N EDYTA FRACKIEWICZ BY: ADVERSE EVENT REPORTED ON: 06/19/14 SECTION V: REVIEWED BY MANAGEMENT BY:

OMPLAIN! RECORD

cc: QA/QC Packaging

RY

Production Shipping / Receiving

Form # VD1





CaseID: 10302334

SAE-0023-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B50413, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B50413 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis including microbial results were reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B50413. The Baby Teething bulk lot # 121648 was tested for total Atropine and Scopolamine and the results were with in specification of $\frac{1}{2}$ pm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other customer complaints have been received for Hyland's Baby Teething Tablets lot # B50413.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B50413.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

Date

6/26/2014

DSS JUL 1 0 2014



RSE EVENT DATA FORM



| AE #: | 1546 | COMPLAINT #: 2556 |
|--|--|--|
| SECTION | I: PATIENT INFORMATION (IF DIF | FERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS | - 3: | |
| | - | |
| CITY: | | STATE: (b) (6) |
| COUNTRY | ': USA | ZIP CODE: |
| PHONE #: | (b) (6) | |
| E-MAIL: | - | |
| SECTION I | II: PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| indefinity due to other independent production of ordinaries. Great the transport former plants are consistent to transport former part to the former part to the former part to the resident part to the resident part to the resident part to the former part to the former. Former part to the former part to the former part of former part | Theorem and validy years the process of the process | Teething Tablets The discount of the discount |
| SECTION III | CORRECTIVE ACTION: | |
| | | |
| CORRECTIV | /E ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV | L | Do- |
| PÉVIEWED : | BY MANAGEMENT BY | DSS DATE: 06-27-14 JUL 1020 |
| NEVIEWED ! | BY MANAGEMENT BY: | DATE: 06-27-19 JUL 1 0 20 |
| BY: | QA / QC DIRECTOR | DATE: 06-27-14 |

ORM SAE01



by user-facilities, butors and manufacturers DATORY reporting

| 7 | Form Approved: OMB NO: 0910-029 See OMB S | 10302341 1, Expires: 6/30/2015 tatement on reverse. |
|-----|--|---|
| TS. | Mil Keport# 54973 | |
| ers | UF/Importer Report # | |

| | FORM FDA 3500A (2/13) | | | Page ' | l of ³ |
|------------------------------|---|--------------------|---------------------|------------|---------------------------------|
| | A. PATIENT INFORMATION | | | | C. SUSPECT |
| | 1. Patient Identifier 2. Age at Time of Event: | | 3. Sex | 4. Weight | 1. Name (Give lab |
| | of Event: 6 | Months | Female | Ibs | #1 HYLAND'S |
| | Date | | Male | or | #2 |
| | In confidence of Birth: B. ADVERSE EVENT OR PROD | LICT DROPLE | - | kgs | 2. Dose, Frequen |
| | | | | | #13 TABS Q |
| | | roduct Problem (e | e.g., defects/malfi | unctions) | #2 |
| | Outcomes Attributed to Adverse Event (Check all that apply) | | | | 4. Diagnosis for U |
| | Death: (mm/dd/yyyy) | Disability o | or Permanent Da | mage | #1 TEMP RELI |
| | Life-threatening | Congenita | I Anomaly/Birth D | efect | |
| | Hospitalization - initial or prolonged | | ous (Important M | 1 | #2 6. Lot# |
| | Required Intervention to Prevent Per | manent Impairmen | t/Damage (Devio | es) | #1109341 |
| | 3. Date of Event (mm/dd/yyyy) | 4. Date of This | Report (mm/dd | | |
| | 05/24/2014 PRESENT | | 06/24/2014 | | #2 |
| | 5. Describe Event or Problem | | | | 9. NDC# or Unique 54973-7504 |
| | CHILD STARTED HAVING TREMOR SEIZURES) MEMORIAL DAY WEEK | END AND THE | SEIZURES A | INI ARE | 10. Concomitant M |
| 云 | COMING MORE FREQUENTLY, ALM | OST ON DAIL | Y BASIS. | | |
| | | | 25 | | 1 |
| PLEASE TYPE OR USE BLACK INK | | D. SUSPECT | | | |
| 3 B | | 2 6 | | | |
| CS | | 2. Common Device | | | |
| 쮱 | | 3. Manufacturer Na | | | |
| 田田 | | 4 14 - 4 - 1 # | | | |
| | | | | 1 | 4. Model# |
| ASE | | | | | Catalog # |
| | | | | | Serial # |
| | | | (Continue on | page 3) | 6. If Implanted, Giv |
| ľ | 3. Relevant Tests/Laboratory Data, Including | g Dates | | | 8. Is this a Single-u |
| | EEG RESULTS INCONCLUSIVE | | | 1 | Yes |
| J | | | | | 9. If Yes to Item No |
| ı | | | | | 1 |
| - 1 | | | | į | |
| ı | | | | 1 | 10. Device Available |
| - 1 | | | | 1 | Yes N |
| | | | (Continue on) | page 3) | 11. Concomitant Me |
| 7 | Other Relevant History, Including Preexistance, pregnancy, smoking and alcohol use, | ting Medical Con- | ditions (e.g. alle | | 1 |
| | | | | İ | 1 |
| | RANDMOTHER'S SON (CHILD'S U | NCLE) HAS A | HISTORY OF | 7 | E. INITIAL REP |
| | DISORDER | | | İ | 1. Name and Addres |
| | | | | | (5) (6) |
| | | | | | |
| | | | | - 1 | |
| | | | | | Phone # |
| Ĺ | | | Continue on p | age 3) | (b) (6) |
| SI | Ibmission of a report door not con | etituta an adm | iaaiaa ébat | | |

| ORY reporting | UF/Importe | r Report # | | | • |
|--------------------------------------|--------------------|---------------------------------------|---------|----------------------------|---------------------------------------|
| of ⁵ | | | | | |
| C. SUSPECT PR | ODUCT(S) | | | | FDA Use On |
| Name (Give labeled | | | | | |
| #1 HYLAND'S TE | ETHING TABLE | ETS | | | |
| #2 | | | | | |
| 2. Dose, Frequency & | Route Used | 3. Therapy from/to (| Dates | (If unknown, estimate) | give duration) |
| #1 3 TABS QD X | 2 MONTHS | #1 | | | |
| #2 | | #2 | | | - |
| 4. Diagnosis for Use (I | , | | | t Abated Afte | |
| #1 TEMP RELIEF | TEETHING PA | | | Yes No | Doesn' |
| #2 | | | | <u> </u> | Apply Doesn |
| 6. Lot# | 7. Exp. Date | L | | Yes No | L_I Apply |
| #1109341 | _ #1 | | | t Reappeared roduction? | After |
| #2 | #2 | | #1 🔲 | Yes 🗌 No | Doesn' |
| 9. NDC# or Unique ID 54973-7504-1 | | - | #2 🗍 | Yes No | Doesn' |
| 10. Concomitant Medic | al Products and T | herapy Dates (/ | | | Apply Apply |
| | | | | a seemone or | , , , , , , , , , , , , , , , , , , , |
| | | | | | |
| | | | | | |
| D SUSPECT MES | NCAL DEVICE | | (0 | Continue on | page 3) |
| D. SUSPECT MED 1. Brand Name | JICAL DEVICE | | | | , |
| Common Device Nan | | | 100 | | |
| 2. Common Device Nan | ne | | 2b. F | Procode | |
| 3. Manufacturer Name, | City and State | | | | |
| | | | | | |
| 4. Model# | Lot# | | | 5. Operator | of Device |
| Catalog # | Expiratio | n Date (mm/dd/ | (vvvv) | Health | Professional |
| | | · · · · · · · · · · · · · · · · · · · | ,,,,, | Lay Use | erPatient |
| Serial # | Unique lo | lentifier (UDI) # | | Other: | |
| 6. If Implanted, Give Dat | te (mm/dd/yyyy) | 7. If Explant | ed. Giv | re Date (mm/d | divvvv |
| | | 1 | | | , , , , , |
| 8. Is this a Single-use D | evice that was Re | processed and | Reuse | d on a Patient | ? |
| 9. If Yes to Item No. 8, E | nter Name and Ad | dress of Repro | cessor | | |
| | | | | | |
| | | | | | |
| 10. Device Available for | Evaluation? (Do no | of send to EDA) | | | 1 |
| Yes No | | Manufacturer on | : | | |
| 11. Concomitant Medica | _ | | | (mm/dd/yyy | |
| ··· Conconneate medica | rroddets and m | arapy Dates (2 | xciude | rearment of e | reint) |
| | | | | | |
| E. INITIAL REPOR | TED | | (C | ontinue on p | age 3) |
| 1. Name and Address | TEN | | | | 100 |
| (b) (6) | | | | L | SS 1020 |
| | | | | JUL | 1020 |
| | | | | | ~ U ZU1 |
| Phone # | Fm: | ail Address | | | |
| b) (6) | | | | | , 1 |
| | 3. Occupation | | | itial Reporter | Also Sent |
| Yes No | NA | | | Yes No | Unk. |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| | | | | | | | FDA USE ONLY |
|---|----------------|---------------------------|-------------------------|--|-------------------------|---|--|
| | | | | ge | 2 of ⁵ | | |
| 1.0 | 030234 | 11-01-00-0 | 92 | | | UFACTURERS ONI | LY |
| 1. Cneck One | | 12.0 | ı-/ιmporτer ι | Report Mumber | Type of Reportable | | 2. If Follow-up, What Type? |
| User Facility | Impo | orter | | | ☐ Death | | Correction |
| 3. User Facility or Impo | orter Name | /Address | | | Serious Injury | | Additional Information |
| | | | | | Malfunction | | Response to FDA Request |
| | | | | | | | Device Evaluation |
| | | | | | 3. Device Evaluated b | y Manufacturer? | Device Manufacture Date (mm/yyyy) |
| 4 Contact Borner | | | E Dhana N | | Not Returned to | | |
| 4. Contact Person | | | 5. Phone N | umber | 11 = - | aluation Summary Attache ge to explain why not) or | 5. Labeled for Single Use? |
| 6. Date User Facility or | r I | 7. Type of Repo | rt | 8. Date of This Report | provide code: | ge to explain why hoty of | ☐ Yes ☐ No |
| Importer Became Aware of Event (mm | /dd/yyyy) | Initial | | (mm/dd/yyyy) | | | |
| | | Follow-up # | | | 1 1 | Evaluation Codes (Refer | r to coding manual) |
| 9. Approximate | 10. Event | Problem Codes | | ng manual) | Patien Code | ·t | - |
| Age of Device | Patient [| | | | Device | • | |
| | Code | | | | Code | | |
| | Device Code | | - | | Method | ; | |
| 11. Report Sent to FDA | ? | 12. Location V | Vhere Event | Occurred | Results | | |
| Yes | | Hospit | al | Outpatient Diagnostic Facility | | | |
| □ No (mm/dd/ | | Home | | Ambulatory | Conclusions | \$ | |
| 13. Report Sent to Man | ufacturer? | 1 | g Home ient Treatmer | Surgical Facility | 7. If Remedial Action I | nitiated, Check Type | 8. Usage of Device |
| Yes(mm/dd/ | YYYY | Facility | | | Recall | Notification | ☐ Initial Use of Device ☐ Reuse |
| ∐ No , | | Other: | | (Specify) | Repair | Inspection | Unknown |
| 14. Manufacturer Name | /Address | | | | Replace Relabeling | Patient Monitoring Modification/ | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| | | , | | | | Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| | | | | | Other: | | - |
| | | | | | | | |
| C ALL MANUEA | OTUBER | | | | 10. Additional Mar | nufacturer Narrative | and / or 11. Corrected Data |
| G. ALL MANUFA | | | ices) | 2. Phone Number | 11 | | |
| Name | | ing one for Det | | 310-768-0700 | | | |
| EDYTA FRACKIEWI | CZ | | | 3. Report Source (Check all that apply) | 1 | , | |
| Address | | | | Foreign | | | |
| HYLAND'S, INC. 154 W. 131ST ST | PEET | | | Study | 11 | | |
| LOS ANGELES, CA | | | | Literature | | | , |
| Email Address | | | | ✓ Consumer | | | i |
| Lines Addition | | | | Health Professional | | | • |
| Date Received by Manufacturer (mm/do | d/vvvv) | 5. | | User Facility Company | | | |
| 36/20/20 | | (A)NDA # | | Representative | | | |
| 6. If IND, Give Protocol | | IND#_ | | Distributor | | | |
| | | BLA# | | Other: | | | |
| 7. Type of Report | | PMA/ 510(k) # | | | | | |
| (Check all that apply) | | Combination | | | | | |
| 5-day 30-day | | Product | Yes | | | | |
| 10-day Initial | - | Pre-1938 | Yes | | · | | Doo |
| 15-day Follow | /-up # | OTC Product | ✓ Yes | | | | D\$ S JUL 1 0 20 |
| 9. Manufacturer Report | Number | 8. Adverse Ev SEIZURES | ent Term(s) | |] | | . |
| 54973 AE # 154 | 7 | SELEUKES | | | | • | 20L 1.0 50 |
| · | | | , | | | | |
| | | | | | | | - |

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CaseID: 10302341





| | 41-01-00-03 | COMPLAINT #: | 2557 | |
|--|--|--|---|--------------|
| 1.03023 | 41-01-00-03 | DATE OF COMPLAINT: | 06/20/2014 | |
| PRODUCT: | HYLAND'S TEETHING TABLETS | ITEM CODE: | TEETT125 | |
| SIZE: | 125 TABLETS | LOT NO.: | 109341 | |
| REPORTER: | b) (6) | | | |
| ADDRESS: | | | | |
| | (b) (6) | (b) (C) | | |
| CITY: | | STATE: (b) (6) | | - |
| | USA b) (6) | ZIP CODE: | | |
| PHONE #: | | | | |
| E-MAIL: NATURE OF COMPLAI | CALLER'S GRANDSON STARTED TEETHING II | N MAY. THE WEEKEND OF MEMO | RIAL DAY CHILD STARTED HAVIN | G |
| BASIS. EEG WAS SET WAS GIVING 3 TABS E OR REPLACEMENT EV FEBRUARY 2014. SHE WEBSITE AND WWW. | NT: TREMORS FROM HEAD TO TOE (MINI SEIZUR UP. STILL HAVING SEIZURES AND GOT HIS FIRST TOOTH. VERY DAY SINCE APRIL. LAST DOSE WAS YESTERDAY AF VEN AFTER I OFFERED IT TO HER. SHE CONFIRMED THAT SEWANTED TO READ LITERATURE ON THE 2010 RECALL OF HYLANDS.COM. TOLD HER NOT TO USE THE TABLETS. TOLD BOTTLE AND NOT TO USE. SHE SAID THAT SHE WILL NOT | GRANDMOTHER'S SON HAS SEIZ TER SHE SAW THE FACEBOOK PO SHE PURCHASED THIS RECALLED HYLAND'S TEETHING TABLETS AN A LIEB THE BEASONS SON THE | ZURE DISORDER. DAUGHTER DST. DOES NOT WANT A REFUND DBOTTLE AT WALMART IN | |
| | FOR ADDITIONAL SPACE PLEASE USE REVERSI | E OR ATTACH A SEPARATE SHEE | 7 | _ |
| | | | | |
| PRODUCT RECEIVED INSPECTION: | FOR Y N PR | ODUCT BEING RETURNED FOR IN | NSPECTION: Y N (CIRCLE ONE) |) : |
| | 1 | DATE REQUESTED PRODUCT BE I | RETURNED: | |
| | | UPS CALL TA | AG ISSUED: Y CIRCLE ONE) | <u> </u> |
| | | DATE PRODUCT | RECEIVED: | i |
| SECTION II: | INVESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | TO THE STATE OF TH | | | <u> </u> |
| | | | | _ |
| | | | | - : |
| ADVERSE EVENT FORV | VARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | 06/20/14 | | - |
| | VARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDYTA FRA | CKIEWICZ | _ |
| SECTION III: | CORRECTIVE ACTION: | | ONCINOL | _ |
| | | | | |
| | | | · | - |
| | • | | | _ |
| CORRECTIVE ACTION(S | OCOMPLETED BY: | DATE: | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #:1 | 1547 | |
| ADVERSE EVENT SERIO | ous: (Y)/ N | | | : |
| ADVERSE EVENT REPO | | BY: _EDYTA FRACKIEW | /ICZ | DSS |
| SECTION V: | | | | - ; |
| REVIEWED BY MANAGE | MENT BY: KWALT | DATE: <i>O</i> | 7-01-14 | L 1 0 2014 |
| BY: | QUIC BOUT | DATE: | 96-30-14 | - |

cc: QA/QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 10302341

Product in Inventory:

No units of Hyland's Teething Tablets (TEET), lot # 109341, are currently in the Standard Homeopathic Co. (SHC) warehouse. This lot was a part of the Teething Tablets recall performed by SHC and was withdrawn from the market in 2010.

Review of Records:

The Hyland's Teething Tablets (TEET), lot # 109341 associated manufacturing and packaging records were reviewed and did not reveal any issues.

Retention Samples:

No retention sample for this lot could be located and therefore an inspection was not possible

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other customer complaints have been received for of Hyland's Teething Tablets (TEET), lot # 109341.

Conclusion:

Hyland's Teething Tablets (TEET), lot # 109341 was subject to an SHC recall and withdrawn from the market in 2010.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/27/14 Date

> **DSS** JUL 1 0 2014



RSE EVENT DATA FORM



| AE #: | 1547 COMPLAINT #: _2557 | ! |
|-------------------------------|--|------------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS: | | 1. |
| CITY: | (b) (6) | |
| COUNTRY: | USA ZIP CODE: | |
| PHONE #: | ZIF CODE; | |
| E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| | which we will be a served of the served of t | |
| SECTION III: | CORRECTIVE ACTION: | |
| | ACTION(S) COMPLETED BY: DATE: | |
| SECTION IV: REVIEWED BY BY: | MANAGEMENT BY: QUE BOUL QA/QC DIRECTOR DATE: 07-01-1505 DATE: 06-30-14 | S 2014 |

10302641-02-00-01

rs and mai ORY repor

CaseID: 10302641
Form Approved: OMB No. 0910-0291, Expulses: 6/30/2015
See OMB statem-ent on reverse.

54973 AE # 1545

| F | 0 | R | M | F | DA | 3500A | (2/1) | 13 |
|---|---|---|---|---|----|-------|-------|----|
| | | | | | | | | |

| M FDA 350 | 0A (2/13) | | | | Page | |
|-----------------|--------------------------|------|----------|--------|-----------|--|
| ATIENT IN | ORMATION | . * | | | | |
| ient Identifier | 2. Age at Time of Event: | 1 | Years | 3. Sex | 4. Weight | |
| confidence | Date of Birth: | | | ✓ Male | or kgs | |
| DVERSE E | VENT OR PR | ODUC | T PROBLE | M | | |

. 🗸 Adverse Event and/or Product Problem (e.g., defects/malfunctions) Outcomes Attributed to Adverse Event (Check all that apply) Disability or Permanent Damage Death: (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy) Date of This Report (mm/dd/yyyy) 06/12/2014 -- 06/19/2014 06/24/2014

5. Describe Event or Problem

GAVE CHILD A FEW MOLDY TABLETS (1 TAB AM AND 1 TAB PM) A WEEK AGO 06/12/14 AND AFTER THE EVENING DOSE ABOUT 15 MINUTES LATER HE WOKE UP AND HE WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN - FUSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING,

Received

OCT 23 2014

CDR

(Continue on page 3)

Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NONE

PLEASE TYPE OR USE BLACK

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| f 10 | | | | | | | | =DAI | ise Only |
|--|---------------------------------------|--|--|----------------------------|--|--------|--|-------------------|----------------------|
| C. SUSPECT PR | ODUCT(S) | | | | | | | -DA (| ise Omy |
| 1. Name (Give labeled | | eler) | | | | | | | |
| #1 HYLAND'S BA | BY TEETHING | G TA | BLETS | | | | | | |
| #2 | | | | | | | | | |
| 2. Dose, Frequency & | Route Used | | 3. Thera | apy Da | ates (| f unkr | own, g | ive du | ration) |
| #11 TAB QD OR | | s. | from/ | to (or l | best e | stimat | e) | | |
| | D10 11 2 110 | | | | | | | | |
| #2 | | | #2 | 15.5 | | | 1.46 | | |
| Diagnosis for Use (| | | | | | | d After Dose F | | ed? |
| #1 TEMP RELIEF | TEETHING F | MIAS | | #1 | Y | es [| No | \checkmark | Doesn't Apply |
| #2 | | | | #2 | | F | ¬ No | | Doesn't |
| 6. Lot# | 7. Exp. Dat | е | | | | es L | | | Apply |
| #1A79913 | #1 | | | | vent Reintro | | eared | After | • |
| #2 | #2 | | | #1 | □ Y | es [| No. | \checkmark | Doesn't Apply |
| 9. NDC# or Unique ID | | | | #2 | | es [| ☐ No | [] | Doesn't |
| 54973-3127-3 | | | | #2 | ⊔' | es [| | _ 🗀 | Apply |
| | | | apy Date | æ (Ε.Λί | | | ue on | | |
| D. SUSPECT ME | DICAL DEVI | CE | apy Succ | | | | | | |
| D. SUSPECT ME 1. Brand Name | DICAL DEVIC | CE | apy Succ | a (LAI | | | | | |
| | | CE | ap) 5000 | es (Ext | (C | | ue on | | |
| 1. Brand Name | ame | CE | <u>.</u> | as (Ext | (C | ontin | ue on | | |
| Brand Name Common Device Na | ame | CE | | | (C | ontin | ue on | | |
| Brand Name Common Device Na | ame | CE | | | (C | rocod | ue on | pag | e 3) |
| Brand Name Common Device Na Manufacturer Name | nme o, City and State | CE | <u>.</u> | | (C | rocod | le orator | pag | e 3) |
| Brand Name Common Device Na Manufacturer Name | nme e, City and State Lot # | | Date (mr. | | (C | rocod | le orator | pag of Do | evice |
| Brand Name Common Device Na Manufacturer Name Model # Catalog # | Lot # | ation | Date (mn | n/dd/y | (C | rocod | le Derator Health Lay Us | pag of Do | evice |
| Brand Name Common Device Na Manufacturer Name Model # | Lot # | ation | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | n/dd/y | (C | rocod | le perator | pag of Do | evice |
| Brand Name Common Device Na Manufacturer Name Model # Catalog # | Lot # | ation ie Idei | Date (mn | n/dd/y; | (C 2b. P | 5. Op | Deerator Health Lay Us Other: | of Do | evice evice essional |
| 1. Brand Name 2. Common Device Na 3. Manufacturer Name 4. Model # Catalog # Serial # 6. If Implanted, Give D | Lot # Expire Unique | ation ue Ide | Date (mnntifier (U | m/dd/y; DI) # | (CC 2b. P 2b. P d, Giv | 5. Op | berator Health Lay Us Other: | of Do | evice essional |
| Brand Name Common Device Na Manufacturer Name Model # Catalog # Serial # | Lot # Expire Unique | ation ue Ide | Date (mnntifier (U | m/dd/y; DI) # | (CC 2b. P 2b. P d, Giv | 5. Op | berator Health Lay Us Other: | of Do | evice evice essional |
| 1. Brand Name 2. Common Device Na 3. Manufacturer Name 4. Model # Catalog # Serial # 6. If Implanted, Give D 8. Is this a Single-use | Lot # Expir: Unique tate (mm/dd/yyyy) | ation lde | Date (mr. ntifier (U | n/dd/y; DI) # plante and R | (C 2b. P 2b. | 5. Op | Derator Health Lay Us Other: | of Do | evice ssional tient |
| 1. Brand Name 2. Common Device Na 3. Manufacturer Name 4. Model # Catalog # Serial # 6. If Implanted, Give D 8. Is this a Single-use | Lot # Expir: Unique tate (mm/dd/yyyy) | ation lde | Date (mr. ntifier (U | n/dd/y; DI) # plante and R | (C 2b. P 2b. | 5. Op | ie Derator Health Lay Us Other: | of De Profe er/Pa | evice sssional tient |
| 1. Brand Name 2. Common Device Na 3. Manufacturer Name 4. Model # Catalog # Serial # 6. If Implanted, Give D 8. Is this a Single-use | Lot # Expire Unique Device that was | e Idea | Date (mn ntifier (U 7. If Exp ocessed | n/dd/y, DI) # plante and R | (C 2b. P 2b. | 5. Op | Derator Health Lay Us Other: | of De Profe er/Pa | evice sssional tient |
| 1. Brand Name 2. Common Device Na 3. Manufacturer Name 4. Model # Catalog # Serial # 6. If Implanted, Give D 8. Is this a Single-use Yes No 9. If Yes to Item No. 8, | Lot # Expire Unique Device that was | Reproduction National | Date (minifier (U | m/dd/y)# DI)# and R and R | (C 2b. P 2b. | 5. Op | ie Derator Health Lay Us Other: | of Do Profeser/Pa | evice sssional tient |

E. INITIAL REPORTER

1. Name and Address

(b) (6)

OCT 28 2014

(Continue on page 3)

Phone # (b) (6) Email Address

| Health P | rofessional? | 3. Occupation |
|----------|--------------|---------------|
| Yes | √ No | NA |

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

Initial Reporter Also Sent Report to FDA Yes No V Unk



10302641-02-00-02

| F. FOR USE BY | USER F/ | ACILITY/II | MPO | RIE | :K (U | evic | es Only) |
|---|--------------|---------------------|-------------------|-------|---------------------------------------|-----------|---------------------------------------|
| 1. Check One | | | _ | | | | Number |
| User Facility | Impo | | | _ | | | |
| 3. User Facility or Imp | orter Name | Address | | | | _ | |
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| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| 4. Contact Person | | | | 5. PI | hone Nu | ımber | 1 |
| 6. Date User Facility o | | 7. Type of R | 22201 | 4 | · · · · · · · · · · · · · · · · · · · | a Da | ate of This Report |
| importer Became Aware of Event (mm | | _ | lepo. | ı | | | ate of This Report nm/dd/yyyy) |
| Allung D | VGW 33,7,7 | Initial | " | | | i | |
| 2 A versulas ata | Lio Event | Problem Cod | | | | | |
| Approximate Age of Device | 1 _ | Problem Cod | des (| Rete: | to cou | g ma | nual) |
| 1 | Patient Code | |]- | | | | - |
| 1 | Device | | <u> </u> | | | | |
| Sent to ED/ | Code _ | | | | | | 1- |
| 11. Report Sent to FDA | 4? | 12. Locati | ion Wi ospital | | Even |)ccuri | red Outpatient |
| Yes | Vyyyy) | | ospitai ome | i | | اسا | Diagnostic Facility |
| 13. Report Sent to Mar | |] | ursing | Hom | ne | | Ambulatory Surgical Facility |
| · | iutacturer . | l Ho | utpatie | | reatment | ŧ | outgrout aums; |
| Yes | Vyyyy) | | acility | | | | |
| ∏ No , | | П~ | ther: _ | | | (Sp | ecify) |
| 14. Manufacturer Name | e/Address | | | | | _ | |
| l | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| G. ALL MANUFA | CTURER | RS | | | | | |
| Contact Office (and | Manufactu | ring Site for | Devi | ces) | | ı | hone Number |
| Name EDYTA FRACKIEWI | 100 | | | _ | | | -768-0700 |
| Address | .02 | | | | | | eport Source Check all that apply) |
| | | | | | | | Foreign |
| HYLAND'S, INC. 154 W. 131ST ST | TREET | | | | | | Study |
| LOS ANGELES, CA | | 1 | | | 1 | <u></u> Γ | Literature |
| Email Address | | | | | | | Consumer |
| STANDARD@HYLANE | DS.COM | | | | | | Health Professional |
| 4. Date Received by | | 5. | | | | | User Facility |
| Manufacturer (mm/de 06/19/20 | | (A)NDA# | <i>-</i> | | | | Company Representative |
| | | IND# | <i>-</i> | _ | | | Distributor |
| 6. If IND, Give Protocol | 1# | BLA# | _ | _ | | | Other: |
| | | PMA/ | | _ | | | |
| Type of Report (Check all that apply) | | 510(k)# | _ | | | | |
| 5-day 30-da | | Combinat Product | tion | | Yes | | |
| 7-day Period | | Pre-1938 | i. | | Yes | _ | |
| 10-day 📝 Initial | _ | OTC Prod | | _ | Yes | | |
| <u> </u> | w-up # _1 | - | | | | | |
| 9. Manufacturer Report | | 8. Advers | | | , , | ץידיי | , |
| 54973 AE # 154 | 15 | | | | | | G, FUSSY |
| i | | 1 | | | | | |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | FDA USE ONLY |
|---|---|
| : 10 | |
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | |
| Maidiction | Response to FDA Request |
| | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | Device Manufacture D ate |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | |
| | Yes No |
| 6. Event Problem and Evaluation Codes (Refer to | - L coding manual) |
| Patient | |
| Code | |
| Device |]_[|
| Code | |
| Method - |]-[]-[] |
| | |
| Results - | J - - |
| | |
| Condusions | |
| 7. If Remedial Action Initiated, Check Type 8 | Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| | If action reported to FDA under |
| Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | ramara rapating names : |
| | |
| 10. Additional Manufacturer Narrative a | nd / or 11. Corrected Data |
| 10. Additional manufacturer Harrative | ind / of the cled Data |
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CaseID: 10302641

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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CUSTOMER COMPLAINT RECORD



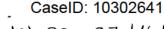
| SECTION I: | | MPLAINT | | | | | |
|------------------------------------|---|--|---|---|----------------------------------|--|---|
| | <u> </u> | | | COMPLAI | INT#: _2 | 555 | |
| TAKEN BY: | | EDYTA FRACKI | EWICZ | DATE OF COMPL | AINT: _0 | 6/19/14 | |
| PRODUCT: | | HYLAND'S BAB | Y TEETHING TABLETS | ITEM C | CODE: _E | TETT40 | |
| SIZE: | (b) (6) | 40 TABLETS | | LOT | T NO.: _A | 79913 | |
| REPORTER: | (b) (6) | | | W. W. L. W. W. W. W. W. W. W. W. W. W. W. W. W. | | | |
| ADDRESS: | | | * | 1170 | | | |
| | | | | | | | |
| CITY: | | 1-41-6004 | | STATE:(b) (| (6) | | |
| COUNTRY: | USA | | 17.705 | ZIP CODE: | | | |
| PHONE #: | (b) (6) | | | | | | |
| E-MAIL: | | | | | | - | |
| CRYING. HER FRI A REFUND FOR \$ | KING, EYED EVERY (IENDS HA' 4. WE WI | AM AND 1 ES ROLLED IN BAC OTHER NIGHT WAI VÉ ALSO COMPLAI LL SEND A REFUNI | TAB PM) A WEEK AGO 06/12/ K OF HEAD, WOULD NOT STO KING UP IN THE MIDDLE OF TI NED ABOUT THE BABY TEET | IG 1 TABLET QD X 2 MONTHS. GA 14 AND AFTER THE EVENING DO DP CRYING, WOULD NOT GO TO S HE NIGHT SHAKING, EYES ROLLI HING TABLETS BEING MOLDY. D ETS. CONTACT YOUR DOCTOR | SE ABOUT SLEEP. H. NG BACK | 15 MINUTES AS BEEN AC OF HEAD, NO ANT A REPLA | S LATER HE WOKE TING WEIRD SINCE DT SLEEPING, ACEMENT WANTS |
| | | FOR ADDITIO | ONAL SPACE PLEASE USE RE | VERSE OR ATTACH A SEPARAT | E SHEET | | |
| | | | | | | | • |
| PRODUCT RECEIVINSPECTION: | | | CIRCLE ONE) | PRODUCT BEING RETURNED | FOR INS | PECTION: | Y (N (CIRCLE ONE) |
| ndividual | Case | Safety Re | port | DATE REQUESTED PRODU | ICT BE BE | TURNED: | (ONCLE ONE) |
| | | | 8 (8) 8 () 8 () 8 () | DATE REGOLUTED I RODO | OT BE KE | - | |
| | | | | UPS | CALL TAG | ISSUED: | Y (N) |
| 103 | 302641 | -02-00-03 | erastiet iff a fili | 0.0 | Office the | TOOOLD. | (OINOLL ONL) |
| | | | | DATE PR | ODUCT R | ECEIVED: _ | |
| SECTION II: | INV | ESTIGATION | | | | | |
| INVESTIGATION: | | PLEASE SEE ATTA | CHED INVESTIGATION REPOR | RT. | | | |
| | | | | | | | 1017700 |
| | | 1-547 | - | | | | |
| | | | | | | | 10-20-1 |
| | | | | 7,11 | | | |
| ADVERSE EVENT F | FORWARD | DED TO PHARMAC | ST / NURSE FOR EVALUATIO | N ON: 06/1 | 19/14 | | |
| ADVERSE EVENT F | FORWARE | DED TO PHARMACI | ST / NURSE FOR EVALUATION | N BY: ED | YTA FRAC | KIEWICZ | |
| SECTION III; | 9 | CORRECTIVE ACT | ON: | | | | |
| 06/26/14: PREPARI | ED REFUN | ID REQUEST TOTA | NING \$ 4.00 07/16/14: MAILE | D REFUND CHECK # 511649 TOTA | ALINO 6 4 | 00 | |
| | | | TENTO V TIOU. OTT TO THE MINIEL | STEE GIAD CHECK # 311049 TOT | ALING \$ 4 | 00. | DSS |
| | | | | | | | OCT 2 4 201 |
| | | | (b) (c) | | | | 001 2 7 201 |
| CORRECTIVE ACT | ION(S) CO | MPLETED BY: | (b) (6) | D | ATE:07 | /16/14 | |
| SECTION IV: | ADV | EDEE EVENT DED | ORTO | | | | |
| SECTION IV. | ADV | ERSE EVENT REP | OKIS | , | AE #: | 45 | OCT 23 201 |
| ADVERSE EVENT S | SERIOUS: | | (y), N | | | | 001 20 201 |
| ADVERSE EVENT R | REPORTE | O ON: | 06/19/14 | BY: EDYTA FF | RACKIEWI | cz | |
| SECTION V: | | | | 1 | | | |
| DEMENSES SALL | | | Sel. | , - | | カーヘン | - 14 |
| REVIEWED BY MAN | NAGEMEN | T BY: | 4000 | D/ | ATE: | 0-02 | 2-14 |
| BY: | | 9911 | 1 /sour | \ D∆T | E: 8 | 9-3 | 0-14 |
| - | | QA/QC DIR | ECTOR | | | · | , |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

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07/16/14 marked on

CC -0425- 2014 5AE - 0000 - 3AE



June 26, 2014

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$4.00. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach President

Enc: Refund Check - \$4.00

Individual Case Safety Report

10302641-02-00-04

OCT 24 2014

OCT 23 2014



CUSTOMER COMPLAINT RECORD

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| | Butween 30264 | ď |
|--|---------------|---|
| | Williams | |
| | | |

| SECTION I: | | | + cally article no. |
|--|---|--|---|
| | COMPLAINT | . COMPLAINT #: | +000114000030 |
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 06/19/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT40 |
| SIZE: | 40 TABLETS | LOT NO.: | A79913 |
| REPORTER: (b) (6) | | - AND AND AND AND AND AND AND AND AND AND | |
| DDRESS: | | | |
| | | | |
| CITY: | | (b) (6) STATE: | |
| COUNTRY: US | | ZIP CODE: | |
| PHONE #: | ;) | | _ |
| -MAIL: | | | , |
| THEN-FUSSY, AND EVER CRYING. HER FRIENDS! A REFUND FOR \$ 4. WE! | TABLETS BECAME MOLDY. WAS GIVING 1 T. AM AND 1 TAB PM) A WEEK AGO 06/12/14 A EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CR Y OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIG HAVE ALSO COMPLAINED ABOUT THE BABY TEETHING WILL SEND A REFUND. DO NOT USE MOLDY TABLETS. HE PRODUCT FOR LONGER THAN DIRECTED. | ID AFTER THE EVENING DOSE AB YING, WOULD NOT GO TO SLEEP GHT SHAKING, EYES ROLLING BA TABLETS BEING MOLDY DID NOT | DUT 15 MINUTES LATER HE WOKE HAS BEEN ACTING WEIRD SINCE CON THEAD, NOT SLEEPING, WANT A REPLACEMENT WANTS |
| | FOR ADDITIONAL SPACE PLEASE USE REVERS | SE OR ATTACH A SEPARATE SHE | EŤ |
| PRODUCT RECEIVED FO | R Y N PI | RODUCT BEING RETURNED FOR | NSPECTION: Y N (CIRCLE ONE) |
| dividual Cas | e Safety Report | DATE REQUESTED PRODUCT BE | . (, |
| | | | |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| 103026 | 41-02-00-06 | | |
| ECTION II: | NVESTIGATION | DATE PRODUC | T RECEIVED: |
| ACOTIONIE. | IVESTIGATION | | |
| | DI EAGE GEE ATTACKED ON THE CONTROL OF THE CONTROL | | |
| NVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| NVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| NVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| NVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | 06/19/14 | |
| DVERSE EVENT FORWA | | | RACKIEWICZ |
| DVERSE EVENT FORWA | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | | ACKIEWICZ |
| DVERSE EVENT FORWA | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | RACKIEWICZ |
| DVERSE EVENT FORWA | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | RACKIEWICZ |
| DVERSE EVENT FORWA | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | |
| ADVERSE EVENT FORWA | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | DSS |
| ADVERSE EVENT FORWA ADVERSE EVENT FORWA SECTION III: | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: | | |
| ADVERSE EVENT FORWARDVERSE EVENT | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: COMPLETED BY: | EDYTA FF | DSS 0CT 2 4 2 |
| DVERSE EVENT FORWA | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: | EDYTA FR | DSS 0CT 2 4 2 |
| ADVERSE EVENT FORWARD SECTION III: | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: COMPLETED BY: DVERSE EVENT REPORTS | EDYTA FF | DSS 0CT 2 4 2 |
| ADVERSE EVENT FORWARDVERSE EVENT | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: COMPLETED BY: DVERSE EVENT REPORTS | EDYTA FF | DSS 0CT 2 4 2 |
| ADVERSE EVENT FORWARD SECTION III: CORRECTIVE ACTION(S) ECTION IV: A DVERSE EVENT SERIOU | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: COMPLETED BY: DVERSE EVENT REPORTS | DATE: AE #: BY: EDYTA FRACKIE | DSS 0CT 2 4 20 1545 |
| DVERSE EVENT FORWARD SECTION III: CORRECTIVE ACTION(S) ECTION IV: DVERSE EVENT SERIOU DVERSE EVENT REPORT | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: COMPLETED BY: DVERSE EVENT REPORTS IS: V / N TED ON: 06/19/14 | DATE: AE #: BY: EDYTA FRACKIE | DSS 0CT 2 4 20 1545 |
| DVERSE EVENT FORWARD DVERSE EVENT FORWARD DVERSE EVENT SERIOUD DVERSE EVENT REPORT | ARDED TO PHARMACIST / NURSE FOR EVALUATION ON: ARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: COMPLETED BY: DVERSE EVENT REPORTS IS: V / N TED ON: 06/19/14 | DATE: AE #: BY: EDYTA FRACKIE | DSS 0CT 2 4 2 |

cc: QA / QC Packaging

Production Shipping / Receiving

06-21-19 DATE: _

CaseID: 10302641



Serious Adverse Event SAE-0022-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A79913, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A79913 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification including the mold results for Hyland's Baby Teething Tablets lot # A79913. The Baby Teething bulk lot # 120264 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other SAE (SAE-0041-2013) has been received for Hyland's Baby Teething Tablets lot # A79913. The complaints were reviewed and although they do indicate similar reactions there does not appear to be a trend related to this lot. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A79913.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

6/27/2014

Date

DSS OCT 2 4 2014

Individual Case Safety Report

10302641-02-00-07

OCT 28 2014



ADVERSE EVENT DATA FORM

CaseID: 10302641

10302641-02-00-08

| Initia | ted By: ED | YTA FRACK | IEWICZ | | Date: | 6/19/2014 | | | |
|------------------|---|---------------------|---|----------|----------------------------|----------------------------------|------------------------------|----------------------|----------|
| AE# | 154 | 15 | and respondent and the second | | Complaint #: | 2555 | | | |
| A. | PATIENT INFORMATION | ON | | | C. SUSPECT PRO | DDUCT(S) | | | |
| 1. P | atient Identifier (In confid | | | 1. | | oeled strength & r | nfr/labeler) | | |
| | (b) (6) | | | | | | | | |
| | | | | | #1 HYLAND'S BAI | BY TEETHING TA | ABLETS | | |
| | | | | | *** | | | | |
| | | | | | #2 | | | | |
| | | | | 2. | Dose Frequenc | cy & Route Used | | | |
| | | | | | , | , | | | |
| | | | | | #1 1 TABLET EVE | RY DAY OR TW | ICE A DAY X 2 M | ONTHS | |
| | Phone | # or E-mail / | Address | | | | | - | |
| 2. A | ge at Time of Event: | 1 YEAR | OLD | D | #2 INITIAL REPO | RTER | | | |
| | - | | | 1. | Name and Add | | Phone # | (b) (6) | |
| | OR | | | | | (b) (6) | | | |
| D | ate of Birth: | 1 1 | · · · · · · · · · · · · · · · · · · · | | | | | | |
| 3. S | SexF | emale | | l ⊢ | | | | | |
| | T N | Male | | 2. | Health Professi | | 3. Occupation | IOTUED | |
| 4. W | /eight: | | lbs. | 4. | Yes No Initial Reporter | Also Sent Report | | IOTHER | |
| | OR | | kas | | ☐ Yes ALL MANUFAC | ☐ No | Unknown | | |
| | | | kgs. | G | | - Name/Address | | 2. Phone Number | |
| 3 . 1. | ADVERSE EVENT OR Adverse Event | PRODUCT and/or | PROBLEM Product Problem | | | | | 310-768-O700 | |
| | | | (e.g., defects/malfunctions) | | | HYLAND'S, INC | C. | Report Source | |
| | | , | | | | 10 W. 131ST STF S ANGELES, CA | | (Check all that | |
| 2. | Outcomes Attributed to | Adverse Ev | ent (Check all that apply) | | 200 | o mocceo, on | 30001 | apply) | |
| | Death | | Disability or Permanent | | | | | Foreign | |
| | Life-threatening | | Congenital Anomaly/Birth | - | Date Received | _ | 00 | 7_ 1 | |
| - | Hospitalization - | _ | Defect Other Serious (Important | 4. | by Manufacturer | '5. U | SS | Study | |
| L_ | initial or prolonged | _ | Medical Events) | | (mm/dd/yyyy) | TO | 2 4 2014 | Literature | |
| _ | Required intervention to | . Prevent | | | | (A)NDA# | | _ | |
| L | Permanent Impairment/ | | None | | | | | Consumer | |
| | Damage (Devices) | | [4 D-1-0 b-10 f-504 | | | IND# | | _ | |
| э. | Date of Event (mm/dd/y | (ууу) | Date Submitted to FDA (mm/dd/yyyy) | | 06/19/2014 | STN# | : | ☐ Health Profl. | |
| | | | | | | 0111.11 | | User Facility | |
| | 06/12/2014 06/1 | 9/2014 | 07/03/2014 | | | PMA/510(k) # | | User Facility | |
| | Time of Event: | | | | | Combination Product | I I YAS | Company Rep. | |
| 5. | Pre-existing Conditions | / Diagnosis: | | 6. | If IND. | Product | l . | | |
| | NONE | | | | Give Protocol | Pre-1938 | ☐ Yes | Distributor | |
| | | | | | | | | Other: | |
| 3. | Describe Event or Probl | lem: | | | | OTC Product | Yes | | |
| | | | ETS (1 TAB AM AND 1 TAB | | | | | | * |
| | PM) A WEEK AGO 06/1 | 12/14 AND A | FTER THE EVENING DOSE | 7. | | (Check all that ap | | 400 | , |
| | ABOUT 15 MINUTES LA SHAKING, EYES ROLL | ED IN BACK | OF HEAD, WOULD NOT | | 5-day 7-day | | 30-day Periodic | θ€¥ 23 20 | |
| | STOP CRYING, WOUL | D NOT GO 1 | O SLEEP. HAS BEEN SSY, AND EVERY OTHER | 1 - | ☐ 10-day | | Initial | | T |
| | NIGHT WAKING UP IN | THE MIDDL | E OF THE NIGHT SHAKING, | 8. | 15-day Adverse Event | Term(s) | Follow-up #9. Manufacturer I | Report Number (AE #) | |
| | EYES ROLLING BACK | OF HEAD, N | IOT SLEEPING, CRYING. | | SEIZURE LIKE | ACTIVITY, | | | - |
| | | | | l_ | SLEEPLESSNESS, C | KYING, FUSSY | ı 54973 | AE # 1545 | |



10302641-02-00-09

MEDWATCH

PLEASE TYPE OR USE BLACK INK

by user-facilities, ibutors and manufacturers DATORY reporting

| | Form Approved: | OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
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| Mfr Report | 54973 | |
| LIE/Imports | or Donad # | |

CaseID: 10302641

| Mfr Report # 54973 | |
|----------------------|--|
| UF/Importer Report # | |
| | |

| Page | 1 | of | 5 |
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| FORWIFDA 350 | | | | rago | | | | FIDA Use |
|---|---|---|--|------------------|---------------------------|----------------------|--|---|
| A. PATIENT IN | | | | | C. SUSPECT PR | | | |
| Patient Identifier (b) (6) | 2. Age at Time of Event: | ı | 3. Sex | 4. Weight | 1. Name (Give labeled | , | | |
| | or | Years | Female . | lbs | #1 HYLAND'S BA | BY TEETHING TA | ABLETS | |
| In confidence | Date of Birth: | İ | ✓ Male | or kgs | #2 | | | |
| | VENT OR PRODU | CT PROBLE | 1 | ge | 2. Dose, Frequency & | Route Used | Therapy Dates from/to (or best | (if unknown, give durati |
| 1. Adverse Even | at and/or Dro | duct Problem (e. | a defects/maifu | actions) | #1 1 TAB QD OR | BID X 2 MOS. | #1 | , |
| | ted to Adverse Event | duct Problem (e. | g., derects/mailur | ichoris) | #2 | | #2 | |
| (Check all that appl | | | | | 4. Diagnosis for Use (| indication) | <u> </u> | t Abated After Use |
| Death: | (mm/dd/yyyy) | Disability or | Permanent Dam | age | #1 TEMP RELIEF | TEETHING PAIN | 1 | ped or Dose Reduced? |
| Life-threatenin | | Congenital | Anomaly/Birth De | fect | #2 | | #1 | Yes ✓ No Doe App |
| Hospitalization | n - initial or prolonged | Other Serio | us (Important Me | dical Events) | 6. Lot # | 7. Exp. Date | #2 🗌 | Yes No Doe |
| | vention to Prevent Perma | anent Impairment/ | Damage (Devices | 5) | #1A79913 | #1 | 8. Even | t Reappeared After |
| 3. Date of Event (mn | | 4. Date of This f | | <i>yyy)</i> | #2 | _ | | troduction? |
| 5. Describe Event or | 06/19/2014 | L | 06/24/2014 | | 9. NDC# or Unique ID | #2 | #¹ LJ | Yes No ✓ App |
| 5. Describe Event or | Problem | | | | 54973+3127-3 | | #2 | Yes No Doe |
| | FEW MOLDY TABLE | | | , , | 10. Concomitant Medic | al Products and The | rapy Dates (Exclude | |
| | 2/14 AND AFTER HE WOKE UP AND | | | | 1 | | | |
| IN BACK OF HE | AD, WOULD NOT S | TOP CRYING, | WOULD NOT | GO TO | | | | |
| | EEN ACTING WEIR IGHT WAKING UP | | | | | | | |
| | ROLLING BACK O | | | MIGHT | | | (0 | Continue on page 3) |
| CRYING. | | | | 1 | D. SUSPECT ME | DICAL DEVICE | | |
| | | | | | Brand Name | | | |
| | | | | | 2. Common Device Na | me | 2b. I | Procode |
| | | | | | 3. Manufacturer Name | City and State | | |
| | | | | | | • | | |
| | | | | | 4. Model # | Lot # | | 5. Operator of Device |
| | | | | 1 | 4. Model W | 201# | | , |
| | | | | | Catalog # | Expiration | Date (mm/dd/yyyy) | Health Profession Lay User/Patient |
| | | | | ' | Sarial # | llei | | Other: |
| | | | | | Serial # | Unique ide | ntifier (UDI) # | outer. |
| | | | Continuo on o | 2000 | 6. If Implanted, Give Da | ite (mm/dd/yyyy) | 7. If Explanted, Gi | ve Date (mm/dd/yyyy) |
| Relevant Tests/Lab | poratory Data, Including | | (Continue on p | rage 3) | | | <u> </u> | |
| | | , | | | 8. Is this a Single-use I | Device that was Repr | ocessed and Reuse | d on a Patient? |
| | | | | | 9. If Yes to Item No. 8, | Enter Name and Add | ress of Reprocesso | r |
| | | | | | İ | | | |
| | | | | | | | | |
| | | | | | 10. Device Available for | Evaluation? (Do cot | send to EDAL | 200 |
| | | | | j | Yes No | Returned to Ma | • | DSS |
| | | | | | | | | (mm/dd/yyyy) |
| | | | Continue on p | | 11. Concomitant Medic | al Products and Ther | apy Dates (Exclude | trealthbutlof &eft). (|
| Other Relevant Hist race, pregnancy, sm | tory, Including Preexist oking and alcohol use, he | ing Medical Conc epatic/renal dysfur | litions (e.g., aller action, etc.) | gies, | | | | |
| IONE | | | | | | | (0 | Continue on page 3) |
| ONE | | h | | | E. INITIAL REPOR | RTER | | |
| | | | | | Name and Address | | | |
| | | | | | (b) (6) | | APT. | |
| | | | | | | | 001 | 23 2014 |
| | | | | | | | | - |
| | | | | | Phone # | Emai | Address | |
| | | | Continue on p | | (b) (6) | | | |
| rsonnel, user fac | port does not cons ility, importer, dist | ititute an admi | ission that m | edical roduct | 2. Health Professional? | 1 | | Initial Reporter Also Se Report to FDA |
| used or contribu | ted to the event. | inulia | via.ui vi pi | Jauot | Yes 📝 No | NA | | Yes No V Un |



10302641-02-00-10

2 of 5

FDA USE ONLY

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| 1. Chash One | USER FA | | | | | | ACTURERS ONL | |
| 1. Check One | | į. | JF/Importer F | Report Number | 1. Type of Rep | | nt | 2. If Follow-up, What Type? |
| User Facility | [Impo | | | | Death | | | Correction |
| 3. User Facility or Imp | orter Name/ | /Address | | | Seriou | ıs Injury | | Additional Information |
| ĺ | | | | | Malfur | action | | Response to FDA Request |
| l | | | | | | | | Device Evaluation |
| | | | | | 2 Davida Eva | but Mr | | |
| ĺ | | | | | 3. Device Eval | | | Device Manufacture Date (mm/yyyy) |
| 4. Contact Person | . '- | | Ir Shangt | | - | eturned to Mar | | |
| 4. Contact reison | | ! | 5. Phone N | lumber | Yes | _ | tion Summary Attached | |
| - Carlling Spellity C | | = = = = f Ponc | <u></u> | This Danget | ☐ No (At | ttach page to de code: | explain why not) or | 5. Labeled for Single Use? |
| 6. Date User Facility or Importer Became | | 7. Type of Repor | rt | 8. Date of This Report (mm/dd/yyyy) | | e cocc. | | Yes No |
| Aware of Event (mm | n/dd/yyyy) | nitial | | , , | 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 | | -0.5 | |
| I | | Follow-up # | - | | 6. Event Probl | _ | aluation Codes (Refer t | to coding manual) |
| 9. Approximate | 10. Event F | Problem Codes (| | | 1 | Patient Code | - | |
| Age of Device | Patient | | | , | . | Code [| | |
| | Code | | - | - | | Code | | - |
| 1 | Device | | | | | | | |
| ı <u></u> ! | Code | | | | | Method | | |
| 11. Report Sent to FDA | A? | 12. Location W | Vhere Event | Occurred | 1 | Ite | | |
| Yes | | Hospita | al | Outpatient Diagnostic English | | Results | | |
| No (mm/dd/ | Vyyyy) | Home | | Diagnostic Facility | Cor | nclusions | | 1-[|
| 13. Report Sent to Man | oufacturer? | J = | a Home | Ambulatory Surgical Facility | | | | |
| | luiaci | Outpatie | tient Treatmen | | 11 _ | | ated, Check Type | 8. Usage of Device |
| Yes(mm/dd/ | T/VVVV) | Facility | / | | Recall | | Notification | Initial Use of Device |
| No (minute) | 73333 | Other: | | (Specify) | Repair | | Inspection | Reuse |
| 14. Manufacturer Name | -c/Address | <u></u> | | (Specify) | Replac | ce 🔲 | Patient Monitoring | Unknown |
| Per Intercent | Olfran. | | | | Relabe | eling 🔲 | Modification/ | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| ı | | | | | | Ш | Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| | | | | | Other: | | | , |
| | | | | , | | | | |
| | | | | , | 10. Additio | onal Manufac | cturer Narrative | and / or 11. Corrected Data |
| G. ALL MANUFA | CTURER | S | | | | | | ш |
| 1. Contact Office (and | | | ices) | 2. Phone Number | 1 1 | | • | |
| Name | | 7.0 | | 310-768-0700 | | | | |
| EDYTA FRACKIEWI | 1CZ | | | 3. Report Source | 1 | | | |
| Address | | | | (Check all that apply) | | | | |
| HYLAND'S, INC. | | | | Foreign | | | | |
| 154 W. 131ST ST | | | | Study | | | | |
| LOS ANGELES, CA | A 90061 | , | | Literature | 1 | | | |
| Email Address | | | | Consumer | | | | |
| Email Address STANDARD@HYLAND | ne com | | | Health Professional | | | | |
| 4. Date Received by | | T 5. | | User Facility | | | | |
| Manufacturer (mm/do | (d/yyyy) | 5. (A)NDA# | | Company | | | | 1 |
| 06/19/20 | 014 | _ | | - Representative | 1 | | | |
| 6. If IND, Give Protocol | | IND# | | Distributor | 1 1 | | | |
| A | / M | BLA# | | Other: | 1 | | | 200 |
| | | PMAV | , | · | | | | DSS |
| 7. Type of Report (Check all that apply) | | 510(k) # | | | | | | |
| (Check all that apply) 5-day 30-day | | Combination | - Van | l | ! | | | OCT 2 4 2014 |
| 5-day 30-day | | Product | Yes | | | | | <u> </u> |
| ☐ 7-day ☐ Period ☐ 10-day ☑ Initial | | Pre-1938 | Yes | 1 | | | | • * |
| 10-day Initial | | OTC Product | √ Yes | 1 | 1 1 | | | Supra Sil |
| 9. Manufacturer Report | | A division Ev | | | | | | |
| • | | 8. Adverse Eve SEIZURE LI | | | | | | 00- 1711 |
| 54973 AE # 154 | 15 | | | RYING, FUSSY | | | | OCF 23 3 |
| | , | | , | 1 | | | | ~~ 6014 |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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PRAStaff@fda.hhs.gov
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| CaseID: 10307987 Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
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| Mfr Report # 54973 |
| UF/Importer Report # |
| |

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| | FUM | JJUUM | 12113 |

| | FORM FDA 350 | 0A (2/13) | | | , იყe |
|------------------------------|---|-----------------------------|--------------------|-------------------------------------|----------------|
| | A. PATIENT INF | ORMATION | | | |
| | Patient Identifier (b) (6) | 2. Age at Time of Event: | | 3. Sex | 4. Weight |
| | (5) (6) | or2 | Years | ☐ Female | lbs |
| | | Date | | ✓ Male | or |
| | In confidence | of Birth: VENT OR PRODU | OT DOOD! E | | kgs |
| | B. ADVERSE E | VENT OR PRODU | CTPROBLE | VI | |
| | 1. Adverse Even | | duct Problem (e | .g., defects/malf | ınctions) |
| | 2. Outcomes Attribut (Check all that appl) | ed to Adverse Event | | | |
| | Death: | | Disability o | r Permanent Dar | nage |
| | Life-threatenin | (<i>mm/dd/yyyy</i>) g | Congenital | Anomaly/Birth D | efect |
| | ☐ Hospitalization | - initial or prolonged | Other Serie | ous (Important M | edical Events) |
| | Required Inter | vention to Prevent Perm | anent Impairment | /Damage (Device | es) |
| | 3. Date of Event (mm | | 4. Date of This | Report (mm/dd | <i>(yyyy</i>) |
| | | 0/2014 | | 06/26/2014 | |
| | 5. Describe Event or | Problem | | | |
| | CHILD WITH SPE | EECH DELAY REQU | IRES THERA | PY. | |
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| P.L. | | | | | |
| | | | | | |
| | | | | (Continue on | page 3) |
| | 6. Relevant Tests/Lab | oratory Data, Including | Dates | | |
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| | | | | (Continue on | 2000 |
| | 7. Other Relevant Hist | ory, Including Preexist | ting Medical Con | (Continue on ditions (e.g., alle | |
| ŀ | race, pregnancy, smo | oking and alcohol use, h | epatic/renal dysfu | inction, etc.) | J |
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| r-facilities, and manufacturers | | 4973 | | |
| RY reporting | UF/Importer Re | port # | | |
| f <u>5</u> | | | | FDA Use Or |
| C. SUSPECT PRODU | JCT(S) | | | DA USE OF |
| 1. Name (Give labeled streng | | DI PTC | | |
| #1 HYLAND'S BABY | LECITING TA | DLE13 | | |
| #2 2. Dose, Frequency & Rout | n Used | 3. Therany D | ates (If unknown, g | ive duration |
| #1 UNKNOWN DOSE FO | | | best estimate) | warandi |
| #2 | | #2 | | |
| 4. Diagnosis for Use (Indica | ation) | | event Abated After | Use |
| #1 TEMP RELIEF TEE | • | | Stopped or Dose R | teduced? Doesn |
| #2 | AT THE P. L. | | | L Apply |
| 5. Lot# | Exp Date | #2 | | Doesn Apply |
| #1 | #1 | | vent Reappeared Reintroduction? | After |
| ~ . | <u> </u> | 4 #1 | Yes No | Doesn Apply |
| NDC# or Unique ID 54973-3127-3 | dia dia | #2 | Yes No | Doesn Apply |
| 0. Concomitant Medical Pr | outet alon for | apy Dates (Exc | clude treatment of e | |
| | | | | |
| | | | | |
| | | | (Continue on | page 3) |
| D. SUSPECT MEDICA Brand Name | AL DEVICE | | | |
| | | | 2h Broads | |
| 2. Common Device Name | | | 2b. Procode | |
| 3. Manufacturer Name, City | and State | | | |
| . Model # | Lot# | | 5. Operator | of Davies |
| | | | Health | Or Device Professiona |
| Catalog # | Expiration (| Date (mm/dd/yy | yy)] <u></u> | er/Patient |
| Serial # | Unique Iden | ntifier (UDI) # | Other: | |
| . If Implanted, Give Date (n | nm/dd/www | 7 If Evaluate | d, Give Date (mm/d | ld/saaa |
| pianteu, Give Date (II | | n zapiantec | , Give Date (rim/o | <i></i> |
| is this a Single-use Devic | e that was Repro | cessed and Re | sused on a Patient | ? |
| If Yes to Item No. 8, Enter | Name and Addr | ess of Reproce | essor | |
| | | | _ | |
| | | | D: | SS |
| 0. Device Available for Eva | - | , | 11 H 1 | 1 201 |
| Yes No | Returned to Ma | nufacturer on: _ | JUL . (mm/dd/yyy | |
| Concomitant Medical Pro | oducts and Thera | py Dates (Exc | lude treatment of e | vent) |
| | | | | |
| INITIAL DEGRAPM | | | (Continue on | page 3) |
| . INITIAL REPORTE Name and Address | R | | | |
| (6) | | | | |
| | | | 1 10 000 | |
| | | JU | L 10 2014 | } |
| none# | Email (b) (6) | Address | | |
| Hoolth Professional In 12 | (6) (6) | | | |
| Health Professional? 3. (| Danus-Har | | A Initial December | · Alexan |
| Yes No NA | | | 4. Initial Reporte Report to FDA Yes No | _ |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| | | 1.64 W. 1864 H.16 | | L | | | | | | Cas | seID: 1 | 030798 |
|--|--------------------|--------------------|-----------------------|--|----------------------------|-----------------|-----------|---------------------------|-----------|--------------|---|------------|
| | | | | | | | | | F | DA USE ON | LY | |
| | | | | E 10.361 E 11.4 | 2 of ⁵ | | | | | | | |
| | 10307 | 987-01-00 |)-02 | | | | W.E.A.G | TUBERO OL | | | | |
| II. OHECK OHE | | 12. 8 | JF/Importer | Report Number | _ | e of Reportable | | CTURERS ON | IL Y | 2 If Follow | -up, What T | vno2 |
| User Facility | Imp | orter | | | 1 1 7 | Death | | | | | rrection | yper |
| 3. User Facility or Imp | orter Nam | e/Address | | | ┫┨╞ | Serious Injury | y | | | | ditional Infor | mation |
| | | | | | 117 | Malfunction | • | | | | sponse to FI | |
| | | | | | $\parallel \parallel ^{-}$ | | | | | De | vice Evaluat | ion |
| | | | | | 3. Dev | ice Evaluated | by Manu | ufacturer? | | 4 Device N | lanufacture | Date |
| | | | | | 11 | Not Returned | | | | (mm/yyyy | | Date |
| 4. Contact Person | | | 5. Phone I | Number | -1 - | | | Summary Attach | ed | | | |
| | | | | | | No (Attach pa | age to ex | oplain why not) or | - 1 | 5. Labeled | for Single U | lse? |
| Date User Facility o Importer Became | | 7. Type of Report | rt | Date of This Report (mm/dd/yyyy) | 11 | provide code: | E | | | ☐ Ye | s 🗍 1 | No |
| Aware of Event (mm | v/dd/yyyy) | Initial | | , | | | | | <u> </u> | | | |
| | | Follow-up# | | . | 6. Eve | | | ation Codes (Refe | er to coo | ing manual) | | |
| 9. Approximate Age of Device | 10. Event | Problem Codes (| Refer to coo | ling manual) | 11 | Patie Code | | | | - | | |
| Ago of Consc | Patient | | _ | 7- | 11 | Devic | | | | | | |
| | Code L Device [| | | | | Code | e [| | | | | _ |
| | Code | | - | | 11 | Metho | od | | | · | J - L | |
| 11. Report Sent to FDA | ? | 12. Location W | here Event | Occurred | 11 | Resul | ite | | | | 7_ | _ |
| Yes | t | Hospita | al | Outpatient Diagnostic Facility | | 110001 | | | _ | | <u> </u> | ⊣ I |
| No (mm/dd/ | | Home | | ☐ Ambulatory | | Conclusion | ns | | | |] | |
| 13. Report Sent to Man | ufacturer? | | ; Home ent Treatme | Surgical Facility | 7. If Re | medial Action | Initiated | d, Check Type | 8. U | sage of Dev | rice | |
| Yes(mm/dd/ | (1000) | Facility | | | | Recall | ☐ No | otification | 1 | Initial U | Jse of Device | e |
| ∐ No (,,,,,, | | Other: | - | (Specify) | [| Repair | ns Ins | spection | 1 | Reuse | | |
| 14. Manufacturer Name | Address | | | | 1 1 = | Replace | | atient Monitoring | 0.16 | Unknow | | |
| | | | | | | Relabeling | | odification/ djustment | 1 21 | 1 USC 360i(1 | rted to FDA f), list correcting number | ction/ |
| | | | | | | Other: | | | _ '" | movarrepo | rung numb | er. |
| | | | | | | | | | _ | | | |
| | | | | | 10. | Additional Ma | anufactu | rer Narrative | and / | or 1 | 1. Corre | ected Data |
| G. ALL MANUFA | CTURER | S | | | 1 | | | | | | _ | |
| Contact Office (and i | Manufactu | ring Site for Devi | ces) | 2. Phone Number | | | | | | | | |
| Name DYTA FRACKIEWI | CZ | | | 310-768-0700 | | | | | | | | |
| Address | | | | 3. Report Source (Check all that apply) | 11 | | | | | | | 1 |
| YLAND'S, INC. | | | | Foreign | | | | | | | | ŀ |
| .54 W. 131ST ST | | | | Study | | | | | | | | i |
| OS ANGELES, CA | 90061 | | | Literature | | | | | | | | - 1 |
| Email Address | | | | Consumer Health Professional | | | | | | | | |
| TANDARD@HYLAND | S.COM | T- | | User Facility | | | | | | | | |
| Date Received by Manufacturer (mm/do | <i>∀yyyy</i>) | 5. (A)NDA# | | Company | | | | | | | | |
| 06/22/20 | 14 | | | Representative Distributor | | | | | | | _ | |
| . If IND, Give Protocol | # | IND# | | Other: | | | | | | | Į. | DSS |
| | | BLA# | | | | | | | | | | |
| . Type of Report | | PMA/ 510(k) # | | | | | | | | | IJUL | - 11201 |
| (Check all that apply) | | Combination | | | | | | | | | | |
| 5-day 30-day | | Product | Yes | | | | | | | | | |
| 10-day ☑ Initial | | Pre-1938 | Yes | | | | | | | | | |
| 15-day Follow | -up # | OTC Product | √ Yes | | | | | | | | | 1 |
| Manufacturer Report | Number | 8. Adverse Eve | | | | | | | | | | l |
| 4973 AE # 1548 | 8 | SPEECH DEI | LAY | | | | | | | . 11 | L 10 | 2016 |
| | | | | | - | | | | | JU | r TO | ZU14 |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Individual case salety kepole

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CaseID: 10307987

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report

MPLAINT RECORD

COMPLAINT #: 2558



| 10307987 | -01-00-03 | DATE OF COMPLAIN | T: 06/22/14 | 2777110 |
|--|--|-------------------------------|------------------|----------------|
| PRUDUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE | E: BTET | |
| SIZE: | NOT PROVIDED | LOT NO | .: NOT PROVIDE |) |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | | | | |
| | | | | 7. F.W. |
| CITY: | | STATE: | | |
| COUNTRY: USA | | ZIP CODE: | | |
| PHONE #: | | | | |
| E-MAIL:(b) (6) | MOTHER SENT E-MAIL THAT CHILD USI | NG TEETHING TABLETS FROM BIRT | H TO ONE YEAR OF | AGE CHILD 2 |
| NATURE OF COMPLAINT: SENT BY PHARMACIST AND | YEARS OLD AND HAS BAD SPEECH DE | LAY AND GOING TO THERAPY. MOT | HER DID NOT RESP | OND TO E-MAIL |
| | | | | |
| | FOR ADDITIONAL SPACE PLEASE USE RE | VERSE OR ATTACH A SEPARATE S | HEET | |
| PRODUCT RECEIVED FOR INSPECTION: | (CIRCLE ONE) | PRODUCT BEING RETURNED FO | OR INSPECTION: | Y (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT | BE RETURNED: | |
| | | UPS CA | LL TAG ISSUED: | Y (CIRCLE ONE) |
| | | DATE PROD | UCT RECEIVED: | |
| SECTION II: INV | ESTIGATION . | | | |
| | | | | |
| INVESTIGATION:F | PLEASE SEE ATTACHED INSPECTION REPORT. | | | |
| | | | | |
| | - | | | |
| | | | | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION | N ON: 06/22/1 | 4 | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION | N BY: EDYTA | FRACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | |
| | | | | |
| | | | | |
| | - | | | |
| | | | | DSS |
| CORRECTIVE ACTION(S) CO | MPLETED BY: | DATE | Ē: | |
| SECTION IV: ADV | ERSE EVENT REPORTS | AE: | #: 15448 | JUL 11 2014 |
| | | | | |
| ADVERSE EVENT SERIOUS: | Y) N | | | |
| ADVERSE EVENT REPORTE | D ON: 06/22/14 | BY: EDYTA FRAC | CKIEWICZ | |
| SECTION V: | $\sqrt{2}$, 1 | 11 | | . 1 |
| REVIEWED BY MANAGEMEN | IT BY: | DATE | 06-30 | - 14 |
| BY: | Que Bain | DATE: | 06-30 06-30 | 14 |
| | QA / QC DIRECTOR | | | 11 11 |

cc: QA / QC Packaging Production Shipping / Receiving JUL 10 2014

Form # VD1

VENT DATA FORM



| AE #:154 | 548 | |
|----------------------|--|----------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | STATE: | |
| COUNTRY: PHONE #: | USA ZIP CODE: | |
| E-MAIL: | (b) (6) | |
| SECTION II: | PACKAGING INFORMATION: | |
| A | AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| SECTION III: | CORRECTIVE ACTION: | |
| | | |
| | D | SS |
| CORRECTIVE A | ACTION(S) COMPLETED BY: DATE: | 1 1 2014 |
| SECTION IV: | | |
| REVIEWED BY | MANAGEMENT BY: DATE: 06-30-14 | |
| BY: | MANAGEMENT BY: DATE: 06-30-14 QA / QC DIRECTOR DATE: 06-30-14 DATE: 06-30-14 | 10 2014 |





CaseID: 10307987

SAE-0025-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-nine Adverse Events (AE) which also included twenty-one Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

JUL 11 2014

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| Individual Case | Safety Report |
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| by user-facilities, ibutors and manufacturer |
|--|
| DATORY reporting |

| 1 | Form Approved: OMEN | GSG Mastatement on Session |
|---|----------------------|----------------------------|
| 1 | Mfr 54973 | |
| | UF/Importer Report # | |
| | | |

| A. PATIENT INFORMATI | ON ' | | | | C. SUSPECT |
|---|---------------------|----------------------|------------------------------|----------------------|---------------------------|
| 1. Patient Identifier 2. Age at 7 (b) (6) of Even | | | 3. Sex | 4. Weigh | 1 1 |
| or | 13 Mo | nths | Female | | ibs #1 HYLAND'S |
| Date In confidence of Birth | _ | | ✓ Male | or | kgs #2 |
| In confidence of Birth B. ADVERSE EVENT OF | - | PROBLE | vi | | 2. Dose, Frequen |
| | | | | unctions) | #12 TABS O |
| Adverse Event and/or Outcomes Attributed to Adve | | Problem (e | .g., defects/malf | incuonsi | #2 |
| (Check all that apply) | 136 EVEIR | | | | 4. Diagnosis for |
| Death: (mm/dd/) | (7777) | Disability of | r Permanent Da | mage | #1 TEMP REL |
| Life-threatening | | 1 | Anomaly/Birth [| | #2 |
| Hospitalization - initial or p | - | J | ous (Important M | | 6. Lot # |
| Required Intervention to F | | | | | #1 |
| 3. Date of Event (mm/dd/yyyy) 06/25/2014 | 4. 1 | Date of This | 06/30/2014 | | #2 |
| | | | | | 9. NDC# or Uniq |
| 5. Describe Event or Problem (b) CUSTOMER POSTED ON | (6) THA | | D JUNE 25T | | IN 54973-312 |
| AFTER GIVING HER 13 INTO SEIZURE. SINCE RAPID HEARTBEAT, MUS IRRITABILITY, TIREDN | THEN HE'S F | HAD HIGH SS, RASH | FEVERS, V | NITIMO | |
| | | | | | D. SUSPECT 1. Brand Name |
| ļ | | * | | | 2. Common Dev |
| | | | | | 3. Manufacturer |
| · . | | J | JL 16 20 | 14 | |
| | | | 1 0 20 | 17 | 4. Model# |
| | | | A | | |
| | | | | | Catalog# |
| | | | | | Serial # |
| | | | | | 6. If Implanted, |
| | | | (Continue o | n page 3 | |
| 6. Relevant Tests/Laboratory D | ata, Including Da | ates | | | 8. Is this a Singl |
| | | | | | 9. If Yes to Item |
| | | | | | 9. If Yes to item |
| | | | | | |
| | | | | | |
| | | | | | 10. Device Avail |
| | | | | | Yes |
| | | | (Continue o | n page 3 | 11. Concomitan |
| 7. Other Relevant History, Inchrace, pregnancy, smoking and | uding Preexisting | g Medical C | | | |
| UNKNOWN | arabitor dos, riepi | apontona dy. | autotion, oto.) | | |
| | | | | | E. INITIAL F |
| İ | | | | | 1. Name and Ac (b) (6) |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | Phone # |
| | | | (Continue o | | |
| Submission of a report do personnel, user facility, in | es not consti | tute an ac | dmission tha nufacturer o | t medica r produc | al 2. Health Profe |
| personnel, user facility, in caused or contributed to | he event. | | | - p | Yes ✓ |

| Y reporting | UF/Importer Re | eport # | |
|---|-------------------|----------------------------------|-------------------------------------|
| 5 | | | FDA Use O |
| C. SUSPECT PRODU | | | |
| Name (Give labeled stren) #1 HYLAND'S BABY | - | ABLETS | |
| | ISSINING IA | 101110 | |
| #2 2. Dose, Frequency & Rout | te Used | 3. Therapy Date | s (If unknown, give duration |
| #12 TABS ON 06/2 | | from/to (or be | st estimate) |
| | ~, * • | #2 | |
| #2 4. Diagnosis for Use (Indicate) | ation) | 5. Eve | ent Abated After Use |
| #1 TEMP RELIEF TE | | 1 _ | pped or Dose Reduced? Yes No Does |
| #2 | | #' L | Tres V No Apply |
| 6. Lot # | 7. Exp. Date | #2 | Yes No Does |
| #1 | #1 | | ent Reappeare d After introduction? |
| #2 | #2 | #1 | Yes No ☑ Does |
| 9. NDC# or Unique ID | | #2 [| Type DNa Does |
| 54973-3127-3 10. Concomitant Medical F | Products and The | | д — С Аррі |
| | | | (Continue on page 3) |
| D. SUSPECT MEDIC | CAL DEVICE | | |
| 1. Brand Name | | | |
| 2. Common Device Name | | [2 | b. Procode |
| 3. Manufacturer Name, Cit | ty and State | | |
| 4. Model# | Lot# | | 5. Operator of Device |
| | | | Health Professio |
| Catalog # | Expiration | n Date (mm/dd/yy) | (y) Lay User/Patient |
| Serial # | Unique Id | entifier (UDI)# | Other: |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/dd/yyyy) |
| 8. Is this a Single-use Dev | vice that was Ren | processed and Re | used on a Patient? |
| Yes No | mai mas nei | | |
| 9. If Yes to Item No. 8, En | ter Name and Ad | dress of Reproce | ssor |
| | | | |
| | | -11: FT-1: | |
| 10. Device Available for E | _ | ot send to FDA) Manufacturer on: | |
| | _ | | (mm/dd/yyyy) |
| 11. Concomitant Medical | Products and Th | erapy Dates (Exc | aude treatment of event) |
| | | | (Cantinua an man a |
| E. INITIAL REPORT | ER | | (Continue on page 3 |
| 1. Name and Address (b) (6) | | | -40 |
| (0) (0) | | . بحر | JUL 1 7 201 |
| | | 71 | LCA "" |
| | | u | ED TREUM |
| Phone # | En | nail Address | |
| 2. Health Professional? | 3. Occupation | | 4. Initial Reporter Also S |
| 1 | NA | | Report to FDA |

| T. FOR USE DE USER PACIENT DIMPORTER (Devices Only) | | | | | | | |
|--|--|--|--|--|--|--|--|
| 1. Check One 2. UF/Importer Report Number | | | | | | | |
| User Facility Impor | ter | | | | | | |
| 3. User Facility or Importer Name/ | Address | | | | | | |
| | | | | | | | |
| 4. Contact Person | 4. Contact Person 5. Phone Number | | | | | | |
| 6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) | . Type of Report 8. Date of This Report (mm/dd/yyyy) Follow-up # | | | | | | |
| 9. Approximate 10. Event P | roblem Codes (Refer to coding manual) | | | | | | |
| Age of Device | | | | | | | |
| Code | | | | | | | |
| Device Code |]-[| | | | | | |
| | 12. Location Where Event Occurred | | | | | | |
| 11. Report Sent to FDA? | Hospital Outpatient | | | | | | |
| Yes(mm/dd/yyyy) | Diagnostic Facility | | | | | | |
| ∐ No | Home Ambulatory | | | | | | |
| 13. Report Sent to Manufacturer? | Nursing Home Surgical Facility | | | | | | |
| Yes | Outpatient Treatment Facility | | | | | | |
| No (mm/dd/yyyy) | Other:(Specific) | | | | | | |
| 14. Manufacturer Name/Address | (Specify) | | | | | | |
| G. ALL MANUFACTURER | S | | | | | | |
| Contact Office (and Manufactur | | | | | | | |
| Name | 310-768-0700 | | | | | | |
| EDYTA FRACKIEWICZ | 3. Report Source | | | | | | |
| Address HYLAND'S, INC. | (Check all that apply) | | | | | | |
| 154 W. 131ST STREET | Study | | | | | | |
| LOS ANGELES, CA 90061 | Literature | | | | | | |
| Email Address | ✓ Consumer | | | | | | |
| STANDARD@HYLANDS.COM | Health Professional User Facility | | | | | | |
| Date Received by Manufacturer (mm/dd/yyyy) | 5. Company | | | | | | |
| 26/30/2014 | Representative Distributor | | | | | | |
| 6. If IND, Give Protocol# | BLA# Other: | | | | | | |
| | PMA/ | | | | | | |
| 7. Type of Report | 510(k) # | | | | | | |
| (Check all that apply) | Combination Type | | | | | | |
| | Product Yes | | | | | | |
| 7-day Periodic ☐ 10-day initial | Pre-1938 Yes | | | | | | |
| 10-day Follow-up # | OTC Product Yes | | | | | | |
| 9. Manufacturer Report Number | 8. Adverse Event Term(s) | | | | | | |
| 1 | Seizure, fevers, vomiting, tachy- | | | | | | |
| 54973 AE # 1552 | cardia, muscle weakness, rash, | | | | | | |
| | confusion, irritability, lethargy | | | | | | |

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| | | | | FDA USE O | NLY | |
|-----|-----------------------------|-----------------|--------------|-------------|--|--|
| | | | | | | |
| of | 5 | | | | | |
| | H. DEVICE MANUFA | CTURERS | ONLY | | | |
| | 1. Type of Reportable Eve | | | 2. If Folio | w-up, What Type? | |
| - [| Death | | | | Correction | |
| ١ | Serious Injury | | | | Additional Information | |
| -1 | Malfunction | | | | Response to FDA Request | |
| ١ | _ | | | | Device Evaluation | |
| ŀ | 3. Device Evaluated by Ma | nufacturer? | | 4. Device | Manufacture Date | |
| - 1 | Not Returned to Ma | | | (mm/y | | |
| 1 | | ion Summary A | tached | | | |
| ١ | No (Attach page to | | | 5. Labele | ed for Single Use? | |
| - | provide code: | explain why no | i) or | | ☐ Yes ☐ No | |
| ١ | | | | 1 4 | res [] NO | |
| ŀ | 6. Event Problem and Eva | luation Codes | (Refer to | coding manu | al) | |
| | Patient | | 7_ [| | _ | |
| | Code | | J <u>-</u> [| | | |
| 1 | Device Code | | - | | - | |
| - | Г | | | 7 [| | |
| | Method | | | J-[| | |
| ١ | Results | _[| | 7- | - | |
| - | 1100010 | | | | | |
| ١ | Conclusions |]-[| | J-L | | |
| ı | 7. If Remedial Action Initi | ated, Check Ty | pe 8 | . Usage of | Device | |
| | Recall | Notification | | Init | al Use of Device | |
| | Recail | Inspection | | Re | use | |
| ļ | Replace | Patient Monito | oring | Uni | known | |
| | Relabeling | Modification/ | | If action r | eported to FDA under | |
| | | Adjustment | | removal r | 60i(f), list correction/ eporting number: | |
| | Other: | | | | | |
| | | | | | | |
| | 10. Additional Manufa | acturer Narrati | ve a | and / or | 11. Corrected Data | |
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CaseID: 10313881

Individual Case Salety Report

OMPLAINT RECORD

| Hylanis D: 1 | 10313881 |
|--------------|----------|
|--------------|----------|

| 103 | 31,3881-01-00-03 | COMPLAINT #: | 2562 | |
|---------------|---|------------------------------|---------------|---------------------|
| IANEN DI. | CUTTATRACNEWICZ | DATE OF COMPLAINT: | 06/30/14 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | | |
| SIZE: | UNKNOWN | LOT NO.: | UNKNOWN | |
| REPORTER: | (b) (6) | | | |
| ADDRESS: | | | | |
| | | | | |
| CITY: | | STATE: | | |
| COUNTRY: | | ZIP CODE: | | |
| PHONE #: | NOT PROVIDED | | | |
| E-MAIL: | | | | NO O TESTINO |
| DAZED/CONFU | INTO SEIZURE. SINCE THEN HE'S HAD HIGH FEVERS, VOMITING ISION, IRRITABILITY, TIREDNESS, LETHARGY, IT WAS YOU PRO | C DADID HEADTREAT MIISCLE WE | AKNESS KASH | |
| TO HYLAND'S F | REQUEST TO CONTACT THE COMPANY. FOR ADDITIONAL SPACE PLEASE USE REVE | RSE OR ATTACH A SEPARATE SH | EET | |
| PRODUCT REC | CEIVED FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | R INSPECTION: | Y (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT B | BE RETURNED: | |
| | | UPS CAL | L TAG ISSUED: | Y N (CIRCLE ONE) |
| | | DATE PRODU | ICT RECEIVED: | |
| | AND TOTAL ATION | 2,1,2 | | |
| SECTION II: | INVESTIGATION | | | |
| INVESTIGATIO | DN: PLEASE SEE ATTACHED INVESTIGATION REPORT | | | |
| | | | | |
| | | | | |
| | | | | |
| ADVERSE EVE | ENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION | ON: | | |
| | ENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION | | FRACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | |
| <u></u> | | | | |
| | · | | | |
| | | | | |
| | | | | - |
| CORRECTIVE | ACTION(S) COMPLETED BY: | DATE | <u> </u> | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE | #:1552 | |
| ADVERSE EV | ENT SERIOUS: | | | -D***- |
| ADVERSE EV | /ENT REPORTED ON: 06/30/14 | BY: EDYTA FRA | CKIEWICZ | ——DSS |
| SECTION V: | | 7200 | | . 1111 170 |
| | \ \mathread \mathread \ \mathread \ \mathread \ \mathread \mathread \ \mathread \mathread \ \mathread \mathread \ \mathread \mathread \ \mathread | AMIL DAT | E: 07-08- | JUL 172 |
| REVIEWED B | IY MANAGEMENT BY: | N. L. SAIL | 07-08- | 14 |
| BY: | (Numum Dant | DATE: | 01-08- | - 14 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 10313881

Serious Adverse Event SAE-0029-2014

Product in Inventory:

The reporter was only able to provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved, a review the customer complaints and Deviation systems is not possible. Although the lot number of the unit involved cannot be determined, Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum was "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Standard Homeopathic Company will continue to monitor other adverse events related to our Teething products to ensure that significant trends can be observed in a timely manner.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Pur Baur

Date

07-07-14

DSS JUL 17 2014

EVENT DATA FORM



| AE #: | 1552 COMPLAINT #: 2562 | _ |
|------------|--|------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) - | _ |
| ADDRESS: | | |
| CITY: | STATE: | |
| COUNTRY: | USA ZIP CODE: | |
| PHONE #: | | _ |
| E-MAIL: | | _ |
| SECTION II | PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY | |
| | Tastrery laties Tastre | |
| SECTION I | II: CORRECTIVE ACTION: | |
| | | |
| CORRECT | IVE ACTION(S) COMPLETED BY: DATE: | - |
| SECTION I | N: () | DSS |
| | D BY MANAGEMENT BY: MARCHELL DATE: 07-08-14 | JUL 172014 |
| BY: (| DATE: 07-08-14 | |

For use by user-facilities, s, distributors and manufacturers MANDATORY reporting

| | Form Approved: OMB No. 0910-0291, Expires: 6/ See OMB statement on | |
|------------|---|--|
| Mfr Report | [#] 54973 | |
| UF/Importe | r Report # | |

ÇaseID: 10314685

| A. PATIENT INF | | | | Page |
|---|--|---|---|------------------------|
| | ORMATION | | | |
| 1. Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight |
| (b) (6) | of Event: 18 | Months | √ Female | 20-22 g |
| | Date | | Male | OF |
| In confidence | of Birth: | | | k |
| B. ADVERSE E | VENT OR PRODU | CTPROBLE | Λ | |
| 1. Adverse Even | | oduct Problem (e. | g., defects/maift | unctions) |
| Outcomes Attribu (Check all that appl | ted to Adverse Event | | | |
| Death: | | Disability or | r Permanent Dar | mage |
| Life-threatening | (mm/dd/yyyy) ng | Congenital | Anomaly/Birth D | efect |
| ✓ Hospitalization | n - initial or prolonged | Other Serio | ous (Important M | edical Event |
| Required Inter | rvention to Prevent Pern | nanent Impairment | /Damage (Devic | es) |
| 3. Date of Event (mr | n/dd/yyyy) | 4. Date of This | Report (mm/dd | Ууууу) |
| 10/0 | 00/2013 | | 06/25/2014 | |
| Describe Event or CHILD HAD SEI | | SE. | ZURES OCC | HDDFD |
| | MORNING AND EA | | | |
| WORSE. CHILD | TAKEN TO HOSP | ITAL AND COM | NTINUED TO | HAVE |
| SEIZURES IN T | | HOSPITALIZE | | |
| | KING" AND WENT SEA AND VOMITI | | | |
| HAD SEIZURE. | | | | |
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| | | | | |
| | | | (Continue or | n page 3) |
| | boratory Data, Includi | ng Dates | (Continue or | n page 3) |
| EEG NORMAL | • | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | n page 3) |
| EEG NORMAL | | | (Continue or | |
| EEG NORMAL PRESCRIBED DI. | AZEPAM 5MG SUP | POSITORIES | <i>(Continue or</i> | n page 3) |
| EEG NORMAL PRESCRIBED DI. 7. Other Relevant His | AZEPAM 5MG SUP | POSITORIES | <i>(Continue or</i> | n page 3) |
| EEG NORMAL PRESCRIBED DI. 7. Other Relevant His race, pregnancy, sr | AZEPAM 5MG SUP story, Including Preexinoking and alcohol use, ALLERGIES | POSITORIES isting Medical Cor hepatic/renal dysfi | <i>(Continue or</i> | n page 3) |
| PRESCRIBED DI. 7. Other Relevant His race, pregnancy, sr NO KNOWN FOOD NO KNOWN MEDIC | AZEPAM 5MG SUP story, Including Preexinoking and alcohol use, ALLERGIES CATION ALLERGIE | POSITORIES isting Medical Cor hepatic/renal dysfi | <i>(Continue or</i> | n page 3) |
| PRESCRIBED DI. 7. Other Relevant His race, pregnancy, sr NO KNOWN FOOD NO KNOWN MEDIC | AZEPAM 5MG SUP story, Including Preexinoking and alcohol use, ALLERGIES | POSITORIES isting Medical Cor hepatic/renal dysfi | <i>(Continue or</i> | n page 3) |
| 7. Other Relevant His race, pregnancy, sr NO KNOWN FOOD NO KNOWN ENVIR FOLLOW-UP 1 MK | STORY, Including Preexinoking and alcohol use, ALLERGIES CATION ALLERGIE RONMENTAL ALLER | esting Medical Cor hepatic/renal dysfices RGIES | (Continue on ditions (e.g., al unction, etc.) | n page 3) llergies, |
| 7. Other Relevant His race, pregnancy, sr NO KNOWN FOOD NO KNOWN ENVIR FOLLOW-UP 1 MK | STORY, Including Preexinoking and alcohol use, ALLERGIES CATION ALLERGIE RONMENTAL ALLER | esting Medical Cor hepatic/renal dysfices RGIES | (Continue on ditions (e.g., al unction, etc.) | n page 3) llergies, |
| FOLLOW-UP 1 MC | STORY, Including Preexinoking and alcohol use, ALLERGIES CATION ALLERGIE RONMENTAL ALLER | esting Medical Cor hepatic/renal dysfices RGIES | (Continue on ditions (e.g., al unction, etc.) | n page 3) llergies, |
| 7. Other Relevant His race, pregnancy, sr NO KNOWN FOOD NO KNOWN ENVIR FOLLOW-UP 1 MK | STORY, Including Preexinoking and alcohol use, ALLERGIES CATION ALLERGIE RONMENTAL ALLER | esting Medical Cor hepatic/renal dysfices RGIES | (Continue on ditions (e.g., al unction, etc.) | n page 3) llergies, |

| f <u>></u> | | | | F | DA Use O |
|---|------------------|--------------|--------------|-------------------------|----------------|
| C. SUSPECT PROD | |) | | | |
| Name (Give labeled stren #1 HYLAND'S BABY | - | | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Rou | te Used | | | funknown, g | ive duratio |
| #1 INTERMITTENTLY | Q 3-4 HRS | #1 | o (or best e | stimate) | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Indic | ation) | | | Abated After | |
| #1 TEMP RELIEF OF | TEETHING | PAIN | #1 V | ed or Dose R es ∏ No | Doe: |
| #2 | | | | | Appl Does |
| 6. Lot# | 7. Exp. Date | | #2 Y | es No | Appl |
| #1 | #1 | | | Reappeared oduction? | After |
| #2 | #2 | - | #1 🗌 Y | es No | Doe: |
| 9. NDC# or Unique ID 54973-3127-1 | | | #2 TY | es No | Does |
| 10. Concomitant Medical F | Products and The | erany Date | | | Appl eveat) |
| D. SUSPECT MEDIC | AL DEVICE | | (C | ontinue on | page 3, |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 2b. P | rocode | |
| 3. Manufacturer Name, Cit | v and State | | | | |
| | , | | | | |
| 4. Model# | Lot# | | 1 | 5. Operator | of Device |
| Catalog # | Evenient' | Date (m- | (dd/snan) | Health | Profession |
| Catalog # | Expiration | Date (mm | .ou yyyy) | | er/Patient |
| Serial # | Unique Id | entifier (UD | 1) # | Other: | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Exp | lanted, Giv | re Date (mm/c | dd/yyyy) |
| 8. Is this a Single-use Dev | ice that was Don | rocesed : | nd Raues | d on a Pation | nt? |
| Yes No | os mai was nep | | 1160360 | - on a ranen | |
| 9. If Yes to Item No. 8, Ent | er Name and Ade | dress of Re | processor | | |
| | | | | - |) S S |
| 10. Device Available for Ev | | | • | JUL | 187 |
| Yes No | Returned to N | Manufacture | r on: | (mm/dd/yy | <i>yy</i>) |
| 11. Concomitant Medical P | Products and The | erapy Dates | (Exclude | treatment of e | event) |
| | | | | | |
| | | | (C | ontinue on | page 3) |
| E. INITIAL REPORT | ER | | | | |
| (b) (6) | | | | | |
| | | | JU | L 17 | 2014 |
| Phone # (b) (6) | Em | ail Address | | | |
| 2 1116- 12-15 | | | | | |
| 2. Health Professional? 3 | Occupation | | | nitial Reporte | |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.



Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

☐ No

Yes

No

Name

Address

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

36/25/2014

30-day

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

☐ 10-day 🕡 Initial

54973 AE # 1551

15-day Follow-up #_ 9. Manufacturer Report Number

7. Type of Report

5-day

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

Study

3. Report Source (Check all that apply)

Health Professional

Page 2 o

| f <u>5</u> | |
|---|--|
| H. DEVICE MANUFACTURERS ONLY | |
| 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| Death Serious Injury | Correction Additional Information |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | Yes No |
| | |
| 6. Event Problem and Evaluation Codes (Refer to | o coding manual) |
| Patient Code | - |
| Device | 100 |
| Code | |
| Method - | |
| Results | |
| 1053013 | |
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ Adjustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Combination Product

OTC Product Yes

8. Adverse Event Term(s)

Pre-1938

SEIZURES

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.

CaseID: 10314685

FDA USE ONLY



IER COMPLAINT RECORD



| 10314685-0 | 11-00-03 | COMPLAINT #: | 2561 | |
|--|--|---|---|--|
| TAKEN BY: | (b) (6) | DATE OF COMPLAINT: | 06/25/14 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 | |
| SIZE: | 135 TABLETS | LOT NO.: | DOESN'T HAVE BO | OTTLE |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | | | | |
| | | *** | | |
| CITY: | THE RESERVE THE PROPERTY OF TH | STATE: (b) (6) | | |
| COUNTRY: _USA _(b) (6) | | ZIP CODE: | | |
| PHONE #: | | TOTAL WAR ALL MANAGEMENT AND A STATE OF THE | | |
| E-MAIL: | MOTUCE (PERCENTED ON THE PER | E PIS PHONE LINE TO DISCUSS THE TEETH | | STATE OF THE PARTY AND ADDRESS OF THE PARTY AN |
| TO CONSIDER PURCHASING T WONDERS IF THIS COULD HAV MORNING AND EACH EPISODE HAVE SEIZURES IN THE HOSP! HOSPITAL THE DAY BEFORE. BABY HAD JUST ONE DOSE. MO'DEGREES TEMPERATURE. BABY EPISODE. NO OTHER MEDICAL C | HE TEETHING TABLETS FOR THEM BUT /E BEEN RELATED TO HER CHILD'S SEIZ E GOT PROGRESSIVELY WORSE. THE M ITAL. CHILD WAS HOSPITALIZED FOR 4 BABY TOOK NAUSEA AND VOMITING MEDI THER WAS SICK AS WELL. MOTHER RECAL Y NOW HAS SEIZURE MEDICINE ON HAND – CONDITIONS. EEG – NORMAL. FOLLOW-UP CONDITIONS. EEG – NORMAL. FOLLOW-UP | HAS 2 YOUNGER CHILDREN (OTHER THAN TH HAS RECENTLY HEARD ABOUT SEIZURE R | RUMORS AND NOW M RES OCCURRED EAF AND THE BABY CON "PUKING" AND WENT A VOMITING MEDICINE NO STATES MAYBE 99 NO SEIZURES SINCE | AND SHE WANTS IOTHER ALSO RLY IN THE NTINUED TO TO EIS UNKNOWN. ITO 100 CORIGINAL |
| , | FOR ADDITIONAL SPACE PLEASE US | E REVERSE OR ATTACH A SEPARATE SHE | ET | |
| PRODUCT RECEIVED FOR INSPECTION: | Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | | Y N CIRCLE ONE |
| | (0.0000) | DATE REQUESTED PRODUCT BE | , | Since one, |
| | | | | |
| | | UPS CALL | TAG ISSUED: (C | CIRCLE ONE |
| | | | | |
| SECTION II: INVES | TIGATION | DATE PRODUC | T RECEIVED: | MANUAL AND A ALL AND A STATE OF THE AND A STATE OF |
| SECTION II. | HISATION | | | |
| INVESTIGATION: PLE | ASE SEE ATTACHED INVESTIGATION RI | EPORT. | <u> </u> | |
| | | | | |
| | | *************************************** | JUL 16 20 | 014 |
| ADVERSE EVENT FORWARDED | TO PHARMACIST / NURSE FOR EVALUA | ATION ON: 06/25/14 | 10 20 | <i>/!</i> 7 |
| ADVERSE EVENT FORWARDED | TO PHARMACIST / NURSE FOR EVALUA | ATION BY: | | |
| SECTION III: COI | RRECTIVE ACTION: | | | |
| | | | | |
| | , | WEST AND AND AND AND AND AND AND AND AND AND | | DSS |
| | | | | |
| CORRECTIVE ACTION(S) COMP | PLETED BY: | DATE: | | JUL 182 |
| SECTION IV: ADVER | SE EVENT DEDODTS | | | |
| ADVEN | SE EVENT REPORTS | AE #: | 1551 | |
| ADVERSE EVENT SERIOUS: | (Y)/ N | | | |
| ADVERSE EVENT REPORTED O | ON: 06/25/14 | BY: (b) (6) | | |
| SECTION V: | | Dana | | JUL 17 201 |
| REVIEWED BY MANAGEMENT B | | XOTTLE | 07-07-14 | • |
| | Pour Bain | | 07-03 | |
| | | | | |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0028-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-eight Adverse Events (AE) which also included twenty Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tables. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(D)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

6/26/14

D**S**S IUL 182014

CaseID: 10314685

JUL 1 7 2014



ADVERSE EVENT DATA FORM



| AE #: | 1551 | COMPLAINT #: 2561 | |
|--|--|--|----------|
| SECTION | I: PATIENT INFORMATION (IF DIFFERE | NT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | | _ |
| ADDRESS | 3 : | | _ |
| | | (b) (6) | _ |
| CITY: | r: USA | ZIP CODE: | - |
| PHONE #: | (b) (6) | | - |
| E-MAIL: | | | |
| o cotion | DAGNACING INFORMATION. | | |
| SECTION | II: PACKAGING INFORMATION: | | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| ing (2007 in graph of the control of | LA FR THE MATER Gebrus in Material Com | Teething Tablets Bally Teething Tablets Teething Tablets | |
| | | TAR SMARTS AND ADMINISTRATION OF THE SMARTS AND ADMINISTRATION OF | |
| SECTION | III: CORRECTIVE ACTION: | | |
| | | | DSS |
| | | A COLOR DE LA COLO | |
| CORREC | TIVE ACTION(S) COMPLETED BY: | DATE: | |
| SECTION | IV: | | 1 7 2014 |
| REVIEWE | ED BY MANAGEMENT BY: | DATE: 07-07-14 | - · WI7 |
| BY: | QUU B | DATE: 07-07-14 | L |



et Consumer Report

CDER

Casello: 1035954

No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

LUNTARY reporting of ents, product problems and product use errors

FDA USE ONLY
Triage unit sequence # 55 9 30 8

| Adverse Event Reporting Program | product use | errors | 12 | sequence # | <u> </u> | 1308 | |
|--|--|--|---------------|-----------------|-------------------|--|--------------|
| A. PATIENT INFORMATION | | 2. Dose or Amo | ount | Frequer | icy R | oute | \dashv |
| Patient Identifier 2. Age at Time of Event or 3. Sex 4 | . Weight | #1 | | Three | | aken by mouth | \neg |
| 9 Months Female | 18 _{lb} | #2 | | Cally | | | <u> </u> |
| In confidence (b) (6) | r kg | "2 | | | | | |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERR | OR | 3. Dates of Use (/ | f unknown, | give duration) | | 5. Event Abated After Use | |
| Check all that apply: | | (or best estimated #1 4 months | re) | | | Stopped or Dose Reduced #1 Yes No Do | l? pesn't |
| 1. ✓ Adverse Event Product Problem (e.g., defects/malfunction Product Use Error Problem with Different Manufacturer of S | 1 | #2 | | | | Ap | pply |
| 2. Outcomes Attributed to Adverse Event | | 4. Diagnosis or R | eason for | Use (Indication | n) | | pesn't |
| (Check all that apply) | | #1 | | | | 8. Event Reappeared After Reintroduction? | · |
| Death: | · | #2 | | | | #1 Yes No Do | pesn't |
| ☐ Life-threatening ☐ Congenital Anomaly/Birth ☐ ☐ Hospitalization - initial or prolonged ☑ Other Serious (Important M | | 6. Lot# | Т | 7. Expiration | Date | #2 Tyes TNo Do | pesn't |
| Required Intervention to Prevent Permanent Impairment/Damage (I | | #1 | | #1 | | 9. NDC # or Unique ID | ply |
| Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) | | #2 | | #2 | | , | |
| 12/25/2006 07/31/2014 | | E. SUSPECT | MEDIC | AL DEVICE | | | |
| 5. Describe Event, Problem or Product Use Error When my son, (b) (6) (BD(b) (6)) was a | an l | 1. Brand Name | | | | | |
| infant, we used Orajel and found that it didn' | 't work | | | | | | |
| quite well. I started using Hylands Teething 1 which seemed to help his teething pains. On (b) | | 2. Common Device | e Name | | | CTU | |
| (b)(6) he started experiencing seizures. He several different seizure medications, prescri | | | | | | | |
| several different doctors. He has undergone Mi | | 3. Manufacturer N | lame, City | and State | | AUG - 1 2014 | l l |
| EKG and other medical testing. There is no neurological abnormalities. Doctors diagnosed | his with | | | | | | |
| Generalized Epilipsey with Feberile Seizures. Febrile seizures, 13 Epiliptic Seizures.) | (19 | 4. Model # | | Lot# | | 5. Operator of Dev | vice |
| | | | | | | Health Professi | ional |
| | | Catalog # | | Expiration | Date (mm/c | dd/yyyy) 🔲 Lay User/Patier | nt |
| | | | | | | Other: | |
| 6. Relevant Tests/Laboratory Data, Including Dates | | Serial # | | Other# | | | |
| MRI- 2013 EEG | | | | 1 | | | |
| | | 6. If Implanted, G | ive Date (n | nm/dd/yyyy) | 7. If Expla | anted, Give Date (mm/dd/yy | yy) |
| | | 8. Is this a Single | use Devic | e that was Re | nrocessed | and Reused on a Patient? | ,— |
| | | Yes No |) | | | | |
| | | 9. If Yes to Item No | o. 8, Enter N | lame and Addr | ess of Repr | ocessor | |
| 7. Other Relevant History, Including Preexisting Medical Conditions allergies, race, pregnancy, smoking and alcohol use, liver/kidney problem. | | | | | | | |
| Race: White | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | F. OTHER (C | ONCOM | ITANT) ME | DICAL P | RODUCTS | |
| For additional information see B7 below. | | Product names a | | | | | |
| | | | | | | | |
| | | | | | | 10.0 | |
| | | G. REPORTER | R (See co | onfidentiali | ty section | n on back) | |
| C. PRODUCT AVAILABILITY | | 1. Name and Add (b) (6) | ress | | | DS | <u>ख</u> |
| Product Available for Evaluation? (Do not send product to FDA) | | | | | | UG 0 | - W |
| Yes No Returned to Manufacturer on: | 10000 | | | | | UG 0 | 1 20 |
| D. SUSPECT PRODUCT(S) (mm/dd/ | 7777/ | | | | | | |
| 1. Name, Strength, Manufacturer (from product label) | | Phone # (b) (6) | | | E-mail (b) (6) | | |
| #1 Name: teething tablets Strength: Hylands Teething Tablets | | | | | | | |
| Manufacturer: | | 2. Health Professi | | Occupation | | 4. Also Reported to: | \neg |
| #2 Name: | | Yes No | | | | Manufacturer | |
| Strength: Manufacturer: | | If you do NOT w to the manufacti | - | - | _ | User Facility Distributor/Impo | orter |

PLEASE TYPE OR USE BLACK INK

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

... 2007, 2013 EKG- 2009, 2011, 2014

Individual Case Safety Report

10359541-01-00-02

DSS AUG 0 1 2014

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions: Seizures

Allergies: Omnicef, Fat protein in whole milk.

Important Information:

RX Meds: Keppra 150mg Adderol 15mg Clonodine .1mg

Individual Case Safety Report



10359541-01-00-03

FORM FDA 3500A (2/13) A. PATIENT INFORMATION

10384035-01-00-01

BEING DIAGNOSED WITH CROHN'S DISEASE. CUSTOMER'S SISTER HAD A SEIZURE AT THE AGE OF 3 AS A RESULT OF AN ILLNESS THAT STARTS WITH THE LETTER R.

CHILD'S GRANDMOTHER HAD SEIZURES 40 YEARS AGO PRIOR TO

 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) HISTORY OF EAR INFECTIONS AND HAS TUBES PLACED IN THE

EARS.

(Continue on page 3)

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

CaseID: 10384035

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statem ent on reverse.

distributors and manufactur

54973 UF/Importer Report #

Page 1 of 5

Ibs or

kgs

4. Weight

3. Sex

or use by user-facilities,

MANDATORY reporting

| T | | | | | | FDA Use O |
|--|-------------|----------------------|--------------|--------------|----------------------|---------------------------|
| C. SUSPECT P | | | | | | - BA USE U |
| Name (Give labeled #1 HYLAND'S B | | | ABLETS | | | |
| #2 | | | | | | Manager to the same spice |
| 2. Dose, Frequency | & Route U | sed | 3. Thera | py Dates (| lf unknown, g | rive duratio |
| #1 UNKNOWN DOS | | | | (or best e | | |
| #2 | | | #2 | | | |
| 4. Diagnosis for Use | (Indication | 1) | #2 | 5. Event | Abated Afte | r Use |
| #1 TEMP RELIE | F TEETH | HING PAIN | | | ed or Dose F | Reduced? |
| #2 | | | | #1 L Y | es ✓ No | LJ Appl |
| 6. Lot # | 7. 8 | xp. Date | | #2 🗌 Y | es No | Doe: |
| #1 | #1 | | | | Reappeared oduction? | After |
| #2 | #2 | | | #1 ✓ Y | | Doe: |
| 9. NDC# or Unique ID | | | | #2 🗆 Y | es \square No | Does |
| 54973-3127-1 | | ucts and The | rany Dator | | | Appl Appl |
| | | | | (C | ontinue or | r page 3) |
| D. SUSPECT MI | EDICAL | DEVICE | | (0 | orkinge or | page 3) |
| 1. Brand Name | | | | | | |
| 2. Common Device N | lame | | | 2b. P | rocode | |
| 3. Manufacturer Nam | e, City an | d State | | | | |
| | | | | | | |
| 4. Model# | | Lot# | | | 5. Operator | of Device |
| Catalog # | | Expiration | Date /mm/ | (dd/sana) | Health | Profession |
| Catalog # | | Expiration | Date (IIIII) | da yyyy) | Lay Us | er/Patient |
| Serial # | | Unique Ide | ntifier (UD | l) # | Other: | |
| 6. If Implanted, Give | Date (mm/ | dd/yyyy) | 7. If Expl | anted, Giv | e Date (mm/ | dd/yyyy) |
| 3. Is this a Single-use | Dovice t | not was Ban- | | nd Davis | d an a Dation | -10 |
| Yes No | | nat was Repr | ocessed a | na Reuse | on a ratier | itr |
| If Yes to Item No. 8 | , Enter Na | me and Add | ress of Re | processor | D | SS |
| | | | | | ALIC | 1 0 20 |
| | | | | | AUU , | 1 3 20 |
| 0. Device Available | - | | | | | |
| Yes No | <u></u> П | Returned to M | anufacture | on: | (mm/dd/yy | <i>'YY</i>) |
| 1. Concomitant Med | ical Produ | icts and Ther | apy Dates | (Exclude | treatment of | event) |
| | | | | | | |
| E INITIAL DED | DTED | Mark Carrier Service | | (C | ontinue on | page 3) |
| E. INITIAL REPO | | | | | | |
| b) (6) | | | | | | |
| b) (6) USA | 8 | 100 | | | | |
| | | | | A | UG 12 | 201h |
| Phone # b) (6) | | | Address | | | -017 |
| | 12 2 2 | (b) (6) | | 14 + | itial D | an Ala - C |
| Health Professiona Yes No | 17 3. Oct | cupation | | 4. Ir | eport to FD | A |
| | 1.41 | | | 1 1 | Yes N | 40 L/IIInl |

10384035-01-00-02

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

No

Yes

No

Name

Address

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

07/23/2014

30-day

✓ Initial

✓ 15-day Follow-up # 9. Manufacturer Report Number

54973 AE # 1554

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

7. Type of Report

5-day

7-day

10-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

Initial Follow-up # 10. Event Problem Codes (Refer to coding manual)

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Facility

Other:

Outpatient Treatment

Home

Date of This Report (mm/dd/yyyy)

Outpatient

(Specify)

2. Phone Number

310-768-0700

3. Report Source

Foreign

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

Study

(Check all that apply)

Health Professional

Diagnostic Facility

Ambulatory Surgical Facility

Page 2 c

| | | FDA USE ONLY |
|-------------------------------------|------------------------|---|
| of 5 | | |
| | | |
| H. DEVICE MANUFAC | | |
| Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death Serious Injury | | Correction Additional Information |
| Malfunction | | |
| Manufaction | | Response to FDA Request Device Evaluation |
| | | |
| Device Evaluated by Manu | | Device Manufacture Date (mm/yyyy) |
| Not Returned to Manu | | , |
| | Summary Attached | |
| No (Attach page to ex provide code: | oplain why not) or | 5. Labeled for Single Use? |
| E | | Yes No |
| 6. Event Problem and Evalua | tion Codes (Refer to c | odina manual) |
| Patient | mon odda (noor to to | ourig manuary |
| Code | | |
| Device Code | - | - |
| | | |
| Method | |]- |
| Results | _ | |
| | | |
| Conclusions | |]- |
| 7. If Remedial Action Initiated | d, Check Type 8. | Usage of Device |
| Recall No | otification | Initial Use of Device |
| | spection | Reuse |
| | atient Monitoring | Unknown |
| | fiustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | ljustment | removal reporting number: |
| | | |
| | | |
| 10. Additional Manufactu | rer Narrative an | d / or 11. Corrected Data |
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| | | AUG 12 2014 |

CaseID: 10384035

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA # PMA/

510(k)#

Product

Pre-1938

Combination

OTC Product Yes

8. Adverse Event Term(s) SEIZURES

Yes

Yes

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.



| | COM | IPLAINT RECORD | Hyland's |
|---|---|--|--|
| | | | |
| 1038 | 4035-01-00-03 | COMPLAINT #: | 2564 |
| | | DATE OF COMPLAINT: | 07/23/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTET |
| SIZE: | UNKNOWN | LOT NO.: | THREW AWAY BOTTLE |
| REPORTER: (b) (6) |) | | A. A. A. C. C. C. C. C. C. C. C. C. C. C. C. C. |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE: (b) (6) | · · |
| COUNTRY: US | 5A | ZIP CODE: | |
| PHONE #: (b) (| | | |
| E-MAIL; | | | |
| BECAUSE HE WAS TEET INFECTIONS. IN SEPTEM. CONTINUED TO HAVE SI ON HIM AS MUCH PRIOF JUNEBUT EACH TIME THROW AWAY THE BOT MEANS BUT I WILL CON HAPPY NOT SEEING ME AGO PRIOR TO BEING DIA | - 9 MONTHS OLD. I CONTINUED TO GIVE HIM TEET HING, WELL HE WAS HAD ABOUT 4 SEIZURES IN TIMBER WE GOT TUBES IN HIS EARS AFTER HE GOT: EIZURES. WELL HE STARTED HAVING SEIZURES AR TO THAT CUZ HE REALLY WASN'T TEETHING MUCH I REMEMBER GIVING HIM TEETHING TABLETS WITTLESAND WE ARE A MONTH AND HALF FREE OF TINUE TO WORK ON THIS TRIALIF HE HAS ANOTHDICAL BILLS FOR EVERYTIME WE WERE GOING FOR GNOSED WITH CROHN'S DISEASE. CHILD'S AUNT HAD WED HIPPOCAMPAL MALFORMATION; EEG NORMAL. | D ABOUT MY CHILDMY CHILD HAS BE HING TABLETS DURING HIS TEETHING HAT MONTH. THEY KEPT SAYING IT WAS BEEN AND I KNOW I HADN'T BENDED UP HAVING TWO HIN 24 HOURS PRIOR TO. SO I DECIDE SEIZURESAND HE IS NOW 2 YEARS OF THE SEIZURE THEN I WILL CRASH MY TREE SEIZURE AT THE AGE OF 3 AS A RESULTANT WAS AS A SEIZURE AT THE AGE OF 3 AS A RESULTANT WAS AS AS A RESULTANT WAS AS AS A RESULTANT WAS AS AS A RESULTANT WAS AS AS A RESULTANT WAS AS AS A RESULTANT WAS AS AS AS A RESULTANT WAS AS AS AS AS AS AS AS AS AS AS AS AS A | EN SUFFERING FROM FEBRILE ESP DURING THE MONTH OF JULY AS HIS EARS AND EAR LAST ALMOST AN HOUR. HE STILL EEN PUSHING TEETHING TABLETS MORE SEIZURES IN MAY AND D TO DO A TRIAL AND ERROR AND DLD. I'M NOT SUING YOU IN ANY HEORY BUT RIGHT NOWI AM "HER HAD SEIZURES 40 YEARS T OF AN ILLNESS THAT STARTED |
| | FOR ADDITIONAL SPACE PLEASE USE RE | EVERSE OR ATTACH A SEPARATE SHE | ET |
| PRODUCT RECEIVED FO | OR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR I | (CIRCLE ONE) |
| | | | |
| | | UPS CALL | rag issued: (CIRCLE ONE) |
| | | DATE PRODUC | RECEIVED: |
| SECTION II: | INVESTIGATION | 5.112.110200 | |
| | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPOR | RT. | |
| | | | |
| | | | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST / NURSE FOR EVALUATION | N ON: 07/23/14 | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST / NURSE FOR EVALUATION | N BY: EDYTA FF | ACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| | | | |
| | | | |
| CORRECTIVE ACTION(S) | COMPLETED BY: | DATE: | |
| | | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: _ | 1554 DSC |

ADVERSE EVENT SERIOUS:

(Y)/ N 07/23/14

EDYTA FRACKIEWICZ

AUG 1 3 2014

SECTION V:

AUG 12 2014

REVIEWED BY MANAGEMENT BY:

ADVERSE EVENT REPORTED ON:

08-01-14

BY:

10384035-01-00-04



Serious Adverse Event SAE-0031-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-nine Adverse Events (AE) which also included twenty Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(b)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

DSS AUG 1 3 2014

CaseID: 10384035

AUG 12 2014



DISTRIBUTION: FDA

ADVERSE EVENT FILE

CaseID: 10384035

VERSE EVENT DATA FORM

| AE #: | 1554 | COMPLAINT #: 2564 | |
|---|---|---|---------------------|
| SECTION I | <u>.</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) | (6) | |
| ADDRESS: | | | _ |
| CITY: | - | STATE: | |
| COUNTRY: | | JSA ZIP CODE: | |
| PHONE #: | | | |
| E-MAIL: | (b |) (6) | |
| SECTION II | <u>l:</u> | PACKAGING INFORMATION: | |
| | AFFIX | PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| entitleity that is come referred and entitlement Directions; final to trappe 4 terms pro- trict the decoder in a time grown to the chief wheth I solve make to commodate to a six mental and decoder of the trappe. For transport of CALLARS, IPTS, OHANCHAILES SCHIEF, 891 AND AND SCHIEF, 891 AND AND TO THE STORY AND SCHIEF, 891 AND AND SCHIEF, 891 AND AND TO THE SCHIEF AND THE SCHIEF | influences and makeful grantle feeler rechtle feel of gene feel 2 Michaeler onder dan 2 April gestern, long parker steller, long parker steller, and feeler de services as an feeler de services as an feeler de services as an feeler de services as an feeler de services as an feeler de services as an feeler de services as an feeler de services as services as as feeler de services as services as as services as as services as as services as as services as as services as as services as as services as as as services as as as as as as as as as as | Warrings Disease a war and one of the call as well as the control of the call as well as the control of the call as well as the control of the call as well as the control of the call as well as the call as well as the call as the call as well as the call as | |
| SECTION II | <u>l:</u> | CORRECTIVE ACTION: | |
| | | | |
| CORRECTIV | VE ACTIC | N(S) COMPLETED BY: DATE: | DSS AUG 1 3 2014 |
| SECTION IV | <u>/:</u> | AR DRAMA | · · |
| REVIEWED | BY MANA | AGEMENT BY: DATE: 08-01-14 | |
| BY: | | QA/QC DIRECTOR DATE: 07-31-14 | |

AUG 12 2014



CDEK

HUMAN SERVICES nistration

OTC Reporting Form Approved: OMB No. 0910-0291 Expiration Date: 6/30/2015 (See PRA Statement on preceding general information page

6 Case 10. 10387468 L

мерwатси consumer voluntary Reporting (FORM FDA 3500B)

| What kind of problem was it? (Check all that apply) | Did any of the following happen? (Check all that apply) |
|--|---|
| What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker 5 - 8 - 14 Date the problem occurred (mm/dd/yyyy) | Did any of the following happen? (Check all that apply) Hospitalization - admitted or stayed longer Required help to prevent permanent barm (for medical devices only) Disability or health problem Birth defect Life-threatening Death (Include date): Other serious/important medical incident (Please describe below) |
| Tell us what happened and how it happened. (Include as many of the control of the | E Shahing. I had to up then she continue |
| Processiption or over the counter medicine I biologists such as transpercella and transpercella and tensors used for transpercella and transpercella and tensors) and game to nutrition products, and advictmine and medical formula formula and medical scape Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products Commodition products by products by products and products by product | |

For more information, visit http://www.fda.gov/MedWatch

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

| | | | CaseID: 19387468 |
|--|---|--|--|
| | | - About the Products | |
| 10387468-01-00-0 | 12 r pack | age (Include as many name | s as you see) |
| HURA BOX | u teekhin | a tabuts | |
| Name of the company that ma | | J | |
| Hulano | ۸ | | |
| Expiration date (mm/dd/yyyy) | Lot number | I | NDC number |
| | A 228 | 14 | |
| Strength (for example, 250 mg per 500 mL or 1 g) | Quantity (for example, 2 pills, 2 puffs, or 1 teaspoon, etc.) | Frequency (for example, twice daily or at bedtime) | How was it taken or used (for example, by mouth, by injection, or on the skin)? |
| Date the person first started ta | king | Why was the person using | g the product (such as, what condition was it |
| or using the product (mm/dd/y) | mi: 4/6/2014 | supposed to treat?) | |
| Date the person stopped taking using the product (mm/dd/yyy) | | y teethir | 79 |
| Did the problem stop after the person reduced the dose or straking or using the product? | opped Yes No | | |
| Did the problem return if the potential the product again? | erson started taking or using | | ict in case we need to evaluate it? (Do not Ne will contact you directly if we need it.) |
| ☐ Yes ☐ N | o Didn't restart | Yes | □ No |
| Go to Section D (| Skip Section C) | | Applicate to the constitution of the second of the constitution of |
| | | | |
| and the second s | Section C - / | bout the Medical Devic | · |
| Name of medical device | | | |
| Name of the company that ma | kes the medical device | | 4 |
| | <u> </u> | | |
| Other identifying information (| i ne model, catalog, lot, senal, (| or UDI number, and the expi | ration date, if you can locate them) |
| бажения быль настраблять не инболомен до ченовек, гоманос бака и под бака, положения и сек и сек и нажино ишто | | , of a Conference (Ann - Males (Mayeria) - Annes de Million (Mayeria) (Mayeria) (Mayeria) (Mayeria) (Mayeria) (Mayeria) - Mayeria | |
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| Was someone operating the | If yes, who was using it? | | |
| medical device when the problem occurred? | The person who had the | problem | |
| Yes | A health professional (s | uch as a doctor, nurse, or aid | de) |
| □ No | Someone else (Please | explain who) | |
| | | | |
| | | | DSS |
| For implanted medical devices Date the implant was put in (m | | • • • | s taken out (If relevant) (mm/a01/Gy) 4 2014 |
| Date the impant was put in (m | | . Date the miplant was | s taken out (ii relevant) (imitousyyty) 3.2014 |
| Go to Section D | | men Maria Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Sant Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Santa Sa | |
| For more information, visit h | ttp://www.fda.gov/MedWatch | • | oes not constitute an admission that medical educt caused or contributed to the event. |

| | and the second second | | | 5 (Ø8\$ & 10387468 |
|---|--|--|--|--|
| Person's Initials (b) (6) Sex Fen | nale occurred) or | the problem | Weight (Specify lbs or kg) | Race |
| Ma | | | 15 102 | white |
| dividual Case Safety Repo | rt 5/00d | pressure, canc | er, heart disease, or | others) |
| | | Professional Association (Association) (Asso | | |
| 10387468-01-00-03 | | . V _E . | PP 770-1-100 Million - 1 million median com communication of the P parameters of the P | high gala-age man compression data on this state of the s |
| Please list all allergies (such as to gru | rgs, foods, pollen, or of | thers). | | |
| List any other important information a | hout the nerson (such | as smoking on | grancy stacket use | |
| and any other important intermitation a | bodi tile person (such | as smoking, pre | griancy, arconoruse, | ●(C.) |
| List all current prescription medication | s and medical devices | being used. | | |
| | | | | |
| - Milliography in regard in the plants of the program of the program of the plants of | 1995 ANN ANY NO THE Milliodian is despited in my majority of the paper of the paper. | errer nord of the reason of the second point the restriction of the second tensor. | order (No. 400-00 general Artists and produces a size of stage, stately a stately against an analysis of stage | Contribute |
| List all over-the-counter medications a | | 1 | ts, and herbal remed | |
| tylon | al bo | by | | |
| Go to Section E | aligner was traden from est | er bester en en en en en en en en en en en en en | arent en hararen 1940. | en terr i "i soo in properti direkti. I |
| | | | | |
| We will contact you only if we need ad | Section 5 - About t | | | 등 하는 살았다면서 그렇게 하면 소리가 들을 내면 하지 않는 하지만 하는 하는 것 같다. 그리고 있는 것 같습니다. 그렇게 되었다면 하는 것 같습니다. |
| Last name (b) (6) | CHOTHER PROPERTY. TO | | it name | рионс. |
| | | (t |) (6) | |
| Number/Street | | City an | d State/Province | |
| | | | | |
| Country A | | ZIP or 1 (b) (6) | Postal code | |
| Telephone number | Email address | | | Todo la data (m. 1111 |
| b) (6) | Ciriali addiesi | • | | Today's date (mm/dd/yyy) |
| Did you report this problem to the com | pany that makes the p | roduct May we | give your name and | contact information to the company |
| (the manufacturer)? | , , | that ma | kes the product (mar | nufacturer) to help them evaluate the |
| ☐ Yes ☐ No | | product | Yes No | |
| | | | | |
| Coon the product in case the EDA | | Report by M | | |
| Geep the product in case the FDA wanted | ants to contact you re | r more informa | ition. Please do not | send products to the FDA. |
| Mail: | Fax: | | 7 | D00 |
| MedWatch | 1-800-332 | -0178 (toll-free) | | DSS AUG 1 4 2014 |
| Food and Drug Administrati 5600 Fishers Lane | ion | | | AUG 1 4 2014 |
| Rockville, MD 20857 | | | | |
| | Thank was for both | | 464 | |
| | Thank you for helpi | | | |
| For more information, visit http://www | v.fda.gov/MedWatch | | | constitute an admission that medical |



d how it happened. (Include as many details as possible)

no shake and sweam for about Ms minutes she had no strength to stand for sit up and thats not normal for her. I called the or, he was very conserned

CONTINUED ENTRY FOR: List any relevant tests or laboratory data if you know them. (Include dates)

CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.

CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.

USS AUG 1 4 2014





2297630) Printed [17244] at (b) (6)

6:26 AM Caspalle:110887468

Emergency Department

Emergency Department Visit Summary

This discharge plan has been designed to give you information that you will need to care for yourself after you leave the hospital. PLEASE TAKE THIS FORM TO YOUR FOLLOW-UP APPOINTMENT WITH YOUR DOCTOR.

| Name (MRN) Sex Age DOB Were seen by Different MD Genomes this visit Your diagnosis was EPISODE OF SHAKING Pergies as of the medications listed below. DC NOT use any other medicates the checking with your doctor. Contact your doctor to confirm your heredications. All Patients: An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to include medications and supplements such as vitamins and herbs. | ept Info |
|---|---------------------------------------|
| gnoses this visit Your diagnosis was EPISODE OF SHAKING ergies as of (b) (6) No Known Allergies (drug, envir, food or latex) ake only the medications listed below. DC NOT use any other medicates the cking with your doctor. Contact your doctor to confirm your heledications. Indication List Notice You have not been prescribed any medications. All Patients: An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to include | |
| gnoses this visit Your diagnosis was EPISODE OF SHAKING ergies as of (5) (6) No Known Allergies (drug, envir, food or latex) ake only the medications listed below. DC NOT use any other medicatest checking with your doctor. Contact your doctor to confirm your headications. edication List Notice You have not been prescribed any medications. All Patients: An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to include | |
| Your diagnosis was EPISODE OF SHAKING Projes as of (b) (c) No Known Allergies (drug, envir, food or latex) Ake only the medications listed below. DC NOT use any other medical rest checking with your doctor. Contact your doctor to confirm your he dications. All Patients: An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to include | |
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| No Known Allergies (drug, envir, food or latex) ake only the medications listed below. DC NOT use any other medical rest checking with your doctor. Contact your doctor to confirm your housedications. dication List Notice You have not been prescribed any medications. All Patients: An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to include | |
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| You have not been prescribed any medications. All Patients: An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to include | 710 01 |
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| An up-to-date medication list is very important to your safe care. Bring your list to all heal Carry it with you at all times in case of emergency. Update your list whenever you start a change the dose of a current medication, or stop a prior medication. Remember to includ | |
| change the dose of a current medication, or stop a prior medication. Remember to includ | hcare appointments. |
| medications and supplements such as vitamins and herbs. | |
| | new medication, |
| | new medication, |
| Disposition | new medication, e over-the-counter |
| Discharge | new medication, e over-the-counter |
| mmary of Tests and Procedures | new medication, |

Return to the Emergency Department or notify your primary care physician for symptoms that persist or worsen.

Please return to the Emergency Department for any concerns if your primary care physician cannot be

| | Case Salety Report | |
|---|---|--|
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Date:_____

AUG 1 4 2014

560131

| | referral number at of (a) |
|-------------------------|--|
| Laboratory Tests Pendin | g Results |
| Order | Current Status |
| Blood culture (PEDS O | NLY) In process |
| Follow-up Information | |
| Follow up with (b) (6) | Division of Child Neurology. (New onset seizure clinic) |
| Contact information: | |
| (b) (6) | |
| Discharge Instructions | |
| Give her prune or pea | ar juice if she doesn't have a bowel movement. |
| Call the new onset se | eizure clinic above for an appointment for further evaluation. |

Patient/Parent-Guardian Signature:

| (1 | (b) (b) | | |
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| | CaseID. 10390439 |
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| \bigcap | Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse |
| se by user-facilities, | Mf Report # 54973 |
| IDATORY reporting | UF/Importer Report # |
| age 1 of 1/6 | FDA Use Only |
| C. SUSPECT PRODU | CT(S) |

| 10390499:02-00-01 | | | <u> </u> | | |
|--|-------------------------------|--------------------------------|--|----------------------|--|
| UKWI FDA 3000A (2/13) | age 1- | of 1/2 b | | | FDA Use On |
| A. PATIENT INFORMATION | | C. SUSPECT PR | ODUCT(S) | | |
| Patient Identifier 2. Age at Time 3 (6) of Event: | 3. Sex 4. Weight | 1 ' | strength & mfr/labeler) | | |
| or33 Years | Female lbs | #1 HYLAND'S BA | ABY TEETHING TA | ABLETS | |
| Date | Male or | #2 | | | |
| In confidence of Birth: 3. ADVERSE EVENT OR PRODUCT PROBLEM | kgs | 2. Dose, Frequency 8 | Route Used | | (If unknown, give duration) |
| _ | | #13 TABLETS C | NCE ORALLY | from/to (or best e | istimate) |
| Adverse Event and/or Product Problem (e.g | ., defects/malfunctions) | #2 | | | |
| Outcomes Attributed to Adverse Event (Check all that apply) | | #2 4. Diagnosis for Use | (Indication) | #2 | Abated After Use |
| Death: Disability or I | Permanent Damage | 1 | TEETHING PAIN | Stopp | ed or Dose Reduced? |
| (mm/dd/yyyy) Congenital A | Anomaly/Birth Defect | ,,, | 1001111110 17111 | | res ☑ No ☐ Doesn Apply |
| Hospitalization - initial or prolonged Other Seriou | s (Important Medical Events) | #2 | | #2 [] Y | res No Doesn |
| Required Intervention to Prevent Permanent Impairment/E | Damage (Devices) | 6. Lot # | 7. Exp. Date | | — Дергу |
| Date of Event (mm/dd/yyyy) 4. Date of This R | leport (mm/dd/yyyy) | #1A22114 | #1 | | Reappeared After oduction? |
| 07/28/2014 0 | 8/01/2014 | #2 | #2 | #1 🔲 Y | res No Doesn |
| Describe Event or Problem OMAN HAD SEVER PAIN FROM A DENTAL EXTRA | ACTION AND 5 DAYS | 9. NDC# or Unique ID | | #2 🗆 Y | /os Doesn |
| ATER RETURNED TO THE DENTIST WHO RECOM | | 54973-3127-1 | | | — — Дрріу |
| ABLETS ALONG WITH PAIN MEDICATION (HYDR | · • | l . | ical Products and The TIN, COMPAZINE, | 1. | treatment of event) NE, CIMETIDINE. |
| CETAMINOPHEN, QUALITEST NORCO; ALEVE, 1 LTERNATELY). AFTER TAKING 3 TEETHING ? | | | | | ATE. ALSO TAKEN |
| HAKY" WITH HER "HEART BEATING TOO FAST" | | | RCOAL TABLETS. CO, ALEVE, NEPR | | ACETAMINOPHEN, |
| OMETHING WAS WRONG, LIKE AN ALLERGY". | | QUALITEST NOKO | O, ALEVE, NEFR | | Continue on page 3) |
| EELING NAUSEA, NUMBNESS AND TINGLING IN ANDS. WHILE WATCHING TV SHE CLOSED HE | I | D. SUSPECT ME | DICAL DEVICE | , | y page 57 |
| COORDING TO HER BOYFRIEND WAS SHAKING. | HE CALLED HER | 1. Brand Name | , | | |
| AME AND SHE WAS NOT AWARE OF WHAT WAS (HOUGH SHE HAD A "BLACKOUT" FOR A FEW SI | 1 | 2. Common Device N | ame | 2b. P | Procode |
| HOUGHT IT WAS AN ALLERGIC REACTION AND | | | | | |
| ARE WHERE THEY DID A CT SCAN, MRI, EKG. ESCRIBED HER PAIN AS 10 / 10. URGENT (| | 3. Manufacturer Name | a, City and State | | |
| YMPTOMS AS "MINOR SEIZURE" AND SENT HER | | | | | |
| | FEW MONTHS SHE | 4. Model# | Lot# | | 5. Operator of Device |
| AS USED HYLAND'S BLADDER IRRITATION, EA AGINITIS WITH NO ADVERSE SYMPTOMS. SH | ARACHE DROPS, AND | Catalog # | Expiration | Date (mm/dd/yyyy) | Health Professiona |
| MERGENCY 3 TIMES BECAUSE OF PAIN, ONCE | 1 | · · | Expiration | Date (millowyyy) | Lay User/Patient |
| SEIZURE", AND TWICE SINCE DUE TO EXTREM | ME DENTAL PAIN. | Serial # | Unique Ide | entifier (UDI) # | Other: |
| | l | 6. If Implanted, Give I | Pate (mm/dd/vanar) | 7 If Evployted Gir | ve Date (mm/dd/yyyy) |
| The state of the s | (Co nt inue on page 3) | o. Il impianted, Give t | rate (mileodryyyy) | 7. II Explanted, GIV | e Date (minudaryyyy) |
| Relevant Tests/Laboratory Data, Including Dates Deficial BECAMSE, OF NUS PAIN FROM EXTRE | CTED TOOTH (#11) | 8. Is this a Single-use | | ocessed and Reuse | d on a Patient? |
| Received vain from extra | ,0125 100111 (#11) | Yes No | Enter Name and Add | lana of Danis | |
| KG BECAUSE OF HIGH HEART RATE. FLUIDS WERE OFF DUE TO NAPOR IN OU | A | 19. II Tes to item No. 6 | , Enter Name and Add | ress or Reprocessor | |
| FLUIDS WERE OFF DUE TRECEIVED | . | | | | |
| | | | | | DSS |
| COR SEP 03 2014 | | 10. Device Available f | or Evaluation? (Do not | t send to FDA) | _ |
| CDR SET Y | . | Yes No | Returned to M | fanufacturer on: | SEP 0 5 |
| ADB (| Continue on page 3) | 11. Concomitant Medi | ical Products and Ther | rapy Dates (Exclude | treatment of event) |
| Other Relevant History, Including Preexisting Medical Condrace, pregnancy, smoking and alcohol use, hepatic/renal dysfun | | | | | |
| race, pregnancy, smoking and alcohol use, hebatic/renal dysfun STORY OF VERTIGO 5 YEARS AGO AND DIZZI | | | | <i>(</i> | 'ontinue on no 2' |
| IZURE. NO FAMILY HISTORY OF SEIZURES. | ASTHMA | E. INITIAL REPO | RTER | () | continue on page 3) |
| NTROLLED SINCE CHILDHOOD, INHALER FOR APPLYLACTIC ALLERGIES SYMPTOMS THAT | | 1. Name and Address (b) (6) | | | |
| ICLULDE: COUGH UNCONTROLLED, HIVES IN | • | (b) (b) | | SED V | 1 2041 |
| OSED THROAT, CAN'T BREATHE, USES ADORE | X OR BENADRYL, | | | SEP 04 | k 2014 |
| PIPEN. PRE-EXISTING CONDITIONS: FIBRO | · . | | | | • . |
| USEA, ESOPHAGITIS, GUTD, VULVODYNIA, I | DO MILL DINKKHEN | | | | 3/ |
| 4 | Continue on page 3) | (B) (6) ** | Ema (b) (6 | iii Address) | 4 |
| bmission of a report does not constitute an admi | | 2. Health Professional | 17 3. Occupation | 14. 1 | nitial Reporter Also Sent |
| sonnel, user facility, importer, distributor, manu- | | Yes No | NA | - | Report to FDA |
| used or contributed to the event. | | | 1 | | Yes No V Unk. |

FDA USE ONLY e 2 of 12 10390459-02-00-02 H. DEVICE MANUFACTURERS ONLY 1. Check One 2. UF/Importer Report Number 1. Type of Reportable Event 2. If Follow-up, What Type? User Facility Importer Death Correction 3. User Facility or Importer Name/Address Serious Injury Additional Information Malfunction Response to FDA Request Device Evaluation 4. Device Manufacture Date 3. Device Evaluated by Manufacturer? (mm/yyyy) Not Returned to Manufacturer 4. Contact Person Yes Evaluation Summary Attached Phone Number 5. Labeled for Single Use? No (Attach page to explain why not) or provide code: 6. Date User Facility or 7. Type of Report 8. Date of This Report Yes No Importer Became Aware of Event (mm/dd/yyyy) (mm/dd/yyyy) Initial 6. Event Problem and Evaluation Codes (Refer to coding manual) Follow-up # Patient Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) Code Patient Device Code Device Method Code 11. Report Sent to FDA? 12. Location Where Event Occurred Results Hospital Outpatient
Diagnostic Facility Yes (mm/dd/yyyy) Home Conclusions ∏ No Ambulatory Nursing Home Surgical Facility 13. Report Sent to Manufacturer? 7. If Remedial Action Initiated, Check Type 8. Usage of Device Outpatient Treatment Initial Use of Device Yes Facility Recall Notification (mm/dd/yyyy) No Reuse Other: Repair Inspection (Specify) Unknown Replace Patient Monitoring 14. Manufacturer Name/Address If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: Modification/ Relabeling Adjustment Other: 10. Additional Manufacturer Narrative and / or 11. Corrected Data G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number 310-768-0700 EDYTA FRACKIEWICZ Report Source (Check all that apply) Address Foreign HYLAND'S, INC. Study 154 W. 131ST STREET LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 07/30/2014 Distributor IND# 6. If IND, Give Protocol # Other: BLA# SEP 0 5 2014 PMA/ 7. Type of Report 510(k)# (Check all that apply) Combination Product 5-day 30-day Yes 7-day Periodic Yes Pre-1938 Initial OTC Product Yes SEP 04 2014 9. Manufacturer Report Number 8. Adverse Event Term(s) SEIZURES 54973 AE # 1555

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Individual Case Safety Report

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.

CaseID: 10390459

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10390459-02-00-03

FORm 1 DA 00000 (20 10) (00000000000000)

ATION PAGE)
user-facilities,
ors, and manufacturers
FORY reporting
e 3 of 12

| B.5 | 5. Describe Event or Problem (continued) |
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| B6 | Relevant Tests/Laboratory Data, Including Dates (continued) |
| 5.0 | Relevant Tests/Laboratory Data, Including Dates (continued) |
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| B.7 | Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) |
| PC | OS (POLYCYSTIC OVARIES), BIPOLAR. |
| l | |
| | LERGIES: "ALMOST EVERYTHING": BEE AND WASP STINGS, SHELLFISH, CHLORINE, FLUORIDE, DOMESTICONE |
| (S | ILICONE), MEDICATIONS: IBUPROFEN, SOMA, RANITIDINE, FERROUS SULPHATE, Q-VAR (INHALER), CAYENNE |
| НО | RSERADISH, SEASONAL TREES, POLLEN, MOLD, PETS. |
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| Cor | ncomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish) |
| PE: | RCOCET, DILAUDID, DEMEROL. |
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| l | DSS |
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| Oth | er Remarks |
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| | SEP 04 2014 |
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OMER COMPLAINT RECORD



| 10390459-02-0 | 0-04 | COMPLAINT #: | 2565 |
|---|--|--|---|
| | TOTH GOOLD | DATE OF COMPLAINT: | 07/30/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 |
| SIZE: | 135 TABLETS | LOT NO.: | A22114 |
| REPORTER: (b) (6) | | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: USA | | ZIP CODE: | |
| PHONE #: | | | |
| E-MAIL: | | | |
| FAST", "EDGY, LIKE SOMETI AND HANDS. WHILE WATCH WAS NOT AWARE OF WHAT REACTION AND WENT TO U IN HER SINUS AREA THAT O PAIN MEDICATIONS SINCE " AGO AND DIZZINESS BUT N SEIZURE" AND SENT HER TO IRRITATION, EARACHE DRO ONCE AFTER THE "SEIZURE | WHO RECOMMENDED TEETHING TABLET NEPROXEN ALTERNATELY). AFTER TAKING 3 TE HING WAS WRONG, LIKE AN ALLERGY". SHE EXPI HING TV SHE CLOSED HER EYES AND ACCORDIN WAS GOING ON AS THOUGH SHE HAD A "BLACKI RGENT CARE WHERE THEY DID A CT SCAN, MRI, ORRESPONDED TO THE AREA OF HER TOOTH E: THE EXTRACTION 5 DAYS PREVIOUSLY AND DESC EVER A SEIZURE. (NO FAMILY HISTORY OF SEIZU D EMERGENCY TO ATTEND TO THE DENTAL PAIN PS AND VAGINITIS WITH NO ADVERSE SYMPTOM ", AND TWICE SINCE DUE TO EXTREME DENTAL! ING THE PAIN" (OF THE TOOTH EXTRACTION). | EETHING TABLETS SHE TELT SHAN ERIENCED FEELING NAUSEA, NUMB G TO HER BOYFRIEND WAS SHAKIN OUT FOR A FEW SECONDS. SHE TH EKG. MRI WAS CLEAR. CT SCAN W XTRACTION. IT WAS "INCONCLUSIVI CRIBES HER PAIN AS 10/10. THERE URES). URGENT CARE ASSESSED H I. IN THE PAST FEW MONTHS SHE H IS. SHE HAS BEEN TO THE EMERGE | Y' WITH HER "HEART BEATING TOO NESS AND TINGLING IN HER NOSE G. HE CALLED HER NAME AND SHE HOUGHT IT WAS AN ALLERGIC 'AS FOR THE PAIN SHE WAS HAVING E''. SHE HAS BEEN ON DIFFERENT IS A HISTORY OF VERTIGO 5 YEARS HER SYMPTOMS AS "MINOR IAS USED HYLAND'S BLADDER NCY 3 TIMES BECAUSE OF PAIN, |
| - AMPAGAMAN | FOR ADDITIONAL SPACE PLEASE USE REV | EDSE OB ATTACH A SEGADATE SHI | |
| | TOTAL OF AGE TELAGE OGE NEW | ENSE ON ATTACH A SEPANATE SHE | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | (CIRCLE ONE) |
| | | | |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| | | DATE PRODUC | CT RECEIVED: |
| SECTION II: INV | ESTIGATION | | |
| INVESTIGATION . | N. SACE OF ATTACKED WATER TO A TO A TO A TO A TO A TO A TO A TO | | |
| INVESTIGATION: F | PLEASE SEE ATTACHED INVESTIGATION REPORT | | |
| | | | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION (| ON: 07/30/14 | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION E | BY: TUTTI GO | DULD |
| SECTION III: | CORRECTIVE ACTION: | | |
| MAILED REFUND CHECK # 5 | 11715 TOTALING \$ 7.00. | | |
| CORRECTIVE ACTION(S) CO | (b) (6) | DATE | 00/12/14 |
| 00111120111211011(0) 00 | | DATE: | 08/12/14 DSS |
| SECTION IV: ADV | ERSE EVENT REPORTS | AE #: | SEP 0 5 2014 |
| ADVERSE EVENT SERIOUS: | $\left(\begin{array}{c} \\ \\ \end{array}\right)_{l}$ N | | DEF U D ZU14 |
| ADVERSE EVENT REPORTED | | ≱ BY: TUTTI GOULD | |
| SECTION V: | \ | . 1 | 4 |
| REVIEWED BY MANAGEMEN | TBY: | DATE: | 08-21-14 SEP 04 2014 |
| BY: - | AMC Bring | DATE: _ | 08-21-14 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 10390459

Mailed on 08/12/14

ec 0534-2014

SAE-0032-2014

July 31, 2014

(b) (6)

Dear (b) (6)

Pursuant to your phone call regarding our Hyland's Baby Teething Tablets, we regret that you did not have a satisfactory experience with our product.

Pursuant to your request for a refund, we are issuing a check to you for your purchase price of \$7.00. We appreciate your keeping us informed of your experience with our medicines.

We appreciate every comment our customers take the time to communicate to us. We hope this experience will not deter you from pursuing homeopathic treatment in the future. Please contact us when we can be of continued service.

Sincerely,

Dan Krombach President

Enc: Refund Check - \$7.00

DSS SEP 0 5 2014

SEP 04 2014

OMPLAINT RECORD

| CaseID: 10390459 |
|---------------------|
| CaseID: 10390459 |
| Menson 12/1/2/18/11 |
| hilands |
| Hylands Oxfices |
| 2007 |

| 103904 | 59-02-00-07 | COMPLAINT #: | 2565 | 28 1170° |
|---|---|---|---|---------------------------------------|
| TAKEN BY: | TUTTI GOULD | DATE OF COMPLAINT: | 07/30/14 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 | - Color |
| SIZE: | 135 TABLETS | LOT NO.: | A22114 | 6929 |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | <u></u> | | | |
| | | | | |
| CITY: | | STATE: (b) (6) | | |
| COUNTRY: USA (b) (6 | | ZIP CODE: | | |
| PHONE #. | | | | MARK of this had different to the set |
| FAST, "EUGY, LIKE SOME AND HANDS. WHILE WAT! WAS NOT AWARE OF WHI REACTION AND WENT TO IN HER SINUS AREA THAT PAIN MEDICATIONS SINCE AGO AND DIZZINESS BUT SEIZURE" AND SENT HER IRRITATION, EARACHE DR ONCE AFTER THE "SEIZUR | WOMAN HAD SEVERE PAIN FROM A DENTAL WHO RECOMMENDED TEETHING TABLETS IN THE PROXEN ALTERNATELY). AFTER TAKING 3 TEET THING WAS WRONG, LIKE AN ALLERGY. SHE EXPER CHING TV SHE CLOSED HER EYES AND ACCORDING THAT WAS GOING ON AS THOUGH SHE HAD A "BLACKOU URGENT CARE WHERE THEY DID A CT SCAN, MRI, EKE CORRESPONDED TO THE AREA OF HER TOOTH EXTRET THE EXTRACTION 5 DAYS PREVIOUSLY AND DESCRIPTED TO THE DENTAL PAIN. IN COPE AS SEIZURE. (NO FAMILY HISTORY OF SEIZURE OF BEREGECY TO ATTEND TO THE DENTAL PAIN. IN COPS AND VAGINITIS WITH NO ADVERSE SYMPTOMS OF SEIZURE, AND TWICE SINCE DUE TO EXTREME DENTAL PAIN. HING THE PAIN" (OF THE TOOTH EXTRACTION). | ALONG WITH PAIN MEDICATION (HITHING TABLETS SHE "FELT SHAKY IENCED FEELING NAUSEA, NUMBHO O HER BOYFRIEND WAS SHAKING TFOR A FEW SECONDS. SHE THIG. MRI WAS CLEAR. CT SCAN WAS TACCTION. IT WAS TNCONCLUSIVE BES HER PAIN AS 10/10. THERE ISES.). URGENT CARE ASSESSED HEN THE PAST FEW MONTHS SHE HAS DEEN TO THE EMEDICATION. | IYOROCODONE ACETAMINOP "WITH HER "HEART BEATING SESS AND TINGLING IN HER N 5. HE CALLED HER NAME AND OUGHT IT WAS AN ALLERGIC AS FOR THE PAIN SHE WAS H ". SHE HAS BEEN ON DIFFER SA HISTORY OF VERTIGO 5 Y ER SYMPTOMS AS "MINOR SUSED HYLAND'S BLADDER NOW 3 TIMES BEAD DER NOW 3 TIMES BEAD DER | HEN. TOO JOSE D SHE AVING JENT |
| | FOR ADDITIONAL SPACE PLEASE USE REVERS | SE OR ATTACH A SERABATE SUE | F7 | |
| | | SE ON ATTAON A SEPARATE SHE | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y N P | RODUCT BEING RETURNED FOR I | NSPECTION: Y (CIRCLE OF | NET |
| | • | DATE REQUESTED PRODUCT BE | RETURNED: | |
| | | UPS CALL 1 | rag issued: | N NEY |
| | | DATE PRODUCT | RECEIVED: | |
| SECTION II: IN | VESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | | | | |
| ADVERSE EVENT FORWAR | DED TO PHARMACIST / NURSE FOR EVALUATION ON: | 07/30/14 | | |
| | DED TO PHARMACIST / NURSE FOR EVALUATION BY: | TUTTI GOL | (ID | |
| SECTION III: | CORRECTIVE ACTION: | 10111000 | | |
| | | | | |
| | | | | DSS |
| CORRECTIVE ACTION(S) CO | OMPLETED BY: | DATE: | | |
| SECTION IV: ADV | VERSE EVENT REPORTS | AE #: | 1555 | SEP 0 5 2014 |
| | | roe ff. | | · |
| ADVERSE EVENT SERIOUS: | | | | |
| ADVERSE EVENT REPORTE SECTION V: | 07/30/14 | BY: TUTTI GOULD | | |
| REVIEWED BY MANAGEMEN | VT BY: | DATE: (| 08-06-14 | |
| BY: | ON BOUN | DATE: | 08-06-14 08-06-14 | |

cc: QA / QC Packaging

Production Shipping / Receiving

SEP 04 2014

CaseID: 10390459



10390459-02-00-08



SAE-0032-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A22114, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A22114 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A22114. The Baby Teething bulk lot # 122944 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured two other complaints (CC-0332-2014 & CC-0456-2014) have been received for Hyland's Baby Teething Tablets lot # A22114. The complaints were reviewed and they do not appear to be related. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A22114.

Manufacture and processing occurred within established procedures to ensure product quality.

8/6/2014 Date

DSS SEP 0 5 2014





SE EVENT DATA FORM

| AE#: | 1555 | *************************************** | COMPLAINT #: 2565 | |
|--|-------------------------|--|--|--------------|
| SECTION | 11: | PATIENT INFORMATION (IF DIFFER | ENT FROM REPORTER ON FORM VD1) | |
| NAME: | | (b) (6) | | |
| ADDRESS | S: | _ | | |
| CITY: | | _ | (b) (6) STATE: | ···· |
| COUNTR | Y: | USA | ZIP CODE: | |
| PHONE # | : | (b) (6) | | , |
| E-MAIL: | | | | |
| SECTION | <u>II:</u> | PACKAGING INFORMATION: | | |
| | AFF | X PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| Interest of design probability (see to a serioral period of the Bergardians of the trapped of the trapped of the trapped of the serioral period of serioral period serioral br>serioral period serioral period serioral period serioral per | A A LIVE TO STATE OF AS | Moreonative Teething Tablets Below to the foundation of the founda | Toothard Tablets Sealing to the sea | |
| SECTION | <u> 111:</u> | CORRECTIVE ACTION: | | |
| | | | | Dss |
| | | | | SEP 0 5 2014 |
| CORRECT | IVE ACT | ION(S) COMPLETED BY: | DATE: | JEP U 9 2014 |
| SECTION I | <u>IV:</u> | 0.1 | 11 | 100 X |
| REVIEWE | D BY MA | NAGEMENT BY: | DATE: 08-06-14 | SEP (14 90%) |
| BY: | | Eur Bam | DATE: 08-06-14 | |
| | | QA / QC DIRECTOR | | |

CaseID: 10395246

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse,

Y reporting of

| e errors | Triage unit sequence # | 661168 |
|--|-------------------------|---|
| of 3 7 | | |
| 2. Dose or Amount | Frequency | Route |
| #1 | | |
| #2 | | |
| #2 | | · II |
| 3. Dates of Use (If unknow | m sive duration) from | 5. Event Abated After Use |
| (or best estimate) | | Stopped or Dose Reduced? |
| #1 7/16/20 | 214 | #1 Yes No Doesn't Apply |
| #2. | | #2 Yes No Doesn't |
| 4. Diagnosis or Reason fo | ,, | Apply |
| #1 perparent | - teetning | 8. Event Reappeared After Reintroduction? |
| #2 | | #1 Yes No Doesn't |
| 0.1-4# | T7.5-1-0-5-1 | #2 Yes No Doesn't |
| 6. Lot# #1 | 7. Expiration Date | Apply |
| #2 | | 9. NDC # or Unique ID |
| | #2 | |
| E. SUSPECT MEDIC 1. Brand Name | CAL DEVICE | |
| i. Drano Name | | |
| | | |
| 2. Common Device Name | | 2b. Procode |
| • | Ci | TU |
| 3. Manufacturer Name, Cit | ty and State | |
| | AUG 1 | 9.2014 |
| | | 9 5014 |
| 4. Model # | Lot# | 5. Operator of Device |
| | | Health Professional |
| · · · · · · · · · · · · · · · · · · · | | |
| Catalog # | Expiration Date (| mm/dd/yyyy) Lay User/Patient |
| | | Other: |
| Serial # | Unique Identifier | (UDI) # |
| | | . · · |
| 6. If Implanted, Give Date | (mm/dd/www) 7 If E | explanted, Give Date (mm/dd/yyyy) |
| | | implement, one bate (minutaly)))) |
| | ice that was Reproces | ssed and Reused on a Patie t3 S S |
| ∐ Yes ∐ No | | |
| 9. If Yes to Item No. 8, Enter | Name and Address of | Reprocessor AUG 1 9 2 |
| , | | |
| CTUER (CONCO | NTANT) MEDICA | |
| F. OTHER (CONCON Product names and therap | | |
| rioduci names and merap | y dates (exclude treati | ment of event) |
| | none | |
| | • • • | ŀ |
| G. REPORTER (See | confidentiality sec | tion on back) |
| 1. Name and (b) (6) | | July 10 and 10 |
| Name: | | |
| Address: | | |
| | | |
| City: | | |
| Phone # | E-mai | |
| (b) (6) | (b) (d | |
| | | |
| 2. Health Professional? 3. | Occupation | 4. Also Reported to: |

Adverse Event Reporting Program Page A. PATIENT INFORMATION 1. Patient Identifier | 2. Age at Time of Event or Date of Birth: (b) (6) Female 6 mon ms In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROF Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: ■ Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 4. Date of this Report (mm/dd/yyyy) 7/17/2014 5. Describe Event, Problem or Product Use Error amonth old male with hissiness which mother attributed to teethir Mother purchased oragel at local Family Dollar and "coated his whole mouth " at 1145 pm on 7/16/14 Mom awoke to feed child at 530 AM gan bothe, 30 min later child auske 6. Relevant tists/Laboratory Data, Including Dates and child make a know moth sand. 2 nows later, child again awakened + scenea & rak dithouth breating, Momer concerned 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) Prserve NKDA Born full term C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) ☐ No Returned to Manufacturer on: (mm/dd/yyyy) SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label)
#1 Name: Orasci Telming Pain Medicine
Stylength: Benzolaine 7.5% 3,5%
Manufacturer: Church + Dwight 3,5% #2 Name: Yes No Manufacturer Strength: 5. If you do NOT want your identity disclosed User Facility Manufacturer: to the manufacturer, place an "X" in this box: Distributor/Importer

TION PAGE) **ARY** reporting of d product problems

Adverse Event Reporting Program

rage 3 of 3

| B.5. Describe Event or Problem (continued) |
|--|
| note: |
| Per "htlp://wnw.fda.gov/Druss/Drus Sately/ |
| Vcm 402240, nm |
| [Milidocaine containing topical modications] |
| "Is NOT approved by FDA to treat techning pair but |
| B.6. Relevant Tests/Laboratory Data, Including Dates (continued) |
| tube form which mother got |
| tube from which mother got medication clearly states name of |
| med "Oraje! Teeting Pain Medicine" |
| |
| |
| B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) |

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

AUG 1 9 2014

use by user-facilities, listributors and manufacture ANDATORY reporting

| ers | Mfr Report # 54 97 3 UF/Importer Report # | |
|-----|---|--|
| | or milporter Neport # | |

| Page 1 of ⁶ | • | |
|------------------------|---|--|
|------------------------|---|--|

| 54973 | h | |
|---------------------|---|--|
| F/Importer Report # | | |
| | | |

| | | | | | | FDA USE Only |
|--|--|--|-------------------------------------|---------------------|---------------------------------------|---|
| A. PATIENT INF | | | C. SUSPECT PROI | . , | | |
| Patient Identifier b) (6) | of Event: | 3. Sex 4. Weight | 1. Name (Give labeled str | | | |
| | or | ib | H1 HYLAND'S BABY | / TEETHING TA | BLETS | |
| In confidence | Date of Birth: | Male kg | #2 HYLAND'S TEET | | <i>i</i> | |
| | VENT OR PRODUCT PRO | kg | 2. Dose, Frequency & Ro | oute Used | 3. Therapy Dates from/to (or bes | s (If unknown, give duration) st estimate) |
| | | | #1 3 TABLETS ONC | Œ | #1 | |
| Outcomes Attribute | ted to Adverse Event | blem (e.g., defects/malfunctions) | #2 3 TABLETS ONC | CE | #2 | |
| (Check all that apply | | | 4. Diagnosis for Use (Ind | | 5. Ever | ent Abated After Use |
| Death: | (mm/dd/yyyy) Disa | ability or Permanent Damage | #1 TEMP RELIEF T | EETHING PAIN | 1 | pped or Dose Reduced? |
| Life-threatening | g Con | ngenital Anomaly/Birth Defect | #2 TEMP RELIEF T | TEETHING PAIN | - | Apply Apply |
| Hospitalization | - initial or prolonged | ner Serious (Important Medical Events | 6. Lot # | 7. Exp. Date | | Yes No Doesn't |
| Required Inten | vention to Prevent Permanent Impa | | | #1 | | ent Reappeared After |
| 3. Date of Event (mm | | of This Report (mm/dd/yyyy) | 1 - | - | Rein | ntroduction? |
| | KNOWN | 08/09/2014 | #2 9. NDC# or Unique ID | #2 | | Yes No Apply |
| 5. Describe Event or I SHE EXPERIENCE | | AKING 3 TABLETS OF OUR | 9. NDC# or Unique ID 54973-3127-1 / | // 54973-7504 | _1 #2 [| Yes No Doesn't |
| HYLAND'S TEETH | HING TABLETS. THINGS | S HAVE SETTLED DOWN | 10. Concomitant Medical | | | |
| SOME, BUT SHE | STILL HAS A REALLY D | IZZY / SHAKY FEELING. | | | , | |
| | | |]] | | | |
| | | | | | | |
| | | | | | î, | (Continue on page 3) |
| | | | D. SUSPECT MEDI | ICAL DEVICE | | |
| | | | 1. Brand Name | | | |
| | ************************************** | _1 | 2. Common Device Name | e | 2b | . Procode |
| | Receive | ea | 3. Manufacturer Name, C | he and State | | |
| | . | | 3. Manufacturer mana, 2 | illy and state | | |
| | AUG 19 20 | A 14 | | | | |
| | MUU AU | <i>,</i> , , , , , , , , , , , , , , , , , , | 4. Model # | Lot# | | 5. Operator of Device |
| | AND | | Catalog # | Expiration | Date (mm/dd/yyyy) | Health Professional |
| | CDR | | | | The second second | Lay User/Patient |
| | | | Serial # | Unique Ider | ntifier (UDI) # | Other: |
| | | | 6. If Implanted, Give Date | - (mm/dd/vvvv) | 17 is Contanted. | Give Date (mm/dd/yyyy) |
| | | (Continue on page 3) | 0. II III prantos, on o occ |) (Hilling (1777) | 7. Il Explaines, - | ilve Date (miredwyyy) |
| 5. Relevant Tests/Lab | boratory Data, Including Dates | | 8. Is this a Single-use De | vice that was Repro | ocessed and Reur | sed on a Patient? |
| | | | Yes No | | 12 | |
| | | | 9. If Yes to Item No. 8, En | iter Name and Addre | ess of Reprocess | or |
| | | | | | | |
| | | | | | | |
| | | | 10. Device Available for E | Evaluation? (Do not | send to FDA) | |
| | | | Yes No | Returned to Ma | anufacturer on: | (mm/dd/yyyy) |
| | | (Continue on page 3) | 11. Concomitant Medical | Products and Ther | apv Dates (Exclu | |
| Other Relevant His | tory, Including Preexisting Medic | ical Conditions (e.g., allergies, | 4 | | · · · · · · · · · · · · · · · · · · · | |
| race, pregnancy, smo | noking and alcohol use, hepatic/rena AD THE INGREDIENTS CON | nal dysfunction, etc.) | | | | |
| | HER FORMS, SO SHE KNO | | E. INITIAL REPORT | TCD. | | (Continue on page 3) |
| LLERGIC REACT | • | | 1. Name and Address | IER | | |
| | | | (b) (6) | | | MIC 9 0 204 |
| | | | | | | AUG 2 0 2014 |
| | | | 1 | | | |
| | | | | | | |
| | | | Phone# | Email (b) (6) | il Address | |
| | | (Continue on page 3) | | | | Man Bank |
| rsonnel, user fac | eport does not constitute a cility, importer, distributor, | | | 3. Occupation | [* | Initial Reporter Also Sent Report to FDA |
| | uted to the event. | / management of product | Yes 📝 No | NA | | Yes No V Unk. |

| | | | | зge | 2 of 6 | _ | | | JA USE ONLY | |
|--|----------------------|--------------------------------|----------------|------------------------------|---------|------------------|-----------------------------------|--------------|-------------------|---------------------------|
| | 10402 | 276-01-00 | -02 | | H. D | EVICE MAN | UFACTURERS O | NLY | | |
| | | | | _ | 1. Typ | e of Reportable | Event | 1 | . If Follow-up, \ | What Type? |
| User Facility | Impo | rter | | | | Death | | - 1 | Correcti | on |
| 3. User Facility or Impo | orter Name/ | Address | | | | Serious Injury | | | Addition | al Information |
| | | | | | | Malfunction | | 1 | Respons | se to FDA Request |
| | | | | | | | | 1 | Device I | Evaluation |
| | | | | | 3. Dev | ice Evaluated b | y Manufacturer? | | . Device Manuf | acture Date |
| | | | | | G. 501 | | o Manufacturer | | (mm/yyyy) | 2010 |
| 4. Contact Person | | [5 | . Phone Nu | ımber | | _ | aluation Summary Attac | had | | |
| - Contact I dison | | ľ | . 1 110110 140 | | ▍▎╞ | . – | ge to explain why not) o | - h | . Labeled for S | ingle Use? |
| 6. Date User Facility or | | 7. Type of Report | | 8. Date of This Report | | provide code: | ge to explain why hot) o | ' l | _ | - |
| Importer Became Aware of Event (mm/ | - 1 | | | (mm/dd/yyyy) | | | | - 1 | Yes | ∐ No |
| Avail of Livery (mm) | 04///// | Initial | | | 6. Eve | nt Problem and | Evaluation Codes (Re | efer to code | ng manual) | |
| | | Follow-up # | | | | Patier | | | | |
| 9. Approximate Age of Device | 10. Event P | Problem Codes (Re | efer to codin | g manual) | | Code | | · | | |
| • | Patient | - | | | | Device Code | | |]_[| |
| i | Code Device | | | | | Code | | <u> </u> | | |
| | Code | | | | | Method | d | | | |
| 11. Report Sent to FDA | ? | 12. Location Whe | ere Event C | Occurred | | Doguli | | | | |
| Yes | | Hospital | | Outpatient | | Result | • <u> </u> | | | |
| No (mm/dd/) | уууу) | Home | | Diagnostic Facility | | Conclusions | s - | - | - | |
| 13. Report Sent to Manu | ufacturer? | Nursing H | lome | Ambulatory Surgical Facility | 7 If Ro | medial Action | Initiated, Check Type | | age of Device | |
| _ ` | | | nt Treatment | t | | | _ | 0. 0. | Initial Use o | f Davice |
| Yes(mm/dd/) | уууу) | Facility | | | | Recall | Notification | | Reuse | , better |
| □ 140 | | Other: | | (Specify) | ╽┃╘ | Repair | Inspection | | Unknown | |
| 14. Manufacturer Name | /Address | | | | | Replace | Patient Monitoring Modification/ | | action reported | to FDA under |
| | | | | | | Relabeling | Adjustment | 21 | USC 360i(f), lis | t correction/ |
| | | | | | | Other: | | _ " | movan oponing | , maniport |
| | | | | | | | | | | |
| | | | | | 10. | Additional Mar | nufacturer Narrative | and / | or 11. | Corrected Data |
| G. ALL MANUFAC | TURER | \$ | | | ''' | ria antiona, mai | india di maratri d | Q.107 | ٠ | 3 00.1100.000 20.00 |
| - Contact Office (and A | | | 98) | 2. Phone Number | | | | | | |
| Name | - Individual Control | mg one for better | | 310-768-0700 | | | | | | |
| DYTA FRACKIEWI | cz | | | 3. Report Source | | | | | | |
| Address | | | | (Check all that apply) | | | | | | |
| YLAND'S, INC. | | | | Foreign | | | | | | |
| .54 W. 131ST ST | REET | | | Study | | | | | | |
| OS ANGELES, CA | 90061 | | | Literature | | | | | | ļ |
| Email Address | | | | Consumer | | | | | | |
| TANDARD@HYLAND: | s.com | | | Health Professional | | | | | | |
| . Date Received by | | 5. | | User Facility | | | | | | |
| Manufacturer (mm/dd | | (A)NDA# | | Company Representative | | | | | | |
| 37/28/20: | | IND# | | Distributor | | | | | | |
| . If IND, Give Protocol | # | _ | | Other: | | | | | | j |
| | | BLA# | | _ | | | | | | |
| . Type of Report | | PMA/ 510(k)# | | | | | | | | 1 |
| (Check all that apply) | | Combination | | | 1 | | | | | l |
| 5-day 30-day | | Product | Yes | | | | | | | l |
| 7-day Periodi | ic | Pre-1938 | Yes | | 1 | | | | | Doo |
| ☐ 10-day | Hith # | OTC Product [| √ Yes | | | | | | | D22 |
| <u> </u> | | 9 Advers Free | t Torm(=) | | | | | | | D SS AUG 2 0 20 |
| . Manufacturer Report | | 8. Adverse Even SEIZURE, DI | | HAKY | | | | | • | 700 2 U ZU |
| 64973 AE # 155 | 6 | | , | | | | | | | 1 |
| | | 1 | | | 1 | | | | | i |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this

collection of information, including suggestions for reducing this burden to:

Individual Case Safety Report

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov valid OMB control number of valid OMB

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 10402276



CUSTOMER COMPLAINT RECOR



| SECTION I: COL | PLAINT | COMPLAINT #: | 2566 | |
|----------------------------------|--|---|----------------------|--------------|
| TAKENERY | CATHEDINE DOW | DATE OF COMPLAINT: | | |
| TAKEN BY: | CATHERINE DOW HYLAND'S BABY TEETHING TABLETS OR | ITEM CODE: | BTET TEET | - |
| PRODUCT: | HYLAND'S TEETHING TABLETS UNKNOWN | LOT NO.: | UNKNOWN | |
| SIZE: (b) (6) | UNKNOWN | LOT NO | ONKNOWN | |
| REPORTER: | Inc | dividual Case Safety | Report | |
| ADDRESS: | | | | |
| | | | | |
| CITY: | | | | |
| COUNTRY: USA | | 10402276-01-00 | -03 | |
| PHONE #: (b) (6) | | | | |
| E-MAIL: | | NAME TO THE PARTY OF THE PARTY | TUDES TABLETS ONCE | |
| NATURE OF COMPLAINT: | SHE EXPERIENCED A SEIZURE AFTER TA | | | AINES IN |
| | VN SOME, BUT I STILL HAVE A REALLY DIZZY / SI | | THE INGREDIENTS CONT | AINED IN |
| THIS PRODUCT IN OTHER FOR | MS, SO SHE KNOWS IT WAS NOT AN ALLERGIC REA FOR ADDITIONAL SPACE PLEASE USE REV | | EET | |
| | | | | \bigcirc |
| PRODUCT RECEIVED FOR INSPECTION: | Y (N) | PRODUCT BEING RETURNED FOR | | CLE ONE) |
| INSPECTION. | (CINCLE CINE) | DATE REQUESTED PRODUCT BE | • | JEE 0112) |
| | | DATE REQUESTED PRODUCT BE | | |
| | | UPS CALL | . TAG ISSUED: (CIRC | CLE ONE) |
| | | OI O O/ILL | (0 | |
| | | DATE PRODUC | CT RECEIVED: | |
| SECTION II: INV | ESTIGATION | | | |
| INVESTIGATION: | See attached Pm 8/11 | /14 | | |
| | | | | |
| | | | • | |
| | | | | |
| | | | | |
| ADVERSE EVENT FORWARD | ED TO PHARMACIST / NURSE FOR EVALUATION | ON: 07/28/201 | 14 | |
| ADVERSE EVENT FORWARD | ED TO PHARMACIST / NURSE FOR EVALUATION | BY: CATHER | INE DOW | |
| SECTION III: | ORRECTIVE ACTION: | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| CORRECTIVE ACTION(S) CO | MPLETED BY: | DATE: | | |
| SECTION IV. ADV | ERSE EVENT REPORTS | ΔE #- | 1556 | |
| SECTION IV: ADV | ERSE EVENT REPORTS | AC #. | 1330 | |
| ADVERSE EVENT SERIOUS: | (Y) / N | | | DSS |
| ADVERSE EVENT REPORTED | O ON: 07/28/2014. | BY: CATHERINE DO | ow | |
| SECTION V: | α_{1} | n [| | AUG 2 0 2014 |
| REVIEWED BY MANAGEMEN | TRY KUL | DATE. | 08-11-14 | 1 |
| VENIEWED BY MANAGEMEN | and Breeze | | | |
| BY: | QA / QC DIRECTOR | DATE: _ | 08-11-14 | |
| | QA / QC DIRECTOR | | | |

cc: QA / QC Packaging Production Shipping / Receiving AUG 1'9 2014





rious Adverse Event SAE-0033-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) and Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-three Adverse Events (AE) which also included twenty-one Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). There have been three Adverse Event (AE) Reports and two Serious Adverse Events (SAE) reported for the Teething Tablets (TEET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

DSS AUG 2 0 2014

CaseID: 10402276



ERSE EVENT DATA FORM



| AE #: | 1556 | | | COMPLAN | NT #: 2566 | |
|--|---|---|--|--|--|--------------|
| SECTION | <u>: PAT</u> | ENT INFORM | ATION (IF DIFFEREN | NT FROM REPORTER ON FO | ORM VD1) | |
| NAME: ADDRESS | (b) (6) | | | | | |
| CITY: | | | | STAT | E: | |
| COUNTRY | USA | | | ZIP CO | DE: | |
| PHONE #: | | | | | | |
| E-MAIL: | (b) (6) | | | | | |
| SECTION | l: PAC | KAGING INFO | RMATION: | | | |
| | AFFIX PACKA | aging Label | HERE | (INCLUDE DRUG FAC | FOUTER CARTON HERE CTS AND PRINCIPAL DISPLAY PANELS) | |
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| SECTION I | <u> :</u> <u>CO</u> | RRECTIVE AC | TION: | | | |
| CORRECT | VE ACTION(S) C | COMPLETED E | Y: | | DATE: | _ Dss |
| SECTION I | V : BY MANAGEME | ENT BY: | T21) | Jeet | DATE: 08-11-14 | AUG 2 0 2014 |
| BY: | | Dru | Bauy | | DATE: 08-11-14 | |





| AE #:15 | 556 | COMPLAINT #: 2566 |
|------------------------|--|--|
| SECTION I: | PATIENT INFORMATION | (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| OIT. | | OTATE. |
| CITY: COUNTRY: | USA | STATE: ZIP CODE: |
| PHONE #: | -00/1 | |
| E-MAİL: | (b) (6) | |
| SECTION II: | PACKAGING INFORMAT | <u>'ION:</u> |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| | Section of the content of the conten | Teething Tablets Teething Tablets Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición Tabletas para la Dentición |
| SECTION III: | CORRECTIVE ACTION: | |
| CORRECTIVE | E ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: | BY MANAGEMENT BY: | DSS AUG 20 DATE: 08-11-14 |
| BY: MA FJB 08-11 | QA/QC DIRECT | Bun DATE: 08-11-14 |

user-facilities, fors and manufacturers FORY reporting

| Fo | TH Approved: OMB N | EID: 10412341 o. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. | |
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| fr Report# | | | |

| | CCC ONLY Statement on Level St |
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| Mfr Report# 54973 | |
| UF/importer Report # | |
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| | FORWIFDA 350 | . , | | | . 49 |
|------------------------------|---|--------------------------|---------------------|--------------------|---------------|
| | A. PATIENT INF | ORMATION | | | |
| | Patient Identifier (b) (6) | 2. Age at Time of Event: | | 3. Sex | 4. Weight |
| | , , | or4 | Months | Female | |
| | 1 1 | Date | | l <u></u> | or |
| | in confidence | of Birth: | | Male Male | k |
| | B. ADVERSE EV | ENT OR PRODU | CT PROBLE | VI | |
| | 1. Adverse Event | and/or Pro | oduct Problem (e. | .g., defects/malfi | inctions) |
| | 2. Outcomes Attribute | ed to Adverse Event | | | * |
| | (Check all that apply | 7 | | _ | |
| | Death: | (mm/dd/yyyy) | _ [Disability or | r Permanent Dar | nage |
| | ✓ Life-threatening | | Congenital | Anomaly/Birth D | efect |
| | | - initial or prolonged | | us (Important M | |
| | | ention to Prevent Perm | anent Impairment/ | Damage (Device | es) |
| | 3. Date of Event (mm/ | | 4. Date of This | Report (mm/dd/ | <i>(YYYY)</i> |
| | | 3/2014 | | 08/10/2014 | |
| | Describe Event or F MONTH OLD BA | Problem | DADY SUPERIL | THE | _ |
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| | AGAIN; THE BAB | Y BEGAN TO BRE | ATHE NORMAL | LY. FATHE | ER. |
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| | | atory bata, including | Dates | | |
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| 7 | Other Relevant Histor | y, Including Preexistir | - MadiI O - d | 4 | aies. |
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| Si | bmission of a repo | rt does not const | ituto an admis | alam that | .go 3) |

| | (Condition on page 3) |
|--|------------------------|
| Submission of a report does not constitute an a | dmission that medical |
| personnel, user facility, importer, distributor, m | anufacturer or product |

| ORY reporting | UF/Importer Re | eport# | | f |
|---|--|---|--|--|
| of <u>5</u> | | | | |
| C. SUSPECT PROD | UCT(S) | | | FDA Use Only |
| 1. Name (Give labeled stre | | | | |
| #1 HYLAND'S BABY | TEETHING TA | BLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & Rou | ite Used | 3. Therapy | Dates (If unknown, r best estimate) | give duration) |
| #1 1TAB DISSOLVED | SYRINGE | #1 | nesi esilmale) | 1 |
| #2 | | #2 | | |
| 4. Diagnosis for Use (Indic | ation) | 5. | Event Abated After | |
| #1 TEMP RELIEF TE | ETHING PAIN | #1 | Stopped or Dose | □ Doesn't |
| #2 | | _ | | Apply |
| 6. Lot# | 7. Exp. Date | #2 | Yes No | Doesn't Apply |
| #1A22314 | #1 | 8. | Event Reappeared Reintroduction? | After |
| #2 | #2 | #1 | | Doesn't |
| 9. NDC# or Unique ID 54973-3127-1 | | #2 | ☐ Yes ☐ No | Doesn't |
| 10. Concomitant Medical P | roducts and There | 1 | | Apply (|
| , | | -61 -area (C) | | overk) |
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| | | | | - 1 |
| | | | | nage 3) |
| D SUSPECT MEDIC | AL DEVICE | | (Continue on | page 3) |
| D. SUSPECT MEDIC | AL DEVICE | | (Continue or | page 3) |
| 1. Brand Name | AL DEVICE | | | page 3) |
| Brand Name Common Device Name | | | (Continue on | page 3) |
| Brand Name Common Device Name | | | | page 3) |
| Brand Name Common Device Name Manufacturer Name, City | and State | | 2b. Procode | |
| Brand Name Common Device Name Manufacturer Name, City | | | 2b. Procode | of Device |
| Brand Name Common Device Name Manufacturer Name, City | and State | ate (mm/dd/y) | 2b. Procode 5. Operator Health | of Device Professional |
| Brand Name Common Device Name Manufacturer Name, City Model # Catalog # | Lot # | | 2b. Procode 5. Operator Health Lay Use | of Device |
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| 1. Check One | | 2. UF | /Importer R | eport Number | | |
|---|----------------|---|--------------|---------------|---|------------|
| User Facility | import | ter | | | | |
| 3. User Facility or Imp | orter Name/ | Address | | | | |
| | | | | | | |
| 4. Contact Person | | | | 5. Phone Nu | ımber | _ |
| Date User Facility or Importer Became Aware of Event (mm) | 1 | Type of Rollinitial | | | 8. Date of This (mm/dd/yyyy) | |
| 9. Approximate | 10. Event Pr | roblem Cod | les (R | efer to codin | ng manual) | |
| Age of Device | Patient | | _ | | | |
| | Code | | | | | |
| | Device Code | |]- | | | |
| 11. Report Sent to FDA | .? | 12. Locatio | on Wh | ere Event (| Occurred | |
| Yes(mm/dd/ | /уууу) | ☐ Ho | spitai me | | Outpatien Diagnostic | c Facility |
| 13. Report Sent to Man | ufacturar? | | rsing H | Home | Ambulato Surgical F | |
| 13. Report Sent to Man | ufacturer: | _ ou | - | nt Treatmen | - | -aum, |
| No (mm/dd/ | YYYY) | | her: | | | |
| 14. Manufacturer Name | | | | | (Specify) | |
| G. ALL MANUFA | CTURERS | S | | | | |
| 1. Contact Office (and | | | Devic | es) | 2. Phone Numb | ber |
| Name | | • | , | | 310-768-07 | |
| EDYTA FRACKIEWI | CZ | | | | 3. Report Sour | ce |
| Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA | | | | | (Check all that Foreign Study Literature Consumer | |
| Email Address | | | | | Health Profe | esional |
| STANDARD@HYLAND | S.COM | | | | User Facility | |
| Date Received by Manufacturer (mm/do | d/yyyy) | 5. (A)NDA # | | _ | Company | |
| · | ļ | IND# | | | Representati | tive |
| 6. If IND, Give Protocol | # | BLA# | | | Other: | |
| 7. Type of Report (Check all that apply) | - | PMA/ 510(k) # Combinati | | | | |
| 5-day 30-day | | Product | | Yes | | |
| 10-day Initial | nc | Pre-1938 | | Yes | | |
| | v-up # | OTC Prod | uct | ✓ Yes | | |
| 9. Manufacturer Report | Number | 8. Adverse | Even | nt Term(s) | ······································ | |
| 54973 AE # 155 | .8 | STOPPED |) BRI | EATHING | | |

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | | FDA USE ONLY |
|---|-----------------------------------|---|
| : 5 | | |
| H. DEVICE MANUFA | CTUBERS ONLY | |
| Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death | | Correction |
| Serious Injury | | Additional Information |
| Maifunction | | Response to FDA Request |
| | | Device Evaluation |
| B. Device Evaluated by Man | ufacturer? | 4. Device Manufacture Date |
| Not Returned to Man | ufacturer | (mm/yyyy) |
| Yes Evaluation | n Summary Attached | |
| No (Attach page to e provide code: | xplain why not) or | 5. Labeled for Single Use? |
| provide code. | | Yes No |
| 6. Event Problem and Evalu | ation Codes (Refer to | |
| Patient | | |
| Code | | |
| Device Code | - | - |
| Method | | |
| Method | | |
| Results |]-[|]- |
| Conclusions | | |
| | | |
| . If Remedial Action Initiate | | I. Usage of Device |
| | lotification | Reuse |
| | respection | Unknown |
| | Patient Monitoring Modification/ | . If action reported to FDA under |
| | djustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | |
| *************************************** | | |
| Additional Manufact | urer Narrative a | nd / or 11. Corrected Data |
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CaseID: 10412341

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PAS 10 May 12 M OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Valid OMB control number."
Please DO NOT RETURN this form to the above PRA Staff email address.

Individual case safety kepole

PLAINT RECORD



| 10412341-01-00-03 | COMPLAINT #: 2008 |
|---|---|
| PRODUCT: HYLAND'S BABY TEETHING TABLETS | DATE OF COMPLAINT: 08/03/14 |
| SIZE: 135 TABLETS | ITEM CODE: _BTETT135 |
| REPORTER: (b) (6) | LOT NO.: A22314 |
| ADDRESS: | |
| | |
| CITY: | STATE: (b) (6) |
| COUNTRY: USA | |
| PHONE #: | ZIP CODE: |
| E-MAIL: | |
| BACK TO GET HER BREATHING AGAIN; THE BABY BEGAN TO BREATHE NORM, WE WERE ON THE LINE. CHILD ALSO TAKES MEDICATION FOR ACID REFLUX. | NAD COLIC. |
| FOR ADDITIONAL SPACE PLEASE USE REVEI | RSE OR ATTACH A SEPARATE SHEET |
| PRODUCT RECEIVED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) |
| | DATE REQUESTED PRODUCT BE RETURNED: |
| | UPS CALL TAG ISSUED: Y (CIRCLE ONE) |
| | DATE PRODUCT RECEIVED: |
| SECTION II: INVESTIGATION | |
| INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. | |
| | |
| | |
| | |
| ADVERSE EVENT FORWARDED TO CUADANCIOS AND TO STANDARD | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | |
| SECTION III: CORRECTIVE ACTION: | TUTTI GOULD |
| STATE ACTION. | |
| | |
| | |
| | |
| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: ADVERSE EVENT REPORTS | D 35 |
| C C C C C C C C C C C C C C C C C C C | AE #: 1558 AUG 2 5 2014 |
| ADVERSE EVENT SERIOUS: (Y) / N | |
| ADVERSE EVENT REPORTED ON: 08/03/14 | BY: TUTTI GOULD |
| SECTION V: | 0 1 |
| REVIEWED BY MANAGEMENT BY: | DATE: 08-15-14 |
| BY: Ville / Dans | DATE: 08-15-14 |

cc: QA / QC Packaging

Production Shipping / Receiving

AUG 22 2014 VD1





SAE-0034-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A22314, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A22114 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A22314. The Baby Teething bulk lot # 122944 was tested for total Atropine and Scopolamine and the results were with in specification of \leq 40 ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A22314. A search of the complaints related to lots packaged with the same bulk lot # 122944 was performed and three complaints were found (CC-0322-2014, CC-0456-2014 & CC-0534-2014/SAE-0032-2014). The complaints were reviewed and although a previous SAE has been reported related to this bulk lot the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A22314.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by Date

DSS AUG 2 5 2014

CaseID: 10412341

E EVENT DATA FORM



| AE #:1 | 1558 COMPLAINT #:2658 | |
|--|--|-----------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | STATE: (b) (6) | |
| COUNTRY: | USA ZIP CODE: | |
| PHONE #: E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | |
| , | AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| Americanicanic Immerciny systems of complex exchanges and complex exchanges exchanges and complex exchanges are studied, but to complex exchanges and complex exchanges and complex exchanges and complex exchanges and complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe a force of the complex exchanges and describe and describe a force of the complex exchanges and describe and desc | Teething Tablets For its event of the control of t | |
| SECTION III: | CORRECTIVE ACTION: | |
| | E ACTION(S) COMPLETED BY: DATE: DS(| |
| SECTION IV: | Y MANAGEMENT BY: DATE: 08-14-08-15-14 | , |
| BY: | Y MANAGEMENT BY: DATE: 08-15-75 QA / QC DIRECTOR DATE: 08-15-75 | -1 |

AUG 22 2014 SAEO1

are Holdings

CaseID: 10430246

Form Approved: OMB No. 0910-0291 Expires: 12/31/2011 Phase Forward FDA Facsimile Approval: 07/12/2006

| 1 110 | se i ciwara i bin i acsimile rippi cval. 07/12/200 |
|---------------|--|
| Mfr report # | NSR_01615_2014 |
| UF/Importer I | Report# |
| | FDA Use On |

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| FORM FDA 3500 | A (6/10) | Pag | ge1_ of | 14 | | | | FDA Use Only |
|---|--|---|--|----------------------|---------------------------------|-------------------|--|--|
| A. PATIENT INF | ORMATION | | | C. SUSP | ECT PRO | DUCT(S | 5) | |
| Patient Identifier | 2. Age at Time of Event: | 3. Sex 4. W | 3 | 1. Name (Give | | | , | |
| Unknown | or 9 months | Female | lbs | #2 Teethi | | | | |
| In confidence | Date of Birth: | ✓ Male | - 11 | 2. Dose, Frequ | ency & Route | Used | 3. Therapy Date: | s (if unknown, give duration) |
| B. ADVERSE EV | ENT OR PRODUCT | PROBLEM | | #1 (2 mg/ | kg, (co | ont.) | #1 (Unknown | |
| 1. Adverse Event | and/or Product | Problem (e.g., defects/ m | alfunctions) | #2 (DF) | | | #2 (Unknown | 1) |
| 2. Outcomes Attributed (Check all that apply) | to Adverse Event | | - 11 | 4. Diagnosis f | | tion) | | ent Abated After Use |
| Death: | Disabilit | y or Permanent Damage | . [[| #1 Haeman | | | | opped or Dose Reduced? |
| Life-threatening (n | mm/dd/yyyy) Congen | tal Anomaly/Birth Defect | t IL | #2 Teethi 6. Lot# | | xp. Date | #2 | Yes No Doesn't |
| Hospitalization - init | | erious (Important Medica | al Events) | #1 | #1 | xp. Date | | vent Reappeared After |
| Required Intervention | on to Prevent Permanent Imp | airment/Damage (Device of This Report <i>(mm/dd/</i> | II. | #2 | #2 | | | Reintroduction |
| J. Date of Event (min | | 9/2014 | "" | 9. NDC# or U | nique ID | | #1 [| Yes No Doesn't |
| 5. Describe Event or Pr | oblem | | | | | | #2 [| Yes No Doesn't Apply |
| Citation(s): | s J. Propranolol | -related | | 10. Concomita | nt Medical Pr | oducts and | Therapy Dates (i | Exclude treatment of event) |
| hypoglycaemic | seizure in a 9- | month-old infa | | | | | | |
| _ | ce of regular fee f treatment. Brit | | - 11 | | | | | |
| Dermatology 2 MedDRA Version | 2014;171(S1):117. | | | | | | | |
| MedDRA Versio | on 16.1 | | | G. ALL M | ANUFAC | TURERS | 3 | |
| _ | of Event or Probleted in the litera | | | 1. Contact Of | ice - Name/A | ddress | <u> </u> | 2. Phone Number |
| healthcare pr | rofessionals from | the United | | | turing Site for Di ar Health | | oldings, | 434-326-1014 |
| | a 9 month old tw ritability, rece | , | - 11 | | Mastronai | | . D. sultants, | 3. Report Source (Check all that apply) |
| (route and fo | rmulation unknow | n), 2 mg/kg, | | | - | _ | o Beach, | Foreign |
| | in two divided d ging haemangioma | | | FL 32963 | USA | | | Study |
| pinna, in com | mbination with un | specified | | | | | | ✓ Literature Consumer |
| | (route, dose, and teething. No co | | t.) | | | | | Health Professional |
| | | | | | rer (mm/dd/yy) | yy) (A)N (| _{DA #} 78-213 | User Facility |
| 6. Relevant Tests/Labo | ratory Data, Including Date | 2000 | <u>. </u> | 08/22/2 | | " | ND# | Company |
| | r | Received | 3 | 6. If IND, Give | Protocol# | s ⁻ | TN# | Representative Distributor |
| | | 000 0 0 004 | | 7. Type of Re | | 510(| MA/ | Other: |
| | | SEP 0 2 2014 | | (Check all tha | 30-day | Com | bination | (cont.) |
| | | | | 7-day | Periodic | Prod | 1938 Yes | - Doc |
| | | CDR | | 10-day | | ОТС | | <u> </u> |
| | ab data is appended | | | . Manufactur | Follow-up# | Proc | luct | - ISEP 0 3 2014 |
| (e.g., allergies, race, p dysfunction, etc.) | y, Including Preexisting Med pregnancy, smoking and alcol | | | NSR_0161 | | ну | dverse Event Ten poglycaemic ont.) | |
| Relevant Hist Teething (Tee | ory: ething), Irritable | e (Irritable) | | E. INITIAI | REPOR | TER | | |
| Concomitant of | | - | | 1. Name and (b) (6) | Address | | Phone # | |
| Rapidly enlar | ging haemangioma | on the left | \mathcal{H} | United B | Lingdom |) | | |
| pinna (Haemar | ngioma) | | \mathcal{A} | | | • | CED A | 2 2014 |
| | | | | | | | SEF U | EU. |
| Submission of a report | does not constitute an adm | ission that medical ne | rsonnel. | 2. Health Prof | essional? | 3. Occup | ation | 4. Initial Reporter Also |
| | listributor, manufacturer or | | | ✓ Yes | No | Unkno | wn · | Sent Report to FDA Yes No Unk. |

3500A Facsimile

Individual Case Safety Report



10430246-01-00-02

NorthStar Healthcare Holdings Mfr Report #: NSR_01615_2014

CaseID: 10430246

3

B5. Describe event or problem (continued)

medications were reported. Therapy with propranolol was initiated on an unknown date and five months later, the patient experienced generalized seizure secondary to hypoglycaemia, difficult to rouse and floppy, developed jerky stiff movements before becoming pale and unresponsive, and was diagnosed with ketonic hypoglycaemia. Laboratory tests revealed capillary blood glucose: 1.1 mmol/L, serum glucose: 0.8 mmol/L, serum cortisol response: normal, urine: positive for ketones, temperature: 35.4 degrees Celsius, hypoglycaemia: < 3.5 mmol/L, and persistently low CBG in the early hours of the morning. Treatment included oral Dextrogel, buccal midazolam, fluids, antibiotics, antivirals, and warming. Subsequently, he made a complete recovery within 24 hours. Computed tomography head scan and metabolic study were normal. Therapy with propranolol was weaned down and stopped over seven days. On reassessment he had two further episodes of hypoglycaemia. He had no further seizures. The severity of his condition was presumed to be exacerbated by propranolol, with twice daily dosing and the use of teething gel as possible contributing factors. An additional bottle feed was sufficient to prevent any further episodes of hypoglycemia. The authors stated, "Informing parents about the risk of hypoglycemia in infants taking propranolol is important throughout the course of treatment. The need to avoid prolonged fasting and to continue regular feeds should be clearly emphasized. This is important not only in premature neonates during their first year of life but also in children up to the age of five years." No additional information was available at the time of this report.

Literature article is attached.

C2. Dose, frequency and route used for suspect product #1 (continued)

daily [given in two divided doses])

C3. Therapy dates/durations used for suspect product #1 (continued)

until not continuing)

G3. Report source (continued)

Foreign: United Kingdom

G8. Adverse event terms (continued)

Drug interaction

DSS I**SE**P 0 3 2014

SEP 02 2014

Individual Case Safety Report



10430246-01-00-03

NorthStar Healthcare Holdings Mfr Report #: NSR_01615_2014

CaseID: 10430246

Page <u>3</u> of <u>3</u>

| B6. Lab Data | | | | | | | |
|--------------|-------------------------|----------------------------|--------------------|----------------------|-----------------------|-----------|-----------|
| Panel | Test | Results | <u>Units</u> | <u>Low</u> Normal | <u>High</u> Normal | Normal? | Test Date |
| Laboratory | test | | | | | | |
| | Blood sugar | <3.5 (hypoglycemia) | mmol/L | | | Depressed | |
| | Capillary blood glucose | persistently low CBG | | | | Depressed | |
| | Capillary blood glucose | 1.1 | mmol/L | | | | |
| | Serum glucose | 0.8 | mmol/L | | | | |
| | Urinalysis | positive for ketones | | | | | |
| Vital signs | | | | | | | |
| | Body temperature | 35.4 | degrees Celsius | | | | |

DSS SEP 0 3 2014

SEP 02 2014

Owen and Hughes: Propranolol-related hypoglycaemic seizure in a 9-month old infant: the importance of regular feeding throughout the course of treatment. British Association of Dermatologists 2014 171 (Suppl. 1), pp 115-130.

| CaseID: 1043601 | 8 |
|--|---|
| roved: OMB No. 0910-0291, Expires: 6/30/ | |

| oved: C | MB No. | 0910-0 | 291, Expire | s: 6/30/2015 |
|---------|--------|--------|--------------|--------------|
| | 5 | iee OM | 3 statemernt | on reverse. |
| | | | | |

| • | See OMB s |
|------------------------------|----------------------|
| cilities, I manufacturers | Mfr Report # 54973 |
| reporting | UF/Importer Report # |
| | |

| FORM | FDA | 3500A | (2/13) | ۱ |
|----------|-----|-------|--------|---|
| 1.017161 | | 3300 | (2010) | , |

| A. PATIENT IN | FORMATION | | | |
|--|---|--|--|---|
| 1. Patient Identifier | | • | 3. Sex | 4. Weight |
| (b) (6) | of Event: 10 | Months | Female | (b |
| | Date | | ☐ Male | or |
| In confidence | of Birth; | OT DDOD! E | | kg |
| B. ADVERSE E | VENT OR PRODU | | | |
| 1. Adverse Ever | | oduct Problem (6 | .g., defects/malf | unctions) |
| 2. Outcomes Attribu (Check all that app | ited to Adverse Event | | | |
| Death: | | Disability o | or Permanent Da | mage |
| Life-threateni | (mm/dd/yyyy) ng | Congenita | Anomaly/Birth D | Defect |
| Hospitalizatio | n - initial or prolonged | Other Seri | ous (Important M | ledical Events |
| Required Inte | rvention to Prevent Pem | nanent Impairmen | t/Damage (Devic | es) |
| 3. Date of Event (m) | | 4. Date of This | Report (mm/dc | |
| 05/25/2014 5. Describe Event or | 05/31/2014 | | 06/26/2014 | l |
| THE WEEK OF U SYMPTOMS - TE SECONDS AND O WEEK. WENT T OCCURING AT T SEIZURE BUT S SINCE STOPPIN | SING THE TABLE CNSING UP, SHAK CCCURRED ABOUT O THE EMERGENC | ING THAT LA 10 TIMES OV Y ROOM BUT OR COULD NO BE SEIZURE G TABLETS, | STED 5 - 1 ER A PERIO SYMPTOMS W T TELL IF TYPE ACTI | OD OF A ERE NOT THIS WAS VITY. |
| 6. Relevant Tests/La NONE | iboratory Data, Includi | ng Dates | (Continue o | n page 3) |
| | | | (Continue o | n page 3) |
| 7. Other Relevant Hi | story, including Preex moking and alcohol use, | isting Medical Co | onditions (e.g., a | illergies, |
| | HER HAS A HIST | | | |
| | | | | |
| | | | (Continue o | n naga 31 |

| | 4 | | |
|---------------------------|---------------------------------|----------------------|--|
| e 1 of <u>5</u> | | | FDA Use Only |
| C. SUSPECT | PRODUCT(S) | | |
| | beled strength & mfr/labeler) | | |
| bs #1 HYLAND'S | BABY TEETHING TO | ABLETS | |
| #2 | | | |
| os . | cy & Route Used | 3. Therapy Dates | (If unknown, give duration) |
| | - | from/lo (or best | |
| #1 1-2 TABS | BID-TID X 1WEEK | #1 | |
| #2 | | #2 | |
| 4. Diagnosis for | | Stor | t Abated After Use ped or Dose Reduced? |
| #1 TEMP REL | IEF TEETHING PAIN | #1 🗸 | Yes No Doesn't |
| #2 | | | Арріу |
| 6. Lot # | 7. Exp. Date | #2 [| Yes No Doesn't |
| #1812113 | #1 | | t Reappeared After |
| | | 1 - | troduction? |
| #2 | #2 | #1 | Yes No Apply |
| 9. NDC# or Uniqu | | #2 | Yes No Doesn't |
| 54973-312 | Medical Products and The | read Dates (Evelue | a Irealment of event |
| 1 1 | medical Products and The | waby bates (Excide | e nodinion or evenil |
| | | | |
| S | | | |
| 11 | F | | (Continue on page 3) |
| D SUSPECT | MEDICAL DEVICE | | Continue on page 5) |
| 1. Brand Name | WEDIOAE BETTOE | | |
| | | | |
| 2. Common Devi | ce Name | ²⁶ | Procode |
| 3. Manufacturer | Name, City and State | | # # Production of the Producti |
| 11 | | | |
| 4. Model# | Lot# | | 5. Operator of Device |
| | Explestion | Date (mm/dd/yyyy) | Health Professional |
| Catalog # | Expiration | Date (Illinoid yyyy) | Lay User/Patient |
| Serial # | Unique Id | entifier (UDI) # | Other: |
| | | | |
| 6. If implanted, 0 | live Date (mm/dd/yyyy) | 7. If Explanted, 0 | live Date (mm/dd/yyyy) |
| - | Deulee that was Par | recessed and Paul | red on a Patient? |
| 8. Is this a Singl | e-use Device that was Rep No | a vuesseu eilu neu: | On a - dilette |
| | No. 8, Enter Name and Ad | dress of Reprocess | or |
| | | | |
| | | | |
| | | | |
| | able for Evaluation? (Do no | - | D |
| ☐ Yes ☐ | No Returned to | Manufacturer on: | (mm/dd/w/SS |
| 11. Concomitant | Medical Products and The | erapy Dates (Exdu | de treatment of event) |
| -1.1 | | | SEP 0 5 2 |
| li I | | | (Continue on more Of |
| E MITH | CRARTER | 4 | (Continue on page 3) |
| E. INITIAL R | | | |
| 1. Name and Ad (b) (6) | ui v.93 | | |
| | | | |
| | | | |
| | | | • |
| Phone # | Em | all Address | |
| (b) (6) | | | |
| 2. Health Profes | sional? 3. Occupation | . 1 | Initial Reporter Also Sent Report to FDA |
| □ vac | No NA | | TO Vac TO Na TO Use |

| 1. Check One | | | 2. UFAm | porter R | eport Nu | imbar |
|---|--|---|-----------|--------------------|--|--|
| User Facility | [] Imp | orter | 2. 0., | , portor 11 | | |
| 3. User Facility or Imp | | | | | | |
| 3. Osei Facility of Imp | orter Name | yAddress | | | | |
| 4. Contact Person | | | [5, F | hone No | umber | |
| | | | | | | |
| Date User Facility of Importer Became Aware of Event (mm | r v/dd/yyyy) | 7. Type of F | | | 8. Date (mm/i | of This Report dd/yyyy} |
| 9. Approximate Age of Device | 10. Event | Problem Cod | ies (Refe | r to codin | g manua | 1) |
| Age of Device | Patient Code | ····· | 7- | | | |
| | Device [| | 7.7 | | = | |
| | Code | | J-L | | | <u></u> |
| 11. Report Sent to FDA | 7 | 12. Locati | on Where | Event C | ccurred | |
| Yes | | ☐ Ho | spital | | | utpatient agnostic Facility |
| No (mm/dd/ | (צצצצי | Ho | me | | | mbulatory |
| 13. Report Sent to Manufacturer? Nursing Home Surgice | | | | urgical Facility | | |
| Yes Outpatient Treatment Facility | | | | | | |
| □ No (mm/dd/yyyy) □ Other: | | | | | | |
| L | | | | | (Specil | y) |
| 24 14 6 4 11 | 14. Manufacturer Name/Address | | | | | |
| 14. Manufacturer Name | e/Address | | | | | |
| 14. Manufacturer Name | e/Address | | | | | |
| 14. Manufacturer Name | e/Address | | | | | |
| G. ALL MANUFA | CTURER | | | | | |
| G. ALL MANUFA(| CTURER | | Devices) | | | e Number |
| G. ALL MANUFAO 1. Contact Office (and I Name | CTURER Manufactur | | Devices) | | 310-7 | 58-0700 |
| G. ALL MANUFA(| CTURER Manufactur | | Devices) | | 310-76 3. Repo | 11007 |
| G. ALL MANUFAO 1. Contact Office (and I) Name EDYTA FRACKIEWI | CTURER Manufactur | | Devices) | | 310-76 3. Repo | nt Source k all that apply) |
| G. ALL MANUFAO 1. Contact Office (and I) Name EDYTA FRACKIEWI Address | CTURER Manufactur CZ | | Devices) | | 310-7 3. Repo (Chec | nt Source sk all that apply) |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. | CTURER Manufactur CZ REET | ing Site for | Devices) | | 310-76 3. Repo (Chec | nt Source sk all that apply) |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST | CTURER Manufactur CZ REET | ing Site for | Devices) | | 310-76 3. Repo (Check Fore Stud | nt Source ik all that apply) ign guature sumer |
| G. ALL MANUFAC 1. Contact Office (and I Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA | CZ REET 90061 | ing Site for | Devices) | | 310-76 3 Repo (Check Fore Stud | rt Source rt Source rk all that apply) rign riy ature sumer |
| G. ALL MANUFAO 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by | CTURER Manufactur CZ REET 90061 | ing Site for | Devices) | | 310-70 3. Repo (Chec | rt Source rk all that apply) ign ly ature sumer th Professional |
| G. ALL MANUFAC 1. Contact Office (and I Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND | CZ REET 90061 S.COM | ing Site for | | | 310-70 3. Repo (Chec Fore Stud Uiter V Con: Heal User | nt Source ik all that apply) ign ity atture sumer th Professional Facility pany resentative |
| G. ALL MANUFAG 1. Contact Office (and I Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dd | CZ REET 90061 S.COM | ing Site for | | | 310-70 3. Repo (Check Fore Stud Ulter Con: Heal User Com Repp | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/do | CZ REET 90061 S.COM | 5. (A)NDA # | | | 310-70 3. Repo (Chec Fore Stud Uiter V Con: Heal User | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/do 26/25/20 6. If IND, Give Protocol | CZ REET 90061 S.COM | 5. (A)NDA # IND # BLA # | | | 310-70 3. Repo (Check Fore Stud Ulter Con: Heal User Com Repp | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |
| G. ALL MANUFAG 1. Contact Office (and I Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dd | CZ REET 90061 S.COM | 5. (A)NDA # IND # BLA # PMA/ 510(k) # | | | 310-70 3. Repo (Check Fore Stud Ulter Con: Heal User Com Repp | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/da | CZ REET 90061 S.COM | 5. (A)NDA # IND # BLA # | On | Yes | 310-70 3. Repo (Check Fore Stud Ulter Con: Heal User Com Repp | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dd 26/25/20 6. If IND, Give Protocol 7. Type of Report (Check all that apply) 5-day 30-day 7-day Periodi | CTURER Manufactur CZ REET 90061 S.COM | 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combinati | On | | 310-70 3. Repo (Check Fore Stud Ulter Con: Heal User Com Repp | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |
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| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/do | CTURER Manufactur CZ REET 90061 S.COM Wyyy) 14 | 5. (A)NDA # BLA # PMA/ 510(k) # Combinati Product Pre-1938 OTC Prod | on | Yes Yes Yes | 310-70 3 Report (Check C | rt Source k all that apply) ign iy ature sumer th Professional Facility pany esentative ibutor fr: |
| G. ALL MANUFAC 1. Contact Office (and I) Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dd 26/25/20 6. If IND, Give Protocol 7. Type of Report (Check all thal apply) 5-day 30-day 7-day Period 10-day Initial 10-day Follow | CTURER Manufactur CZ REET 90061 S.COM Vyyyy) 14 # | 5. (A)NDA # BLA # PMA/ 510(k) # Combinati Product Pre-1938 OTC Prod | on | Yes Yes Yes | 310-70 3 Report (Check C | nt Source k all that apply) ign iy ature sumer th Professional Facility peny esentative |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | FDA USE ONLY |
|--|---|
| F 5 | |
| H. DEVICE MANUFACTURERS ONL | Y 2. If Follow-up, What Type? |
| Death Serious Injury Malfunction | Correction Additional information Response to FDA Request |
| | Device Evaluation |
| Device Evaluated by Manufacturer? Not Returned to Manufacturer | 4. Device Manufacture Daite (mm/yyyy) |
| Yes Evaluation Summary Attached | 5. Labeled for Single Use? |
| No (Altach page to explain why not) or provide code: | Yes No |
| 6. Event Problem and Evaluation Codes (Refer | to coding manual) |
| Patient Code | -[|
| Code | |
| Results - | |
| Conclusions - | |
| 7, If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification Repair Inspection | Reuse |
| Replace Patient Monitoring Relabeling Modification/ | 9. If action reported to FDA under |
| Adjustment Cther: | 21 USC 360i(f), list correction/ removal reporting number: |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
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| | DSS |
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CaseID: 10436018

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStati@ida.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

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ADVERSE EVENT SERIOUS:

ADVERSE EVENT REPORTED ON:

06/25/2014

SEP 0 5 2014

REVIEWED BY MANAGEMENT BY:

BY:

SECTION V:

cc: QA/QC

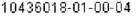
Packaging

Production

Shipping / Receiving

Form # VD1







Serious Auverse Event SAE-0027-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # B12113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B12113 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results were within specification for Hyland's Baby Teething Tablets lot # B12113. The Baby Teething bulk lot # 121015 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other customer complaint (CC-0091-2014) has been received for Hyland's Baby Teething Tablets lot # B12113. The complaints were reviewed and there does not appear to be a trend related to this lot. We will continue to monitor our reported incidents for potential trends. We will continue to monitor complaints and if additional complaints are received on this lot will be evaluated and any possible trend reviewed.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B12113.

Manufacture and processing occurred within established procedures to ensure product quality.

6/26/14

SEP 0 5 2014

CaseID: 10436018

CC-0438-2014 AE-0250-2014



EVENT DATA FORM



| AE #: | 1550 | | COMPLAINT | #: _2560 | | and the same of th |
|--|---|--|--|---|---|--|
| SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFE | RENT FROM REPORTER ON FORI | W VD1) | | |
| AIAAAT. | | (b) (6) | | | | |
| NAME: ADDRESS | | | | | | _ |
| ADDITESS | • | - | | | | |
| CITY: | | - | STATE: | (b) (6) | | |
| COUNTRY | ·: | USA | ZIP CODE: | | | |
| PHONE #: | | (b) (6) | | | | |
| E-MAIL: | | | | | | |
| SECTION I | <u>l:</u> | PACKAGING INFORMATION: | | | | |
| | AFFI | X PACKAGING LABEL HERE | AFFIX COPY OF O (INCLUDE DRUG FACTS PA | | | |
| to the party of th | of the end process to be to process to be to process to said (process to the end of the end to said (process to the end of the end to said (process to | Monte of the second of the sec | And the second of the second o | Ten Ten Ten Ten Ten Ten Ten Ten Ten Ten | with the state of | |
| SECTION II | <u>ll:</u> | CORRECTIVE ACTION: | | | | _ |
| CORRECTIV | VE ACT | TION(S) COMPLETED BY: | | DATE: | | - - - |
| SECTION IV | <u>/:</u> | | | | | DSS |
| SE//IE/WED | BV MA | NAGEMENT BY: | Jult | DATE: | 07-02-14 | SEP 0 5 2014 |
| VE A IEAAED | АМІТС | Qui V | <u> </u> | | | |
| BY: | *************************************** | QA / QC DIRECTOR | <u>u</u> | DATE: | 97-01-1 | 4 |
| | | | | | | |

DISTRIBUTION: FDA

ADVERSE EVENT FILE

FORM SAED1

| Fo | rm Approve | . 0910-0291 See OMB sta | | |
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| eport # | | | | |

CaseID: 10436103

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| aditie, nd nasufacturers | Mfr Report # 54973 | |
| | UF/Importer Report # | |
| | | |

FORM FDA 3500A (2/13)

Page 1

(b) USA

Phone #

2. Health Professional?

Yes No

(b) (6)

| of 5 | | | | FDA Use O |
|---|-------------------|----------------|--------------|---|
| C. SUSPECT PROD | | | | |
| Name (Give labeled stren | | | | |
| #1 HYLAND'S BABY | TEETHING TA | ABLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & Rou | te Used | | | funknown, give duration |
| #1 1 TABLET SL PR | N X 1 MO | from/to (o | r best es | stimate) |
| #2 | | #2 | | |
| 4. Diagnosis for Use (Indic. | ation) | 5. | | Abated After Use ed or Dose Reduced? |
| #1 TEMP RELIEF TE | ETHING PAIN | | - | es 🗆 No 🗀 Does |
| #2 | | - | | Apply |
| 6. Lot # | 7. Exp. Date | #2 | 2 N | es No Does |
| #1 | #1 | 8. | | Reappeared After |
| #2 | #2 | | Reintro | oduction? es □ No □ Does |
| 9. NDC# or Unique ID | | | · (¥_) 1. | es Lino Li Apply |
| 54973-3127-3 | | #2 | 2 🗌 Y | es No Does |
| 10. Concomitant Medical P | roducts and The | rapy Dates (E. | xclude t | reatment of event) |
| ORAJEL | | | | |
| | | | | |
| | | | | |
| | | | (C | ontinue on page 3) |
| D. SUSPECT MEDIC | AL DEVICE | | | |
| 1. Brand Name | | | | |
| 2. Common Device Name | | | 2b. Pt | rocode |
| 3. Manufacturer Name, City | y and State | | 1 | |
| | | | | |
| 4. Model # | Lot# | | | F. Ozerstan of Deviler |
| 4. MOGEL # | Lot # | | - | 5. Operator of Device |
| Catalog # | Expiration | Date (mm/dd/ | <i>YYYY)</i> | Health Profession |
| | | | | Lay User/Patient |
| Serial # | Unique Idea | ntifier (UDI)# | | Other: |
| 6. If Implanted, Give Date (| mm/dd/yyyyl | 7. If Evaluate | ed. Give | e Date (mm/dd/yyyy) |
| | | | , | (|
| 8. Is this a Single-use Devi | ce that was Repr | ocessed and | Reused | on a Patient? |
| Yes No | - N | | | |
| 9. If Yes to item No. 8, Ente | r Name and Addi | ess of Repro | cessor | |
| | | | | |
| | | | | |
| 10. Device Available for Eva | aluation? (Do not | send to FDA) | | |
| Yes No | Returned to Ma | anufacturer on | c | |
| 1. Concomitant Medical Pr | roducte and The | any Dates /E | xclude t | (mm/dd/yyyy) |
| Conconneant medical Pi | oducis and ther | apy vales (E | ACIOUE I | reament of event) |
| | | | | n - |
| | | | (Co | ontinue (Rip@e 3) |
| | | | | |
| E. INITIAL REPORTE | R | | | |
| E. INITIAL REPORTE 1. Name and Address (b) (6) | R | | | ontin a (%) 2014 |

| | A. PATIENT INF | ORMATION | | and the second | |
|------------------------------|---|---|------------------------|---------------------------------------|-----------|
| | Patient Identifier (b) (6) | | | 3. Sex | 4. Weight |
| | (6) (6) | of Event: | Months | Female | <u> </u> |
| | | Date | | | or |
| | In confidence | of Birth: | | ✓ Male | k |
| | B. ADVERSE E | VENT OR PRODUC | TPROBLE | W | |
| | 1. 🕢 Adverse Even | t and/or Proc | duct Problem (e | .g., defects/malf | unctions) |
| | Outcomes Attribu (Check all that appi | ted to Adverse Event | | | |
| | Death: | ,, | ☐ Disability o | r Permanent Dar | mage |
| | ✓ Life-threatenin | (mm/dd/yyyy) | | Anomaly/Birth D | |
| | | n - initial or prolonged | | ous (Important M | |
| | 1 — | vention to Prevent Perma | | | |
| | 3. Date of Event (mr. | | | Report (mm/dd | |
| | | 07/00/2014 | | 08/18/2014 | |
| | 5. Describe Event or | | | | |
| | | S THAT APPROXIM | | | |
| | | LD SON BABY TEET ER, HIS SON HAD | | | |
| | GIRLFRIEND TO | OK THEIR SON TO | THE EMERG | ENCY ROOM | AFTER |
| | THE EPISODE. | THE CHILD WAS S | | | |
| ž | | AN UNKNOWN AMOUN OSE OF TEETHING | | | |
| X | | EIZURE APPROXIM | | | |
| AC | 08/18/114 FOU | LOW-UP: SEIZURE | DESCRIPTION | n ac curin | CDACING |
| BL | | FTING, SHAKING, | | | SPACING |
| SE | UNRESPONSIVE. | CALLED 911 AND | IN THE H | SPITAL TH | |
| 2 | SEIZURES NOW. | FINE AND SENT HI | M HOME. | CHILD STIL | L HAVING |
| Ö | obabondo mom | Receiv | hal | | |
| ÞΕ | | | Vu | | |
| ΤY | | SEP 04.2 | Of A | | |
| SE | | V 1 2 | U17. | | |
| PLEASE TYPE OR USE BLACK INK | | CDR | | | |
| Ы | | ODI | | | |
| | | | | (Continue on | page 3) |
| | 6. Relevant Tests/Lat | | Dates . | <u>/•</u> | 1 - 3/ |
| | EEG AND MRI W | ERE NORMALT | céinè | a | |
| | CHILD GIVEN K | EPPRA BY HOSPITA | L. \ | | |
| | | SEF | , 0 3×5 0k | } | |
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| | | | <i>3</i> 13 1 2 | | |
| | | 2 | | | |
| | 7 Other Pelayant His | togy Including December | Mdi10 | (Continue on | page 3) |
| | race, pregnancy, sm | tory, Including Preexisti toking and alcohol use, he | patic/renal dysfo | inctions (e.g., all inction, etc.) | ergies, |
| | NO PRE-EXISTIN NO FEVER. NO | G CONDITIONS. HISTORY OF SEIZ | | ES OR ILLN | ESSES. |
| | | or obla | OWNO IN IN | | |
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| l | | | | (Continue on | |
| 5 | Submission of a re | port does not cons | titute an adn | nission that r | nedical |

caused or contributed to the event.

4. Initial Reporter Also Sent Report to FDA

Yes No V Unk. SEP 04 2014

Email Address

3. Occupation NΑ

| 01. 001 01 | 30LK I | | III VINTE | $K \cup D$ | HANGER | Only) |
|---|--------------|-----------------------|--------------|------------|---------------------|-------------------|
| 1. Check One | | | 2. UF/Imp | orter R | eport Nu | ımber |
| User Facility | lmt | oorter | | | | |
| 3. User Facility or Imp | orter Nam | e/Address | | | | |
| | | | | | | |
| 4. Contact Person | | | T6 D4 | No. | | |
| 4. Contact Leison | | | 3. Ph | one Nu | imber | |
| 6 Data Harr Frailite | | I | l | | | |
| Date User Facility or Importer Became | | 7. Type of R | eport | | 8. Date ((mm/c) | of This Report |
| Aware of Event (mm | /dd/yyyy) | Initial | | | | |
| | | Follow-t | ıp# | | | |
| 9. Approximate | 10. Event | Problem Cod | | to codin | o manuai | n |
| Age of Device | | | | 0 000111 | y manuai | , |
| | Patient Code | | - | | . _ | |
| | Device [| | ╡늗 | | | |
| | Code | | _]-[| | | |
| 11. Report Sent to FDA | ? | 12. Locatio | n Where E | event O | ccurred | |
| Yes | | Пно | spital | | Пои | itpatient |
| □ No (mm/dd/) | yyyy) | Пно | me | | | agnostic Facility |
| 13. Report Sent to Man | |] = | sing Home | | | nbulatory |
| | uracturer? | | tpatient Tre | | 30 | irgical Facility |
| Yes(mm/dd/) | anad | | ility | | | |
| No (minodo) | ryyy) | Oth | er: | | | |
| 14. Manufacturer Name | 14 44 | L | | | (Specify | () |
| G. ALL MANUFAC | TURER | S | | | | |
| 1. Contact Office (and N | Manufactu | ring Site for E | evices) | | 2. Phone | Number |
| Name | | | | 3 | 310-76 | 8-0700 |
| EDYTA FRACKIEWIC | CZ | | | | 3. Repor | t Source |
| Address | | | | | (Checi | k all that apply) |
| HYLAND'S, INC. | | | | - 1 | Forei | gn |
| 154 W. 131ST ST | | | | 1 | Study | / |
| LOS ANGELES, CA | 90061 | | | [[| Litera | ture |
| Email Address | | | | [| √ Cons | umer |
| | | | | 1 | Healt | h Professional |
| 4. Date Received by | | 5. | | [| User | Facility |
| Manufacturer (mm/dd/ | YYYY) | (A)NDA# | | [[| Comp | |
| 08/17/201 | . 4 | IND# | | | Repre Distrit | esentative |
| 6. If IND, Give Protocol # | | | | ¦ | Other | |
| | | BLA# - | | — I' | _ ome | |
| 7. Type of Report | | PMA/ | | - | | |
| (Check all that apply) | | 510(k) # | | | | |
| 5-day 30-day | | Combinatio Product | n □ v | es - | | |
| 7-day Periodic | ; | Pre-1938 | | | | |
| 10-day 📝 Initial | | OTC Produ | . ==- | l i | | |
| 15-day Follow-u | лр# | 0.011000 | ct [V]Ye | - | | |
| . Manufacturer Report N | lumber | 8. Adverse | Event Terr | n(s) | | |
| 54973 AE # 1559 | | SEIZURES | 5 | | | |
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This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the Paperwork Reduction Act or 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and minutaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | | FDA USE ONLY |
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| f <u>5</u> | | |
| H. DEVICE MANUFAC | TURERS ONLY | |
| 1. Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death | | Correction |
| Serious Injury | | Additional Information |
| Malfunction | | Response to FDA Request |
| | | Device Evaluation |
| | | |
| 3. Device Evaluated by Manu | | 4. Device Manufacture D ate (mm/yyyy) |
| Not Returned to Manu | | |
| | Summary Attached | |
| No (Attach page to exprovide code: | olain why not) or | 5. Labeled for Single Use? |
| | | Yes No |
| 6 Event Problem and Frederic | | |
| Event Problem and Evalua Patient | tion Codes (Refer to d | coding manual) |
| Code | - | - ' |
| Device | | |
| Code | | |
| Method |]-[|]_[|
| | | |
| Results | |]-[-] |
| Conclusions | | 7 |
| | | |
| 7. If Remedial Action Initiated | , Check Type 8. | Usage of Device |
| Recall No | tification | Initial Use of Device |
| Repair Ins | pection | Reuse |
| Replace Pa | tient Monitoring | Unknown |
| | dification/ 9. ustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | usunent | removal reporting number: |
| | | |
| | | |
| 10. Additional Manufactur | er Narrative an | d / or 11. Corrected Data |
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CaseID: 10436103

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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SEP 04 2014

OMB Statement: "An agency may not conduct or sponsor, and a person is not

Individual Case Safety Report

IPLAINT RECORD



| | 36103-01-00-03 | COMPLAINT #: | 2505 |
|---|---|---|---|
| | | DATE OF COMPLAINT: | 08/17/2014 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT40 |
| SIZE: | 40 TABLETS | LOT NO.: | REFUSES TO PROVIDE |
| REPORTER: | (b) (6) | | |
| ADDRESS: | | | |
| | · | | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: | USA | ZIP CODE: | |
| PHONE #: | (b) (6) | | |
| E-MAIL: | CALLED DEPORTS THAT APPROVE | MATELY ONE MONTH AGO, HE GAVE HIS 6 | MONTH OLD CON BARY TEETHING |
| OF TIME, CALLER ON COURS LATER. CAN EDYTA FRACKIEWICH CHILD STARTED SPASAID CHILD LOOKED IN THE HOSPITAL. HEAMILY HISTORY OF PURSUE LEGAL ACT | GENCY ROOM SOON AFTERWARDS. THE CHILD W. SAVE HIS SON ANOTHER DOSE OF TEETHING TABLE LLER THREATENED LEGAL ACTION IF HE DID NOT H Z FOLLOWED-UP. SPOKE WITH CUSTOMER ON 08/18/14 CING OUT, THEN EYES STARTED SHIFTING, SHAKING, O FINE AND SENT HIM HOME. EEG AND MRI WERE NORN AD ANOTHER EPISODE WHERE HE TOOK A TEETHING T SEIZURES. DOCTORS DON'T KNOW CAUSE OF SEIZUR ION AND WILL CALL THE FDA TODAY. OFFERED HIM A F | ETS AND CLAIMS THAT HE HAD ANOTHER S HEAR FROM SOMEONE BY TOMORROW. HE WAS USING ORAGEL AND THEN STARTEL COULD NOT BREATHE, UNRESPONSIVE. CALL IAL. WANTS TO KNOW WHY BELLADONNA IS I ABLET AND HAD A SEIZURE. CHILD STILL HAY ES BECAUSE ALL MEDICAL TESTS ARE NORM. | E. AFTER AN UNKNOWN AMOUNT SEIZURE APPROXIMATELY 6 8 D. USING THE TEETHING TABLETS. ED 911 AND IN THE HOSPITAL THEY N THE TABLETS. CHILD GOT KEPPRA VING SEIZURES NOW. HE CLAIMS NO AL. GOING TO THE LAWYER TO |
| , | FOR ADDITIONAL SPACE PLEASE US | E REVERSE OR ATTACH A SEPARATE SHE | ET |
| PRODUCT RECEIVE | ED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: Y N (CIRCLE ONE) |
| | ,, | DATE REQUESTED PRODUCT BE | RETURNED: |
| | | | |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| | | | T DECEIVED: |
| | | | |
| ECTION II: | INVESTIGATION | DATE PRODUC | Theorites, |
| SECTION II: | INVESTIGATION | DATE PRODUC | |
| SECTION II: | INVESTIGATION PLEASE SEE ATTACHED INVESTIGATION RE | | |
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| NVESTIGATION: | | EPORT. | |
| NVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION RE | TION ON: 08/17/201 | |
| NVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION RE | TION ON: 08/17/201 | |
| NVESTIGATION: ADVERSE EVENT F | PLEASE SEE ATTACHED INVESTIGATION REPORTED FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUA | TION ON: 08/17/201 | |
| NVESTIGATION: ADVERSE EVENT F | PLEASE SEE ATTACHED INVESTIGATION REPORTED FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUA | TION ON: 08/17/201 | |
| NVESTIGATION: ADVERSE EVENT F ADVERSE EVENT F SECTION III: | PLEASE SEE ATTACHED INVESTIGATION REPORTED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION: | EPORT. ATION ON: (b) (6) | |
| NVESTIGATION: ADVERSE EVENT F ADVERSE EVENT F SECTION III: | PLEASE SEE ATTACHED INVESTIGATION REPORTED FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUA | TION ON: 08/17/201 | 4 |
| ADVERSE EVENT F ADVERSE EVENT F SECTION III: | PLEASE SEE ATTACHED INVESTIGATION REPORTED TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION: | DATE: | 1559 DS |
| NVESTIGATION: ADVERSE EVENT F ADVERSE EVENT F SECTION III: | PLEASE SEE ATTACHED INVESTIGATION REPORTS ORWARDED TO PHARMACIST / NURSE FOR EVALUATION: CORRECTIVE ACTION: ON(S) COMPLETED BY: ADVERSE EVENT REPORTS | DATE: | - DS |
| ADVERSE EVENT F ADVERSE EVENT F SECTION III: CORRECTIVE ACTIONS SECTION IV: | PLEASE SEE ATTACHED INVESTIGATION REPORTS ORWARDED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DN(S) COMPLETED BY: ADVERSE EVENT REPORTS ERIOUS: | EPORT. ATION ON: O8/17/201 (b) (6) DATE: AE #: | 1559 DS |
| NVESTIGATION: ADVERSE EVENT F ADVERSE EVENT F SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT S ADVERSE EVENT R | PLEASE SEE ATTACHED INVESTIGATION REPORTS ORWARDED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DN(S) COMPLETED BY: ADVERSE EVENT REPORTS ERIOUS: | DATE: | 1559 DS |
| ADVERSE EVENT F ADVERSE EVENT F SECTION III: CORRECTIVE ACTIONS SECTION IV: | PLEASE SEE ATTACHED INVESTIGATION REPORTS ORWARDED TO PHARMACIST / NURSE FOR EVALUATION CORRECTIVE ACTION: DN(S) COMPLETED BY: ADVERSE EVENT REPORTS ERIOUS: | DATE: AT BY: EDYTA FRACK! | 1559 DS 1559 SEP 0 5 |
| NVESTIGATION: ADVERSE EVENT F ADVERSE EVENT F SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT S ADVERSE EVENT R | PLEASE SEE ATTACHED INVESTIGATION RECORD TO PHARMACIST / NURSE FOR EVALUATION ORWARDED TO PHARMACIST / NURSE FOR EVALUATION: CORRECTIVE ACTION: DN(S) COMPLETED BY: ADVERSE EVENT REPORTS ERIOUS: EPORTED ON: 08/18/2014 | DATE: AT BY: EDYTA FRACK! | 1559 DS |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

Individual Case Safety Report

10436103-01-00-04



Serious Adverse Event SAE-0036-2014

Product in Inventory:

The reporter was only provide the product name, Hyland's Baby Teething Tablets, not the lot number, location or purchase or date of purchase for the unit involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been eighty-three Adverse Events (AE) which also included twenty-two Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the lot number of the unit involved cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels have been found to meet the specification of 44 ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prebared by

Date

8/19/14

DSS SEP 0 5 2014

CaseID: 10436103

SEP 04 2014







| AE #:155 | 9 | COMPLAINT #: 2569 | |
|--------------------|--|--|--|
| SECTION I: | PATIENT INFORMATION (IF DIFFE | RENT FROM REPORTER ON FORM VD1) | |
| JAME: | (b) (6) | | |
| DUKESS. | | | |
| SITY: | | STATE: (b) (6) | and the second s |
| OUNTRY: HONE #: | USA | ZIP CODE: | |
| -MAIL: | | | A MATERIA DE PROPERTO |
| ECTION II: | PACKAGING INFORMATION: | | |
| AF | FIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | <i>(</i> |
| | Testing Tables Market State S | Can Land | |
| | Att. | lesthing lablets | |
| | | A STANDARD CONTRACTOR OF THE STANDARD CONTRACTOR | |
| | | ACCUMENT OF THE PROPERTY OF TH | |
| | | The state of the s | |
| ECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| | | | |
| | | | DS |
| ORRECTIVE A | CTION(S) COMPLETED BY: | DATE: | SEP 05 |
| ECTION IV: | $\bigcirc n$ | 1214 | |
| EVIEWED BY N | MANAGEMENT BY: | JUI 08-20- | 14 |
| Y: | Que Baix | DATE: 08-20- | -14 |
| | QA / QC DIRECTOR | SEP 04 2 | |



rnet Consumer Report

 CD_{ER}

'OLUNTARY reporting of 14

| | See OMB statement on revers |
|----------|-----------------------------|
| | FDA USE ONLY |
| age unit | 5/05/05/2 |

| The Lori Galety International | events, product problems product use errors |
|---------------------------------|--|
| Adverse Event Reporting Program | product use errors (|
| Adverse Event Reporting Frogram | |

| A DATIENT | NFORMATION | | | _ | . | | | | | _ | |
|---------------------------------------|--------------------------|--|--------------------|---------------------------|---|-------------|---------------------------------------|------------|------------|---------------------|----------------|
| | 2. Age at Time of Ev | ent or 3. Sex | 4. Weight | 2. #1 | Dose or Amount | | Frequen | icy | Route | | |
| (b) (6) | Date of Birth: | | 13 _{lb} | ļ | | | | | | | |
| | 2 Months (b)(6) | Female | | #2 | | | | | | | |
| In confidence | | ✓ Male | orkg | ĺ | | | ľ | | | | |
| B. ADVERSE Check all that apply | | T PROBLEM OR E | RROR | 3. D a | ites of Use (If unki r best estimate) | nown, give | duration) | from/to | | t Abated Af | |
| 1. 🗸 Adverse Eve | nt Product Prob | olem (e.g., defects/malfun | ctions) | #1 1 | 1/2 months | | | | #1 🔲 \ | Yes ✓ No | Doesn' |
| Product Use | Error Problem with | Different Manufacturer | of Same Medicine | #2 | | | | | | / | Apply Doesn' |
| 2. Outcomes Attril (Check all that a) | buted to Adverse Even | t | | | agnosis or Reaso | | | | | Yes No | ☐ Apply |
| Death: | | ✓ Disability or Permanen | t Damage | | Doctor thought early very fus | | was tee | ething | | t Reappeare | ed After |
| | (mm/dd/yyyy) | _ | • | #2 | | | | | #1 🗆 Y | res No | Doesn' |
| Life-threatenin | _ | Congenital Anomaly/B | | | | | | | #0 CJ | Du- | Apply Doesn't |
| Hospitalization | n - initial or prolonged | ☑ Other Serious (Importa nanent Impairment/Dama | nt Medical Events) | 6. Lo #1 | t# | 7. E) #1 | piration l | Date | | ∕es ∏ No | Apply |
| | | | | #2 | | - | | | 9. NDC | # or Unique | ID |
| 3. Date of Event (n | | 4. Date of this Report | mm/dd/yyyy) | | SUSPECT ME | | SEVICE | | | - | |
| | Problem or Product U | 09/28/2014 | | | SUSPECT ME | DICAL | JEVICE | | | | |
| | for complete tex | | | | and Hame | | | | | | |
| | | | | | | | | | $^{\sim}$ | 18 | |
| إ | | | | 2. Co | mmon Device Na | me | | | | 9 | |
| | | | | | | | | SF | P 2 g | 2044 | |
| | | | , | 3. Ma | nufacturer Name, | City and | State | - 0. | . 48 | - 2014 | |
| | | | | | | | | | | | |
| | | | | | | | | | | | |
| | | | | 4. M o | del # | Lo | et# | | | 5. Operato | r of Device |
| | | | | | | | | | | Health I | Professional |
| 6 Relevant Toete// | | | | Cat | talog # | Ex | piration l | Date (mm | /dd/yyyy) | Lay Use | er/Patient |
| 1 | | | | | | | | | | Other: | |
| 6. Relevant Tests/L | aboratory Data, Includ | - | | Sei | rial # | 0 | her# | - | | □ Otner: | |
| See page 3 | for complete tex | ĸt. | | | | | | | | | |
| See page 3 | | | | C 14 la | | | · · · · · · · · · · · · · · · · · · · | | | | |
| | | | İ | o. IT II | nplanted, Give Da | te (mm/do | ן (ענעניי | 7. If Expl | anted, Gi | ive Date (mi | n/dd/yyyy) |
| | | | | | his a Single-use D | evice tha | t was Rep | processe | and Re | used on a P | atient? |
| | | | İ | | Yes No | | | | | | |
| | | | | 9. If Y | es to Item No. 8, Er | iter Name | and Addre | ss of Rep | rocessor | | |
| 7. Other Relevant H | listory, Including Preen | xisting Medical Condition | ns (e.g., | | | | | | | | |
| | for complete tex | | obiems, etc.) | F 0 | THER (CONC | OBALTAN | **** BAC-C | | | | |
| | | | | | THER (CONC oct names and the | | | | | | |
| | | | | | ot hanco and the | rapy date | • (excidue | ucaunen | t or event | DSS | ; |
| | | | | | | | | | | | |
| | | | | | | | | | SF | EP 297 | 2014 |
| | | | | | EPORTER (Se | e confic | lentialit | y sectio | n on ba | ick) | |
| C. PRODUCT A | AVAILABILITY | | | 1. Na r (b) (6) | ne and Address | | | | | | |
| Product Available f | or Evaluation? (Do not | send product to FDA) | | (3) (0) | | | | | | | |
| ☑ Yes ☐ No | Returned to Manu | | | | | | | | | | |
| D. SUSPECT P | RODUCT(S) | (mm | /dd/yyyy) | | | | | | | | |
| | Manufacturer (from pro | duct label) | | _ Phone | # | | Т | E-mail | | | |
| #1 Name: Hyland | s Best Teething | | | (b) (6) | | | - 1 | (b) (6) | | | |
| Strength: | - | | - 1 | | M. D | | | | | | |
| Manufacturer: #2 Name: | | | | | Ith Professional? | 3. Occup | oation | | | Also Repor | |
| %2 Name: Strength: | | | | | Yes No | | | | | ✓ Manufac User Face | |
| Manufacturer: | | | | | ou do NOT want you he manufacturer, pl | - | | _ | | = | or/importer |

B.5. Describe Event or Problem (continued)

My son was a very fussy baby since birth in (b)(6) I took him to the dr around 1 month old and the doctor said he may be teething early and to try teething tablets. I started him on Hylands best teething tablets because my sister had given me a bottle for my 1 year old daughter not to long before that and she had never needed them. My son used them from 1 month old until 2 1/2 months old. When he was 2 1/2 months old I took him to (b) (6) Hospital in (b)(6) for a fever and seizure like symptoms. Once we arrived at the hospital he started having seizure like symptoms again. They did a spinal tap on him to test for menigitis but it came back with blood. They did the spinal tap two times and both times had blood so thy decided to do a catscan. It came back that my son had bleeding on the brain. He also had fractured ribs which I believe were caused when the spinal tap was perfomed. They said the only logical explanation for the bleeding on the brain was abusive trauma. I did not in any way shape or form harm my child. I have three children whom I love with all of my heart and would never ever hurt them. Now I'm hearing all these things about Hylands Best Teething tablets. That they can cause seizure like symptoms and bleeding on the brain and have actually read a few articles where they actually have caused severe issues with children and babies. Im desperately asking you to review this please and get back to me as soon a possible at (b)(6)

I have emailed Hylands several times over the last week and have go I have emailed Hylands several times over the last week and have gotten absolutely no response, please please help me.

Individual Case Safety Report

10483550-01-00-02

DSS SEP 2 9 2014

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

My son had to have brain surgery and had a shunt put in his head. He had to have several cat scans and several mri's. He had to stay in the hospital for a little over a week. He may have disbilities but it's to early to tell.

Individual Case Safety Report

10483550-01-00-03

DSS SEP 29 2014

CasefD:46483556

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:Black/African American Medical Conditions: Gerds (Acid Reflux)

Allergies: none

Important Information:

RX Meds: Shunt in the head

OTC Meds: My aunt who has temporary custody was still giving him the tablets until i seen all issus and told her, Orajel couch n col medicine

Individual Case Safety Report



10483550-01-00-04

DSS SEP 2 9 2014



ine FDA Safety Information and Adverse Event Reporting Program

nsumer Report

CaseID: 10486049

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

ARY reporting FER roduct problems and product use errors

FDA USE ONLY
Triage unit sequence # 5666102

| | Adverse Event Reporting Program | | ilu | | | |
|-------------------------------|--|--|--|--|---|--|
| | A. PATIENT INFORMATION 1. Patient Identifier (b) (6) 2. Age at Time of Event or Date of Birth: 6 Months (b) (6) | 3. Sex | 2. Dose or Amount #1 2 pills #2 | As neede | | tongue |
| INK | Product Use Error Problem with Differe 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: (mm/dd/yyyy) Life-threatening Hospitalization - initial or prolonged Other Required Intervention to Prevent Permanent II 3. Date of Event (mm/dd/yyyy) 4. Date 0 6 / 1 0 / 2 0 1 4 5. Describe Event, Problem or Product Use Erro See page 2 for complete text. | DBLEM OR ERROR g., defects/malfunctions) Int Manufacturer of Same Medicine Dility or Permanent Damage International Anomaly/Birth Defect Serious (Important Medical Events) Impairment/Damage (Devices) International Events (Impairment/Damage (Devices)) International Even | 4. Diagnosis or Reason #1 Fussiness from #2 6. Lot# #1 #2 E. SUSPECT MED 1. Brand Name 2. Common Device Name | 7/01/2014 for Use (Indication) teething 7. Expiration Da #1 #2 DICAL DEVICE | #1 Ves No #2 Yes No 8. Event Reappea Reintroduction #1 Yes No | Reduced? Doesn't Apply Doesn't Apply Pred After Po Doesn't Apply Doesn't Apply Doesn't Apply Reduced? |
| PLEASE TVPE OR LISE BLACK INK | | tes | 3. Manufacturer Name, 4. Model # Catalog # Serial # 6. If Implanted, Give Date Catalog Ca | Lot # Expiration Da Other # | 5. Operat | tor of Device h Professional dser/Patient |
| | 7. Other Relevant History, Including Preexisting allergies, race, pregnancy, smoking and alcohol use page 4 for complete text. | | | evice that was Repr ter Name and Address | rocessed and Reused on a | |
| (| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send pi Yes No Returned to Manufacturer D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product lab #1 Name: Hylands Best Teething table Strength: | on:(mm/dd/yyyy) | G. REPORTER (Set 1. Name and Address (b) (6) | E | section on back) | PSS 3 0 201 |
| ` | Manufacturer: #2 Name: Strength: Manufacturer: | | Health Professional? Yes No If you do NOT want you to the manufacturer, plane. | ır identity disclosed | 4. Also Rep Manufi User F | acturer |

B.5. Describe Event or Problem (continued)

My son was being fussy. I assumed it was his teeth and gave him two of Hyland's Best teething tablets. We then went to lay down and I breastfed him. While nursing he tensed up and began to tremor and shake involuntarily. I placed my hand over his arm and it did not stop the shaking. He was having a seizure. After it stopped (about 30 second's later) I called his doctor. We went in for an exam and a few days later had an EKG on his brain waves. The tests did not find anything wrong. I believe now that it was due to the teething tablets.

Individual Case Safety Report

10486049-01-00-02

DSS SEP 3 0 2014 EKG was inconclusive

Individual Case Safety Report

10486049-01-00-03

DSS SEP 3 0 2014

B.7. Other Relevant History, Including Preexisting

Race:American Indian/Alaskan Native Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds:

Individual Case Safety Report

10486049-01-00-04

CaseID: 1048664900 C

ysfunction, etc.) (continued)

SEP \$ 0 2014



The FDA Salety Information and Adverse Event Reporting Program

mer Report CDER

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

| Y reporting of | |
|--------------------|--|
| uct problems and | |
| product use errors | |

| | FDA USE ONLY | |
|---------------------------|--------------|--|
| Friage unit sequence # | 566093 | |
| | | |
| | | |

| A. PATIENT INFORMATION | | | | | Dose or Amount | Freque | ncy Ro | oute | _ |
|---|----------------|----------------------|-------------------|---------|---|-----------------|----------------|---|-----------|
| 1. Patient Identifier 2. Age at Time (b) (6) Date of Birth | | 3. Sex | 4. Weight | #1 | | | | | |
| 2 Years | _ | ☐ Female | 25 lb | #2 | | | _ | | _ |
| In confidence (b) (6) | | ✓ Male | or kg | #2 | | | | | |
| B. ADVERSE EVENT, PRO | DUCT PRO | BLEM OR ER | RROR | 3. Da | ates of Use (If unknown, | give duration | from/to 5 | . Event Abated After Use | |
| heck all that apply: | | | | (0) | r best estimate) | | s | stopped or Dose Reduced? | |
| = == | | ., defects/malfunct | - | - | 9/30/2011 - 09/3 | 30/2012 | # | 1 Yes No Doesr | n't |
| Product Use Error Problem | | nt Manufacturer o | f Same Medicine | | | | #: | 2 Yes No Doesr | |
| 2. Outcomes Attributed to Adverse (Check all that apply) | Event | | | | agnosis or Reason for Teething | Use (Indicatio | , <u> </u> | Apply Event Reappeared After | |
| Death: | Disabi | ility or Permanent I | Damage | l _ | | | _ | Reintroduction? | -4 |
| (mm/dd/yyyy) ✓ Life-threatening | ☐ Conge | enital Anomaly/Birt | h Defect | #2 | | | # | 1 ☐ Yes ☐ No ☑ Doesn Apply | |
| Hospitalization - initial or prolong | | - | | 6. Lo | t# | 7. Expiration | Date #2 | 2 Yes No Doesn | |
| Required Intervention to Preven | | | | #1 | | #1 | 9. | . NDC # or Unique ID | |
| . Date of Event (mm/dd/yyyy) | 4. Date | of this Report (m | nm/dd/yyyy) | #2 | | #2 | | | |
| 09/06/2012 | 09/2 | 29/2014 | | | SUSPECT MEDIC | AL DEVIC | | | |
| 5. Describe Event, Problem or Prod | | | | 1. Br | and Name | | | | |
| See page 2 for complete | cext. | | | | | | | | |
| | | | | 2. Co | ommon Device Name | | | VIU | _ |
| | | | | | | | | SEP 3 0 2014 | |
| | | | | 3. Ma | nufacturer Name, City | and State | | SU 2014 | _ |
| | | | | | • | | | | |
| | | | | 1 | | | | | |
| | | | | 4. Mc | odel# | Lot# | | 5. Operator of Device | • |
| | | | | | | | | Health Professiona | al |
| | | | | Ca | talog # | Expiration | Date (mm/do | d/yyyy) Lay User/Patient | |
| | | | | | | | | Other: | |
| . Relevant Tests/Laboratory Data, | Including Date | es | | Se | rial # | Other# | | | |
| | | | | | | | | | |
| | | | | 6. If I | mplanted, Give Date (n | mm/dd/vvvv) | 7 If Explan | nted, Give Date (mm/dd/yyyy) | _ |
| | | | | | | ***** | | , | |
| | | | | | this a Single-use Devid ີ Yes ☐ No | ce that was Re | eprocessed a | and Reused on a Patient? | _ |
| | | | | | es to Item No. 8, Enter N | Name and Add | ress of Repro | cessor | <u>-</u> |
| . Other Relevant History, Including | Proprieting I | Jadical Candidan | 200 | | | | • | | |
| allergies, race, pregnancy, smoking | and alcohol us | se, liver/kidney pro | blems, etc.) | | | | | | |
| See pagé for complete | text. | | | F. C | THER (CONCOM | ITANT) ME | DICAL PR | RODUCTS | |
| , | | | | Produ | uct names and therapy | y dates (exclud | de treatment o | of event) | _ |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | G. F | REPORTER (See co | onfidentiali | ty section | on back) | |
| C. PRODUCT AVAILABILITY | / | | | 1. Na | me and Address | | | | |
| roduct Available for Evaluation? (| | oduct to FDA) | | (b) (6 | , | | | <i>*</i> | 20 |
| Yes No Returned to | - | | | | | | | SEP | -0 |
| | | (mm/c | dd/yyyy) | | | | | SEP | 30 |
| . SUSPECT PRODUCT(S) Name, Strength, Manufacturer (fro | m nmdust lahe | e/l | | Phon | e # | | E-mail | | |
| Name: teething tablets | product table | ") | | (b) (6) | | | (b) (6) | | |
| Strength: unsure | | | . " | | M. B | • | | | _ |
| Manufacturer: | | | | | aith Professional? 3. (| Occupation | | 4. Also Reported to: | |
| Name: Strength: | | | | | Yes No | | | Manufacturer User Facility | |
| Manufacturer: | | | | _ | ou do NOT want your id the manufacturer, place | | - | Distributor/Importer | r |
| | Submission of | a report does not | constitute an ada | | that medical personnel | | | | |

B.5. Describe Event or Problem (continued)

I gave my son who is now 3 the teething tablets when he was a infant this recall really worries me when my son was two he began having seizures and almost died in my arms it lasted 15minutes the first tone and was hospitalized in icu. The second time lasted 11minutes was also hospitalized he also crys sometimes when he pees in his diaper it really scares me as a mother to know I was giving my child these harmful tablets I hope that my son has no damage from them.

Individual Case Safety Report

10486072-01-00-02

DSS 6EP **3** 0 2014

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds: Flintstones vitamins

Individual Case Safety Report



10486072-01-00-03

DSS SEP 30 2011



The FDA Safety Information and Adverse Event Reporting Program mer Report CD Form Approved: ON

CaseID: 10501178

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

| Y reporting of | |
|------------------------|--|
| act problems and | |
| product use errors / 3 | |

| 5/ | 060 | 83 | 32 | - | |
|----|-----|------|-------|--------|--------|
| | | | | | |
| | 54 | 5600 | 56683 | 566832 | 566832 |

| | NFORMATION | | | | Dose or Amour | nt Frequ | ency Route | |
|--|--|------------------------------|-----------------|------------------|--|-------------------------------------|--|-------------------------------|
| (b) (6) | 2. Age at Time of Ev | vent or 3. S | Sex | 4. Weight | #1 | | | |
| (5) (5) | 14 Months | | ✓ Female | 22 _{lb} | | | | |
| | (b) (6) | | Male | or | #2 | | | |
| In confidence | | | | kg | | | | |
| | EVENT, PRODUC | CT PROBL | EM OR ER | ROR | 3. Dates of Use (If un (or best estimate) | nknown, give duratio | n) from/to 5. Ev | ent Abated After Use |
| Check all that apply: 1. ✓ Adverse Even | | bloom to an at | | | #1 10/03/2014 - | 10/03/2014 | | ped or Dose Reduced? |
| | nt Product Prol | blem (e.g., de | efects/malfunct | ions) | Principle of the Control of the Cont | 10/03/2014 | #1 💆 | Yes No Doesi |
| | uted to Adverse Ever | | anulacturer o | T Same Medicine | | | #2 | Yes No Does |
| (Check all that app | ply) | nt | | | 4. Diagnosis or Reas #1 Teething bab | | The second secon | Apply ent Reappeared After |
| Death: | | Disability of | or Permanent I | Damage | | * | | introduction? |
| Life-threatening | mm/dd/yyyy) g | Congenita | l Anomaly/Birti | h Defect | #2 | | #1 | Yes No Does |
| Hospitalization | - initial or prolonged [| | | | 6. Lot # | 7. Expiratio | n Data #2 | Yes No Doesi |
| Required Inter- | vention to Prevent Perr | manent Impai | rment/Damage | (Devices) | #1 | #1 | | Apply |
| 3. Date of Event (mr | | | his Report (m | | #2 | #2 | | C # or Unique ID |
| 10/03/2014 | | 10/04/ | | m/aa/yyyy) | E. SUSPECT M | | | 331271 |
| | Problem or Product U | | 2014 | | 1. Brand Name | EDICAL DEVIC | E | |
| See page 2 f | or complete te | xt. | | | Drand reame | | | |
| | | | | | | | | |
| | | | | | 2. Common Device N | ame | | PM . |
| | | | | | | | | ~1U |
| | | | | | 3. Manufacturer Nam | e, City and State | | PT - A a |
| | | | | | | | | CT - 6 2014 |
| | | | | | | | | |
| | | | | | 4. Model # | Lot# | | 5. Operator of Device |
| | | | | | | | | |
| | | | | | | | | Health Professiona |
| | | | | . | Catalog # | Expiration | Date (mm/dd/yyy) | /) Lay User/Patient |
| Polovent Testal | hamter D. C. | | | | | | | Other: |
| . nelevant Tests/La | boratory Data, Includ | ding Dates | | | Serial # | Other# | | - |
| | | | | 2 | | | | |
| | | | | | 6. If Implanted, Give D | ate (mm/dd/ssed | 7 If Evalented | Give Date (mm/dd/yyyy) |
| | | | | | | | | |
| | | | | 2 | 8. Is this a Single-use | Device that was R | eprocessed and R | eused on a Patient? |
| | | | | | Yes No | | | |
| | | | | 1 | 9. If Yes to Item No. 8, E | nter Name and Add | ress of Reprocesso | r |
| | tory, Including Press | xisting Medic | al Conditions | (e.g., | | | | |
| Other Relevant His allergies, race, pred | nancy, smoking and a | alcohol use live | pr/kidnou nech | lame otal | | | | |
| allergies, race, preg | nancy, smoking and a or complete tex | alcohol use, liv | er/kidney prob | lems, etc.) | C OTHER | | | |
| allergies, race, preg | mancy, smoking and a | alcohol use, liv | er/kidney prob | lems, etc.) | F. OTHER (CONC | COMITANT) ME | DICAL PROD | JCTS |
| allergies, race, preg | mancy, smoking and a | alcohol use, liv | er/kidney prob | lems, etc.) | F. OTHER (CONC Product names and th | COMITANT) ME erapy dates (exclud | DICAL PRODU | JCTS nt) |
| allergies, race, preg | mancy, smoking and a | alcohol use, liv | er/kidney prob | lems, etc.) | F. OTHER (CONC Product names and th | COMITANT) ME erapy dates (exclud | EDICAL PRODI | JCTS nt) |
| allergies, race, preg | mancy, smoking and a | alcohol use, liv | er/kidney prob | lems, etc.) | F. OTHER (CONC Product names and th | COMITANT) ME erapy dates (exclud | EDICAL PRODU de treatment of even | JCTS nt) |
| allergies, race, preg | mancy, smoking and a | alcohol use, liv | er/kidney prob | lems, etc.) | Product names and th | erapy dates (exclud | de treatment of ever | nt) |
| See page 4 fo | nnancy, smoking and a or complete tex | alcohol use, liv | er/kidney prob | lems, etc.) | F. OTHER (CONC Product names and the G. REPORTER (S 1. Name and Address | erapy dates (exclud | de treatment of ever | nt) |
| See page 4 fo | nancy, smoking and a or complete tex | alcohol use, liv | er/kidney prob | lems, etc.) | Product names and the | erapy dates (exclud | de treatment of ever | nt) ack) |
| See page 4 fo | //AILABILITY | send product | er/kidney prob | lems, etc.) | G. REPORTER (S 1. Name and Address | erapy dates (exclud | de treatment of ever | nt) ack) |
| See page 4 for PRODUCT AV roduct Available for Yes No | /AILABILITY *Evaluation? (Do not.) Returned to Manuf | send product | to FDA) | | G. REPORTER (S 1. Name and Address Name: (b) (6) | erapy dates (exclud | de treatment of ever | nt) ack) |
| PRODUCT AV | /AILABILITY revaluation? (Do not. | send product | er/kidney prob | | G. REPORTER (S 1. Name and Address Name: (b) (6) | erapy dates (exclud | de treatment of ever | DSS OCT 0 6 2 |
| PRODUCT AVOCATE No. PRODUCT AVOCATE No. PRODUCT AVOCATE NO. PRODUCT NO. PROD | /AILABILITY revaluation? (Do not. Returned to Manuf ODUCT(S) anufacturer (from proc | send product | to FDA) | Vivivi) | G. REPORTER (S 1. Name and Address Name: (b) (6) Address: City: Phone # | erapy dates (exclud | ty section on b State: Zi | DSS OCT 0 6 2 |
| PRODUCT AVOCATION OF THE Name, Strength, Manuel Teething | /AILABILITY /Evaluation? (Do not. Returned to Manuf ODUCT(S) anufacturer (from proc. g tablets | send product facturer on: | to FDA) | Vivivi) | G. REPORTER (S 1. Name and Address Name: (b) (6) Address: City: | erapy dates (exclud | ity section on b | DSS OCT 0 6 2 |
| PRODUCT AV roduct Available for SUSPECT PR Name, Strength, Manage: Teething Strength: Hyland | /AILABILITY revaluation? (Do not. Returned to Manuf ODUCT(S) anufacturer (from proc g tablets is teething tab. | send product facturer on: | to FDA) | V/2222) | G. REPORTER (S 1. Name and Address Name: (b) (6) Address: City: Phone # (b) (6) | erapy dates (exclud | state: Zi | DSS OCT 0 6 2 |
| See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 5 for See page 5 for See page 5 for See page 5 for See page 5 for See page 6 for See pa | /AILABILITY revaluation? (Do not. Returned to Manuf ODUCT(S) anufacturer (from proc g tablets is teething tab. | send product facturer on: | to FDA) | V/2222) | G. REPORTER (S 1. Name and Address Name: (b) (6) Address: City: Phone # (b) (6) 2. Health Professional? | erapy dates (exclud | state: Zi | DSS OCT 0 6 2 |
| PRODUCT AV roduct Available for Yes No SUSPECT PR Name, Strength, Ma Name: Teething Strength: Hyland | /AILABILITY revaluation? (Do not. Returned to Manuf ODUCT(S) anufacturer (from proc g tablets is teething tab. | send product facturer on: | to FDA) | <i>(/////)</i> | G. REPORTER (S 1. Name and Address Name: (b) (6) Address: City: Phone # (b) (6) | ee confidentiali | state: ZI E-mail (b) (6) | DSS OCT 0 6 2 |

B.5. Describe Event or Problem (continued)

Last night I used Hylands teething tablets, 2 of them on my 14 month old baby. That was the beginning of our nightmare! Within 20 minutes of giving this to our baby, she became anxious, jumpy, delerium set in and she was completely spaced out. My husband and I heard a pounding noise from her room around lam, went in to check her and she was sitting in her crib spaced out banging her head on the crib railing. Then it seemed like she was hallucinating. She was babbling the few words she knows over and over for hours. Yet she was still spaced out, not acting herself. This was a very scary event for us as parents to Wittness. I know this was caused from the hylands teething tablets. Please look into this over the counter medicine.

Individual Case Safety Report

10501178-01-00-02

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds: Infant Tylenol

Individual Case Safety Report



10501178-01-00-03



CaseID: 10510040

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

Y reporting of uct problems and product use errors

| | FDA USE ONLY | |
|---------------------------|--------------|--|
| Triage unit sequence # | 567251 | |
| 55425.135 17 | JUIJJI | |
| | • | |
| | | |

| | Damarti | d | product u | ise error | 1 1 1 4 | | | 351 | |
|--|--|--|--------------------------------------|--|--|--------------------------|-------------------------|-----------------------------|------------------------------|
| A. PATIENT IN | Reporting Progr | am | | - - | 119 | L | | | |
| | 2. Age at Time of Ev | vent or 3. Sex | 4. Weight | 2. [| ose or Amount | Freque | ency F | Route | |
| (b) (6) | Date of Birth: | | 35 _{lb} | " | | | 11 | · - | |
| | 1 Years (b)(6) | Female | B | #2 | | - | | | |
| In confidence | | ✓ Male | orkg | | | | | | |
| B. ADVERSE | EVENT, PRODUC | CT PROBLEM OR E | RROR | 3. Dat | es of Use (If unknown | n, give duration | n) from/to | 5. Event Abated | After Use |
| Check all that apply: | | | | l (or | best estimate) | _ | | Stopped or Dose | Reduced? |
| 1. Adverse Event | | blem (e.g., defects/malfur | | | /25/2013 - 06/ | 01/2014 | | #1 ☑ Yes ☐ N | No ☐ Doesn Apply |
| | | h Different Manufacturer | of Same Medicine | | | | | #2 Yes N | lo Doesn |
| (Check all that app | uted to Adverse Ever | nt · | | | gnosis or Reason for eething | r Use (Indicati | | 8. Event Reappe | Apply |
| Death: | | Disability or Permaner | nt Damage | l _ | | | | Reintroduction | n? |
| (r) Life-threatening | mm/dd/yyyy) | Congenital Anomaly/B | lirth Defect | #2 | | | | #1 🗌 Yes 🔲 N | lo ☑ Doesn Apply |
| | • | Other Serious (Imports | | 6. Lot | # | 7. Expiration |) Date | #2 Yes N | |
| Required Interv | vention to Prevent Per | manent Impairment/Dama | age (Devices) | #1 | - | #1 | | | |
| 3. Date of Event (mn | | 4. Date of this Report | | #2 | | #2 | | 9. NDC # or Uniq | ue ID |
| 06/01/2014 | | 10/08/2014 | (питьско уууу) | E. S | USPECT MEDIC | | F | | |
| | Problem or Product U | , , | | | nd Name | LEDEVIC | - | | |
| | or complete te | | | | | | | | |
| | | | | 2 Con | mon Device Name | | | | |
| | | | | 2. CON | on Device Name | | | | |
| | | | | | | | | | |
| | | | | 3. Man | ufacturer Name, City | and State | | | |
| | | | | | | | | | |
| | | | | l | | | | | |
| | | | | 4. Mod | el# | Lot# | | 5. Opera | tor of Device |
| | | | | | | | | ☐ Healt | h Professional |
| | | | | Cata | log# | Expiration | Date (mm/o | (d/yyyy) Lav L | Jser/Patient |
| | | | | | | | - | | |
| 5. Relevant Tests/La | boratory Data, Includ | ding Dates | | Seria | ni # | Other# | | Other | |
| See page 3 fo | or complete te | ĸt. | | | | 0 | | | |
| | | | | 6 141 | lantad Of a Date of | | 1 | | |
| | | | | o. ir im | planted, Give Date (n | nm/ad/yyyy) | 7. If Expla | nted, Give Date (| mm/dd/yyyy) |
| | | | | | | | | and Reused on a | Patient? |
| | | | | 8. Is th | s a Single-use Devic | e that was R | eprocessed | | |
| | | | | │ | s a Single-use Devic Yes | | | | |
| | | | | │ | s a Single-use Devic Yes No to Item No. 8, Enter N | | | | |
| . Other Relevant His | story, Including Pree | xisting Medical Condition | ns (e.g., | │ | res ∐ No | | | | |
| allergies, race, preg | story, Including Pree gnancy, smoking and a or complete te | alcohol use, liver/kidney pi | i ns (e.g., roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter N | lame and Add | ress of Repro | ocessor | |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidney pi | ns (e.g., roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter N | lame and Add | ress of Repro | ocessor RODUCTS | |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidney pi xt . | roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter N | lame and Add | ress of Repro | ocessor RODUCTS | |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidney pi | roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter N | lame and Add | ress of Repro | ocessor RODUCTS | |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidney pi xt . CTU | roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter N | lame and Add | ress of Repro | ocessor RODUCTS | |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidney pi xt . | roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter No. | ITANT) ME | TOTCAL P | RODUCTS of event) | |
| ailergies, race, preg See page 4 fo | nancy, smoking and a | alcohol use, liver/kidney pi xt . CTU | roblems, etc.) | 9. If Yes | Yes No to Item No. 8, Enter N | ITANT) ME | TOTCAL P | RODUCTS of event) | |
| See page 4 fo | VAILABILITY | oct 09 | roblems, etc.) | 9. If Yes | Yes No It to Item No. 8, Enter No. 18, Enter | ITANT) ME | TOTCAL P | RODUCTS of event) | |
| See page 4 fo | VAILABILITY | CTU OCT 09 | roblems, etc.) | 9. If Yes F. OT Product G. RE 1. Name | Yes No It to Item No. 8, Enter No. 18, Enter | ITANT) ME | TOTCAL P | RODUCTS of event) on back) | |
| See page 4 for See PRODUCT AV | VAILABILITY revaluation? (Do not | CTU OCT 09 t send product to FDA) ufacturer on: | roblems, etc.) | 9. If Yes F. OT Product G. RE 1. Name | Yes No It to Item No. 8, Enter No. 18, Enter | ITANT) ME | TOTCAL P | RODUCTS of event) on back) | |
| See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 5 for See page 6 for See pa | VAILABILITY revaluation? (Do not | OCT 0 9 | 2014 | 9. If Yes F. OT Product G. RE 1. Nam (b) (6) | Yes No I to Item No. 8, Enter No. 10 Item No. 8, Enter No. 10 Item | ITANT) ME | TOTCAL P | RODUCTS of event) on back) | |
| See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 5 for See page 5 for See page 5 for See page 5 for See page 6 for See page 7 for See pa | VAILABILITY r Evaluation? (Do not Returned to Manus SODUCT(S) anufacturer (from pro | OCT 0 9 | 2014 | 9. If Yes F. OT Product G. RE 1. Name (b) (6) | Yes No I to Item No. 8, Enter No. 18 IHER (CONCOMINATION OF THE PROPERTIES OF THE PR | ITANT) ME | DICAL Project treatment | RODUCTS of event) on back) | |
| See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 5 for See page 5 for See page 5 for See page 5 for See page 6 for See page 7 for See pa | VAILABILITY r Evaluation? (Do not Returned to Manus SODUCT(S) anufacturer (from pro | OCT 0 9 | 2014 | 9. If Yes F. OT Product G. RE 1. Nam (b) (6) | Yes No I to Item No. 8, Enter No. 18 IHER (CONCOMINATION OF THE PROPERTIES OF THE PR | ITANT) ME | DICAL Project treatment | RODUCTS of event) on back) | |
| See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 5 for See page 5 for See page 5 for See page 6 for See page 7 for See pa | VAILABILITY r Evaluation? (Do not Returned to Manus SODUCT(S) anufacturer (from pro | OCT 0 9 | 2014 | 9. If Yes F. OT Product G. RE 1. Nam (b) (6) | HER (CONCOM) to Item No. 8, Enter No. 14 HER (CONCOM) t names and therapy PORTER (See continuous and Address | ITANT) ME | DICAL Project treatment | RODUCTS of event) on back) | DSS 0 9 201 |
| See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for See page 4 for Suspect PR Name, Strength, Manufacturer: | VAILABILITY r Evaluation? (Do not Returned to Manus SODUCT(S) anufacturer (from pro | OCT 0 9 | 2014 | 9. If Yes F. OT Produc G. RE 1. Name (b) (6) | HER (CONCOM) to Item No. 8, Enter No. 14 HER (CONCOM) t names and therapy PORTER (See continuous and Address | ITANT) ME | DICAL Project treatment | an back) | DSS 0 9 201 |
| C. PRODUCT AV Product Available for Yes No D. SUSPECT PR I. Name, Strength, Matter Hyland's Strength: | VAILABILITY r Evaluation? (Do not Returned to Manus SODUCT(S) anufacturer (from pro | OCT 0 9 | 2014 | 9. If Yes F. OT Product G. RE 1. Name (b) (6) Phone 4 (b) (6) | The Head of the He | ITANT) ME dates (exclude | E-mail (b) (6) | RODUCTS of event) on back) | DSS 0 9 2014 orted to: |

B.5. Describe Event or Problem (continued)

We believe the Hyland's teething tablet are causing my child to have seizures within 24 hours of giving them. Beginning of June, I decided to throw them all away and we have seizure free since. I have spent nights in the hospital for seizures, a few EEGs and MRIs have been done. We have had more than 10 seizures that have started back in 4/2013. He had the most seizures in 7/2013 when he was first two teeth were coming in. And I know I was giving him teething tablets then but just keep thinking it was ear infection related... But now I have a theory it was those tablets! And that make me mad/sad and disappointed.

Individual Case Safety Report

10510040-01-00-02

DSS OCT 0 9 2014 EEG: normal MRI: stated he has a hippocampal malformation

Individual Case Safety Report

10510040-01-00-03

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions: He was diagnosed with Febrile Seizures but not sure anymore

Allergies: n/a

Important Information: n/a

RX Meds:

OTC Meds: Children's Chewable Vitamin

Individual Case Safety Report



10510040-01-00-04



Adverse Event Reporting Program

| | Adverse Event | Reporting Prog | ram | | • | | " 16 | | | | | | |
|---|--|--|------------|-----------------------|----------------------------|-----------------|--|------------|--------------|---|-------------|-----------------------|----------------|
| | A. PATIENT IN | | | | | | Dose or Amount | , | Freque | ncy f | Route | | |
| | 1. Patient Identifier (b) (6) | 2. Age at Time of E Date of Birth: | vent or | 3. Sex | 4. Weight | #1 | | |][| T I | | | |
| | | 9 Months | | Female | lb | #2 | <u></u> | | <u> </u> | | | | |
| | In confidence | (b) (6) | | ☐ Male | or 9.3 kg | "2 | | | | | | | |
| | | EVENT, PRODU | CT PR | OBLEM OR F | | 3 Da | tes of Use (If unk | nown div | e duretion |) framfa | 5 Even | t Abated A | Cor Llea |
| | Check all that apply: | | • • • • • | O D L L III O I C L I | THO IT | (or | r best estimate) | | | , nonvio | | d or Dose F | |
| | 1. 🕢 Adverse Even | _ | | g., defects/malfunc | , | I | 0/10/2014 - | 10/10/ | 2014 | | #1 🔲 \ | Yes ☑ No | Doesn't Apply |
| | | rror Problem wit | | ent Manufacturer | of Same Medicine | | | | | | #2 🗍 ነ | Yes ∏No | ☐ Doesn't |
| | 2. Outcomes Attrib | uted to Adverse Eve ply) | nt | | | | agnosis or Reaso Baby teething | | (Indication | | | t Reappear | — Apply |
| | Death: | | Disa | bility or Permanent | Damage | | | | | | Reint | roduction? | , |
| | Life-threatening | mm/dd/yyyy) g | Cong | genital Anomaly/Bir | th Defect | #2 | | | | | #1 📙 ነ | ∕es ∐No | Doesn't Apply |
| | / Hospitalization | - initial or prolonged | | | | 6. Lot | t# | 7. 8 | xpiration | Date | #2 🔲 Y | res 🗌 No | Doesn't Apply |
| | Required Interv | vention to Prevent Pe | rmanent l | Impairment/Damag | e (Devices) | #1 | | #1 | | t | 9. NDC | # or Unique | |
| | 3. Date of Event (mi | m/dd/yyyy) | 4. Dat | e of this Report (r | nm/dd/yyyy) | #2 | | #2 | | | | | |
| | 10/12/2014 | | | 12/2014 | | | SUSPECT ME | DICAL | DEVIC | Ε | | | |
| | | Problem or Product for complete to | | r | | 1. Bra | and Name | | | | | | |
| | oco pago 2 for complete text. | | | | | | | | | C | TU | | |
| 24 | | | | | | 2. Co | mmon Device Na | me | | | | | |
| Z | | | | | | | | | | (| JCT J | 4 2014 | 4 |
| Š | | | | | | 3. Ma | nufacturer Name | , City and | State | *************************************** | | | |
| ĽĀ | | | | | | | | | | | | | |
| 田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田田 | | | | | | | 3-14 | | | | | | |
| S | | | | | | 4. Mo | G01 # | - 1 | .ot# | | | | or of Device |
| 8 | | | | | | | | | | | | Hearth | Professional |
| TYPE OR USE BLACK INK | | | | | | Cat | talog# | | xpiration | Date (mm/c | dd/yyyy) | Lay Us | er/Patient |
| | 6. Relevant Tests/La | aboratory Data Inch | ding Da | to a | | | | | | | | Other: | |
| PLEASE | | or complete te | | 160 | | Ser | ial# | 0 | ther# | | | | |
| EA | | | | | | | | | | | | | |
| PI | | | | | | 6. If In | nplanted, Give Da | ate (mm/c | (d/yyyy) | 7. If Expla | inted, Gi | ive Date (m | m/dd/yyyy) |
| | | | | | | 8. is ti | his a Single-use I | Device th | at was Re | processed | and Re | used on a l | Patient? |
| | | | | | | | Yes No | | | | | | |
| | | | | | | 9. If Ye | es to Item No. 8, E | nter Name | and Addi | ress of Repr | ocessor | | |
| | Other Relevant His allergies, race, pres | story, including Pre- gnancy, smoking and | existing l | Medical Condition | ns (e.g., oblems. etc.) | | | | | | | | |
| | | | | | | F. O | THER (CONC | OMITA | NT) ME | DICAL P | RODU | CTS | |
| | | | | | [| | ct names and the | | | | | | |
| ı | | | | | .] | See | page 5 for c | omplet | e text | _ | | | |
| | | | | | | | | | | | | | |
| ١ | | | | | | G. R | EPORTER (Se | ne conf | identiali | ty soction | on b | 00/61 | |
| - 1 | C. PRODUCT A | VALLABILITY | | | | 1. Nan | ne and Address | | derraan | ty section | UII Da | (CK) | |
| 1 | Product Available fo | | ot send p | roduct to FDA) | | (b) (6 |) | | | | | 1 | 22 |
| | ✓ Yes No | Returned to Man | - | , | | | | | | | | | SS I 4 2014 |
| | | | | (mm/c | dd/yyyy) | | | | | | | 1 | 4 2014 |
| • | D. SUSPECT PR 1. Name, Strength, M | | oduct lah | ei) | | Phone | # | | | E-mail | | | |
| Λ | #1 Name: Hyland | | | | | (b) (6) | | | | | | | |
| | Strength: Manufacturer: Hy: | land | | | | 2 Head | Ith Professional? | 3.0 | matle- | | | Abr | |
| \lor | Name: | ±aiiu | | | | | ith Professional? Yes ☐ No | Pharmac | | | - 1 . | Also Repo | |
| ľ | Strength: | | | | ĺ | | u do NOT want yo | | | d | | ∐ Manura ✓ User Fa | |
| Ĺ | Manufacturer: | | | | | to th | e manufacturer, p | lace an ") | (" in this b | ox: | l i | Distribut | tor/Importer |
| | FORM FDA 3500 | (1/09) Subn | nission of | a report does not | constitute an adm | ission th | at medical persor | nnel or th | e product | caused or o | ontribute | ed to the ev | ent |

onal Repor

orting of oblems and

رد,

Triage unit sequence #

CaseID: 10519215

OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse,

FDA USE ONLY

B.5. Describe Event or Problem (continued)

Pt was given Hyland Teething Tablets Friday evening. She was acting differently afterward. Pt was admitted for fever, dehydration, N/V, diarrhea, and recent head injury. Pt experienced a seizure (b)(6) during hospital

Individual Case Safety Report

10519215-01-00-02

DSS OCT 1 4 2014

Individual Case Safety Report

DSS OCT 1 4 2014 FC

A. PATIENT INFORMATION

2. Age at Time

of Event:

Date

of Birth:

1. Patient Identifier

In confidence

10529024-01-00-01

Months

9

ruser-facilities, itors and manufacturers TORY reporting

4. Weight

or

Female

✓ Male

| | See OMB statement on reverse |
|----------------------|------------------------------|
| Mfr Report # 5193 | |
| 59973 | |
| UF/Importer Report # | |
| | |
| | |

CaseID: 10529024

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015

| | in confidence | of Birth: | | [A] Male | kgs | |
|-------------------------|--|-----------------------------------|---------------------------------------|---------------------|----------------|--|
| | B. ADVERSE EV | ENT-OR PRODU | CT PROBLE | Misteria interitori | marin mining | |
| | 1. Adverse Even | and/or Pro | duct Problem (e. | .g., defects/malf | unctions) | |
| | 2. Outcomes Attribut | ed to Adverse Event | · · · · · · · · · · · · · · · · · · · | | | |
| | (Check all that apply | 7 | C Divition | | | |
| | Death: | (mm/dd/yyyy) | | r Permanent Dar | | |
| | Life-threatenin | • | | Anomaly/Birth D | | |
| | | - initial or prolonged | | ous (Important M | | |
| | | rention to Prevent Perma | | | | |
| | 3. Date of Event- (mm | 09/00/2014 | 4. Date of This | | <i>(YYYY</i>) | |
| | 5. Describe Event or | | | 10/01/2014 | | |
| | | | | | | |
| E TYPE OR USE BLACK INK | MOTHER SAW THE FACEBOOK POST ABOUT SEIZURES AND BRAIN BLEEDS AND IS CONCERNED THAT WHENEVER SHE GIVES HER CHILD THE TEETHING TABLETS, HE STARTS SHAKING AND WAVING HIS ARMS LIKE HE'S EXCITED AND SQUEEZING HIS HANDS TOGETHER. SHE DOES NOT KNOW WHAT THIS IS BUT DOES NOT THINK IT'S A SEIZURE BECAUSE SHE HAD SEIZURES AS A CHILD. 9 MOS. OLD MALE. TAKING BABY TEETHING TABLETS 2 -3 SL BID X 2 MONTHS. FOLLOW-UP 09/30/14: SHE CALLED THE DOCTOR AND HE SAID HE WILL LOOK INTO THIS WEEK AND SEND CHILD TO A NEUROLOGIST. CHILD IS INTERACTING WITH MOTHER DURING SHAKING BUT EACH TIME IT'S DIFFERENT. SOMETIMES CHILD SHAKES HIS HANDS AND LEGS, SOMETIMES JUST HIS HEAD, SOMETIMES JUST HIS ARMS. AFTER SHAKING HE'S BACK TO NORMAL. SHAKING GOES ON FOR UP TO 30 SECONDS BUT NOT | | | | | |
| ASE | (LIKE A STRAIG SHAKEN SINCE S | HT SMILE WITH N HE DISPOSED OF | O EMOTION) THE TABLET | . HAS NOT | | |
| PLE_{A} | WAS ON SUNDAY, | | | | | |
| Д | | | | | | |
| | | | | (Continue on | page 3) | |
| | 6. Relevant Tests/Labo | eratory Data, Including | Dates | , | , -9- 4/ | |
| | NONE | | | | | |
| | No. | | | | | |
| | | HE (| CEIV | ED | | |
| | - | 00 | T 16 201 | 4 | | |
| | 7. Other Relevant Hier | ry locluding Promisi | | Continue on | | |
| | Other Relevant Historace, pregnancy, smo NONE | king and alcohol use, he | patic/renal dysfur | nctions (e.g., alle | rgies, | |

1 of ⁵ FDA Use Only C. SUSPECT PRODUCT(S) Name (Give labeled strength & mfr/labeler) #1 HYLAND'S BABY TEETHING TABLETS #2 2. Dose, Frequency & Route Used Therapy Dates (If unknown, grive duration) from/to (or best estimate) #12-3 TABS SL BID X 2 MOS #2 Diagnosis for Use (Indication) Event Abated After Use Stopped or Dose Reduced? #1 TEMP RELIEF TEETHING PAIN Doesn't Apply #1 ☐ Yes 📝 No Doesn's #2 Yes No Apply 6. Lot # 7. Exp. Date #1A46514 8. Event Reappeared After #1 Reintroduction? #2 #2 Doesn't #1 Yes No 9. NDC# or Unique ID Doesn't #2 Yes No 54973-3127-1 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) D. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name 2b. Procode 3. Manufacturer Name, City and State 4. Model# Lot # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: Serial # Unique Identifier (UDI) # 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) E. INITIAL REPORTER 1. Name and Address (b) (6) USA OCT 1 6 2014 Phone # (b) (6) Email Address 2. Health Professional? 3. Occupation Initial Reporter Also Sent Report to FDA NA Yes 🗸 No Yes No Unk

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

(Continue on page 3)

Individual Case Safety Report CaseID: 10529024 FDA USE ONLY age 2 of 5 H. DEVICE MANUFACTURERS ONLY 1. Check One Z. UT/IIIIDORLEI NEDULLINGIDEI Type of Reportable Event 2. If Follow-up, What Type? User Facility [Importer ☐ Death Correction 3. User Facility or Importer Name/Address Serious Injury Additional Inform ation Malfunction Response to FDA Request Device Evaluation 4. Device Manufacture Date 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer 4. Contact Person 5. Phone Number Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: Labeled for Single Use? 6. Date User Facility or Type of Report 8. Date of This Report Importer Became Aware of Event (mm/dd/yyyy) (mm/dd/yyyy) Yes ☐ No Initial 6. Event Problem and Evaluation Codes (Refer to coding manual) Follow-up # Patient 9. Approximate 10. Event Problem Codes (Refer to coding manual) Code Age of Device Patient Device Code Code Device Method Code 11. Report Sent to FDA? 12. Location Where Event Occurred Results Hospital Outpatient
Diagnostic Facility Yes (mm/dd/yyyy) Home ☐ No Conclusions Ambulatory Surgical Facility Nursing Home 13. Report Sent to Manufacturer? 7. If Remedial Action Initiated, Check Type 8. Usage of Device Outpatient Treatment Yes Facility Recall Initial Use of Device Notification (mm/dd/yyyy) ☐ No Other: Reuse Repair Inspection (Specify) Unknown Replace Patient Monitoring 14. Manufacturer Name/Address If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: Modification/ Adjustment Relabeling Other: 10. Additional Manufacturer Narrative 11. Corrected Data and / or G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number 310-768-0700 EDYTA FRACKIEWICZ 3. Report Source (Check all that apply) Address Foreign HYLAND'S, INC. 154 W. 131ST STREET Study LOS ANGELES, CA 90061 Literature √ Consumer Email Address Health Professional STANDARD@HYLANDS.COM Date Received by Manufacturer (mm/dd/yyyy) ☐ User Facility Company (A)NDA# DSS Representative 09/28/2014 IND# Distributor 6. If IND, Give Protocol# OCT 1 7 2014 Other: BLA# PMA/ 7. Type of Report 510(k) #

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66

Combination

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

Product

Pre-1938

SEIZURES

(Check all that apply)

☐ 10-day 📝 Initial

54973 AE # 1562

√ 15-day Follow-up # 9. Manufacturer Report Number

30-day

Periodic

5-day

7-day

minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond information unless it displays a currently valid OMB control number.

oef 1 6 2014

Individual Case Safety Report

MPLAINT RECORD



| | 10529024-01-00-03 | COMPLAINT #: | 2572 |
|---|--|--|---|
| | 10029024-01-00-03 | DATE OF COMPLAINT: | 09/28/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 |
| SIZE: | 135 TABLETS | LOT NO.: | A46514 |
| REPORTER: | (b) (6) | | 4.00 |
| ADDRESS | | | |
| | | W. (A) | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: | USA | ZIP CODE: | |
| PHONE #: | (b) (6) | | |
| FOLLOW-UP 09/30/ INTERACTING WITH SOMETIMES JUST BUT NOT LONGER. | MOTHER SAW THE FACEBOOK POST A WHENEVER SHE GIVES HER CHILD THE D SQUEEZING HIS HANDS TOGETHER. SHE DOES NOT KI A CHILD. 9 MONTH OLD MALE. TAKING BABY TEETHING 114: SHE CALLED THE DOCTOR AND HE SAID HE WILL H THE MOTHER DURING SHAKING BUT EACH TIME IT'S D HIS HEAD, SOMETIMES JUST HIS ARMS. AFTER SHAKING HIS FACE HAS AN EVIL SMILE WHEN HE'S SHAKING (LIF SED OF THE TABLETS. LAST EPISODE WAS ON SUNDAY, | B TABLETS 2 – 3 TABLETS UNDER TONG JOK INTO THIS WEEK AND SEND CHILD T HFFERENT. SOMETIMES CHILD SHAKES G HE'S BACK TO NORMAL: SHAKING GC KE A STRAIGHT SMILE WITH NO EMOTIO | KING AND WAVING HIM ARMS LIKE NK IT'S A SEIZURE BÉCAUSE SHE UE TWICE A DAY FOR 2 MONTHS. TO A NEUROLOGIST. CHILD IS SHIS HANDS AND LEGS, |
| | FOR ADDITIONAL SPACE PLEASE USE RE | VERSE OR ATTACH A SEPARATE SHEE | :7 |
| PRODUCT RECEIVE | ED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR IN | (CIRCLE ONE) |
| SECTION II: | INVESTIGATION | UPS CALL TA | , |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPOR | RT. | |
| ADVERSE EVENT F | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION | ION: 09/28/2014 | |
| ADVERSE EVENT F | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION | | ACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | DSS |
| CORRECTIVE ACTIO | DN(S) COMPLETED BY: | DATE: | OCT 1 7 2014 |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: | 1562 |
| ADVERSE EVENT SE | O | | |
| ADVERSE EVENT RE | EPORTED ON: 09/28/2014 | BY: EDYTA FRACKIEV | _ |
| SECTION V: REVIEWED BY MANA | AGEMENT BY: | DATE: | 10-07-14 3014 |
| BY: | Our Bain | DATE: | 10-07-14 |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

CaseID: 10529024



10529024-01-00-04



Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A46514, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A46514associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A46514. The Baby Teething bulk lot # 123453 was tested for total Atropine and Scopolamine and the results were with in specification of \leq ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0646-2014) has been received for Hyland's Baby Teething Tablets lot # A46514. The complaints were reviewed and they do not appear to be related. A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A46514.

Manufacture and processing occurred within established procedures to ensure product quality.

10/6/14

OCT 1 7 2014

Prenared by

Date

OCT 1 8 2014





SE EVENT DATA FORM

| AE #: | 1562 | . COMPLA | INT #: _2572 |
|---|---|---|---|
| SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON F | ORM VD1) |
| NAME: | | (b) (6) | |
| ADDRESS | S: | | |
| CITY: | | STA | TE: (b) (6) |
| COUNTRY | Y: | USA ZIP CC | DE: |
| PHONE #: | : | (b) (6) | |
| E-MAIL: | | | |
| SECTION | <u>II:</u> | PACKAGING INFORMATION: | |
| | AFF | | F OUTER CARTON HERE CTS AND PRINCIPAL DISPLAY PANELS) |
| Conference and project missing the less reduced was restaure Objectationing the margined form; margined form; margined the constraint section of the constraint recommended by an and another formulated, all, (A) IPES, CHARGOUGH, SIMPES, MILLIONS. | Sindre Die 1 (Meter Levi William Film Lander in In Walliam of American In Sindre Sindre Sindre William Sindre Sindre William S | Monte of the control | Teething Tablets Gally Teething |
| SECTION I | III: | CORRECTIVE ACTION: | : |
| | | · | DSS |
| CORRECTI | IVE ACT | TION(S) COMPLETED BY: | DATE:OCT 1 7 201 |
| SECTION IN | <u>v:</u> | , / | |
| REVIEWED | BY MA | NAGEMENT BY: TWULT | DATE: 10-07-14 |
| BY: | | QUA BOUND | DATE: 10-07-14 |

OCT 1 6 2014

us decilities, tors and manufacturers TORY reporting

| CaseID: 10529 | 9055 |
|--------------------------------|---------------|
| Approved: OMB No. 0910-0291 Fx | miree: 6/30/2 |

| | See OMB statement on reverse |
|----------------------|------------------------------|
| Mfr Report # 54973 | |
| JF/Importer Report # | |
| | |

| C CHORECE | 1.11 | | | | FDA Use |
|--|--|--|--|--|--|
| C. SUSPECT PRO | | and the second | | | institution of |
| 1. Name (Give labeled s | - | , | | | |
| #1 HYLAND'S BAE | or regiming | IABLETS | | | |
| #2 | | | | | |
| 2. Dose, Frequency & F | Route Used | 3. Therap | y Dates (I | funknown, g | rive durati |
| #1 1TAB Q30MINS | SX PRSNT | #1 | (or best es | simale) | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (In | dication) | | 5. Event 4 | Abated After | rileo |
| #1 FEMP RELIEF | () | IN DEX | Stoppe | d or Dose F | ≹educed? |
| #2 | | | #1 🗍 Ye | es 🗸 No | Doe App |
| 6. Lot # | 7. Bxo Date | 6 2014 | #2 \(\) Ye | es No | Doe |
| #1 | #1 | , | | Reappeared | After App |
| #2 | - A CONT. 107 | | Reintro | duction? | |
| 9. NDC# or Unique ID | #2 | | #1 🗌 Ye | s No | Doe App |
| 54973-3127-3 | | 1; | #2 Ye | s No | Doe |
| 10. Concomitant Medica | Products and Th | | | | LJ Appi |
| | | | | | |
| | | | | | |
| | | | | | |
| D CUCDECT MES | IOAL DELLO | | (Co | ntinue on | page 3) |
| D. SUSPECT MED Brand Name | CAL DEVICE | | | | |
| | | | | | |
| Common Device Name | e | | 2b. Pro | ocode | |
| . Manufacturer Name, C | ity and State | | | | |
| | | | | | |
| | , | | | | |
| . Model # | Lot# | | 15 | Operator | - (D - · · |
| . Model# | Lot# | | 5 | Operator | |
| Model # Catalog # | | Date (mm/dd | | Health I | Profession |
| | Expiration | | (УУУУ) | Health I | Profession |
| Catalog # | Expiration | Date (mm/dd | (УУУУ) | Health I | Profession |
| Catalog # | Expiration Unique Ide | | (13333) | Health I Lay Use | Profession er/Patient |
| Catalog # Serial # If Implanted, Give Date | Unique Ide | 7. If Explan | (yyyy) ted, Give | Health I Lay Use Other: | Profession er/Patient d/yyyy) |
| Catalog # Serial # If Implanted, Give Date | Unique Ide | 7. If Explan | (yyyy) ted, Give | Health I Lay Use Other: | Profession er/Patient d/yyyy) |
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| \ | A. PATIENT IN | | h/c | | | | | |
|--------------|---|--|---------------------------------------|-------------------------------------|-----------|--|--|--|
| | Patient Identifier (b) (6) | 2. Age at Time of Event: | | 3. Sex | 4. Weight | | | |
| | | or6 | Months | | | | | |
| | In confidence | Date (b) (6) of Birth: | | ☐ Male | or | | | |
| | | VENT OR PRODU | CT PROBLE | M | | | | |
| | 1. Adverse Even | | duct Problem (e | | | | | |
| | 2. Outcomes Attribut | ed to Adverse Event | duct Problem (e | .g., derects/main | unctions | | | |
| | (Check all that appl Death: | y) | - | | | | | |
| - 1 | | (mm/dd/yyyy) | - | r Permanent Dar | • | | | |
| | Life-threatenin | 9 - initial or prolonged | | Anomaly/Birth D | | | | |
| | | vention to Prevent Perma | | ous (Important M | | | | |
| | 3. Date of Event (min | | 4. Date of This | | | | | |
| | 09/00/201 | 2 PRESENT | ſ | 10/01/2014 | ,,,,, | | | |
| | 5. Describe Event or THE REPORTER'S | DAUGHTER, BEG | AN TAKING ' | BABY TEETI | HING | | | |
| ı | TABLETS" WHEN | SHE WAS ABOUT | 4 MONTHS OF | D. THE RE | EPORTER | | | |
| | STATED THAT S BOTTLE, 1 TABI | HE GAVE THE TAB LET BY MOUTH EV | LETS AS DIF | RECTED ON 1 | THE | | | |
| - 1 | WAS VERY CAREE | UL ABOUT THE DO | OSING BECAL | ISE SHE WAS | VERY | | | |
| ž | WARY ABOUT GIV SUPPLEMENT. PF | ING HER DAUGHTI R THE REPORTER | ER ANY KIND | OF MEDICA | ATION OF | | | |
| ΜĒ | FABLETS" WERE | ONLY GIVEN WHEN | N SYMPTOMS | WERE DEFCE | ENT. | | | |
| USE BLACI | THE REPORTER S DAUGHTER "ORAJ | TATED THAT SHE EL" FOR HER TER | | | | | | |
| m l | THAT HER DAUGH | TER HAD HER FIR | RST SEIZURE | E REPORTER WHEN SHE | WAS 6 | | | |
| SE | MONTHS OLD. P | ER THE REPORTER | R. SINCE TH | EN SHE HAT | HAD E | | | |
| <u>۱۷ کی</u> | MORE SEIZURES AND WAS DIAGNOSED WITH EPILEPSY ABOUT 2 WEEKS AGO. THE REPORTER STATED THAT HER DAUGHTER HAD | | | | | | | |
| | ABNORMAL BRAIN | WAVES ON A "BE | WAIN SCAN". | PER THE | | | | |
| ≻ I ∘ | REPORTER, THE DOCTOR STATED THAT THESE SEIZURES ARE NOT CONSIDERED TO BE "GRAND MAL" BECAUSE THEY LAST FOR 3 | | | | | | | |
| _ [^ | MINUTES; PER THE REPORTER, THE DOCTOR STATED THAT "GRAND | | | | | | | |
| PLEASE | MAL" SEIZURES LAST FOR 5 OR MORE MINUTES. THE REPORTER STATED THAT HER DAUGHTER WAS NOW TAKING MEDICATION FOR | | | | | | | |
| 7 7 | HE SEIZURES. | SHE STATED THA | T SHE DISC | ONTINUED D | SING | | | |
| | EETHING, AT A | ING TABLETS" WH ROUND THE AGE O | EN HER DAU: F 12 MONTH: | GHTER STOP S. PER TH | | | | |
| L | (Continue on page 3) | | | | | | | |
| В. | 6. Relevant Tests/Laboratory Data, Including Dates BRAIN SCAN HAD ABNORMAL BRAIN WAVES | | | | | | | |
| | DIAGNOSED WITH EPILEPSY IN SEPTEMBER 2014 (ABOUT 2 WEEKS | | | | | | | |
| A | IAGNOSED WITH | EPILEPSY IN SE | PTEMBER 201 | 4 (ABOUT | 2 WEEKS | | | |
| | CHILD'S SEIZURES WERE NOT CONSIDERED TO BE "GRAND MAL". | | | | | | | |
| | mirn.2 SEIZURE | 5 WERE NOT CON: | SIDERED TO | BE "GRAND | MAL". | | | |
| | | | | | | | | |
| | | | | | | | | |
| 7 | Other Balance Hill | | | Continue on p | age 3) | | | |
| - 1 | race, programcy, smol | ry, Including Preexistir king and alcohol use, he | ng Medical Cond patic/renal dysfun | itions (e.g., aller ction, etc.) | gies, | | | |
| NC | NE | | | | | | | |
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| | | | | | | | | |
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| | | | | | | | | |
| | | | | | | | | |
| | | | 10 | ontinue on p | ana 31 | | | |
| Sub | mission of a ren | ort does not consti | tute an admir | coion that | age 3) | | | |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| . Individua | l Case Safety R | eport | | | CaseID: 10529055 |
|--|--------------------------------------|---|---------------------------------------|----------------------------|--|
| | | | | | FDA USE ONLY |
| | | | - 16 | | |
| FC III. | 0529055-01-00-0 | 2 | 2 of 6 | | |
| 1.6 | | | H. DEVICE MANUFA | | .Y |
| User Facility | mporter 2. Ut/Importer | Report Number | Type of Reportable Event | t | 2. If Follow-up, What Type? |
| User Facility or Importer Na | | | Death | | Correction |
| | | | Serious Injury Malfunction | | Additional Information |
| | | | Manunction | | Response to FDA Request |
| | | | | | Device Evaluation |
| | | | 3. Device Evaluated by Man | | 4. Device Manufacture Date (mm/yyyy) |
| 4. Contact Person | 5. Phone | Number | Not Returned to Man | | |
| , | | | Yes Evaluation No (Attach page to e. | n Summary Attached | 5. Labeled for Single Use? |
| Date User Facility or Importer Became | 7. Type of Report | 8. Date of This Report | provide code: | xpiain wny nor) or | |
| Aware of Event (mm/dd/yyyy) | Initial | (mm/dd/yyyy) | | | Yes No |
| | Follow-up # | | 6. Event Problem and Evalu | ation Codes (Refer | to coding manual) |
| 9. Approximate 10. Ever | nt Problem Codes (Refer to co | ding manual) | Patient Code | _ | _ |
| Age of Device Patient | | | Device | | |
| Code | | | Code | | |
| Device Code | | - | Method | .]- | |
| 11. Report Sent to FDA? | 12. Location Where Even | t Occurred | | | |
| Yes | Hospital | Outpatient Diagnostic Facility | Results | | |
| No (mm/dd/yyyy) | Home | Ambulatory | Conclusions | - | |
| 13. Report Sent to Manufacture | Nursing Home Outpatient Treatme | Surgical Facility | 7. If Remedial Action Initiate | d, Check Type | 8. Usage of Device |
| Yes | - Facility | ait | Recall N | iotification | Initial Use of Device |
| No (minusa))))) | Other: | (Specify) | | espection | Reuse |
| 14. Manufacturer Name/Address | s | (Optiony) | Replace Pa | atient Monitoring | Unknown |
| | | | | lodification/ djustment | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| | | | Other: | | removal reporting number: |
| | | | | | |
| | | | 10. Additional Manufactu | urer Narrative | and / or 11. Corrected Data |
| G. ALL MANUFACTURE | | r de la companya de la companya de la companya de la companya de la companya de la companya de la companya de | | | oonedica bata |
| Contact Office (and Manufact | turing Site for Devices) | 2. Phone Number |]] - | | |
| Name EDYTA FRACKIEWICZ | | 310-768-0700 | | | |
| Address | | Report Source (Check all that apply) | | | , |
| HYLAND'S, INC. | | Foreign | | | |
| 154 W. 131ST STREET | | Study | | | |
| LOS ANGELES, CA 9006 |)1 | Literature | | | |
| Email Address | | Consumer Health Professional | | | |
| STANDARD@HYLANDS.COM | | User Facility | | | |
| Date Received by Manufacturer (mm/dd/yyyy) | 5. (A)NDA # | Company | | | DSS |
| 09/29/2014 | IND# | Representative Distributor | | | 200 |
| 6. If IND, Give Protocol# | | Other: | | | OCT 1 7 2014 |
| | BLA# | | | , | 001 2 1 2011 |
| 7. Type of Report (Check all that apply) | PMA/ 510(k) # | | | | 1 |
| 5-day 30-day | Combination Product Yes | - | | | |
| 7-day Periodic | 1 | | , | - | e de la companya de l |
| 10-day 📝 Initial | Pre-1938 Yes OTC Product Yes | | | | with. |
| 15-day Follow-up# | - | | | | |
| 9. Manufacturer Report Number | 8. Adverse Event Term(s) SEIZURES | | | | OCT TE 2014 |
| 54973 AE # 1564 | | | | | 001 1 4 5014 |
| | I | Į. | ı | | 1 |

This section applies only to requirements of the Paperwork Reduction Act of 1995.

This section applies only to requirements of the Paperwork Reduction Act of 1999.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer

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PRAStaff@fda.hhs.gov

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--- (CORRIGED)

INUATION PAGE) by user-facilities, outors, and manufacturers DATORY reporting rage 3 of 6

CaseID: 10529055

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| REPORTER, HER DUSTINE WAS NOT HAVING SELTERS INVESTIGATED. FOLLOWING MAY OF HER DOGS OF "BAST TEETHIN TABLETS", SHE CALLED DIR EMERGENCY LINE WAS BECAUSE SHE SAW A POST OF PACEBOOK WILLES STATED THAT THE TRETHING TABLETS", SHE CALLED DIR EMERGENCY LINE WAS BECAUSE SHE SAW A POST OF PACEBOOK WILLES STATED THAT THE TRETHING TABLE B. Relevant Tests/Laboratory Data, including Dates (continued) B. Cither Retevant History, Including Preexisting Medical Conditions (e.g., awanges, race, pregnancy, amoking and abcord use, hepeticharal dysfunction, etc.) (continued) Concemilant Medical Products and Therapy Dates (Exclude heatment of evert) (for continued) OTHER Remarks OCT 1.6 2016 | | B.5. Describe Event or Problem (continued) | |
|---|-------|--|--------|
| B6 Relevant Tests/Laboratory Data, Including Dates (continued) B7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hapelic/renal dysfunction, etc.) (continued) | | - INDUCTO - FER INDUCTION, NOBULE CORRELATED THE CRITICAL GROUP OF THE CRITICAL CONTRACTOR OF THE CRITICAL CRITICAL CONTRACTOR OF THE CRITICAL CRIT | |
| B 6 Relevant Tests/Laboratory Data, Including Dates (continued) B 7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pragnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) | | THE DOOR EMBRAGNOT DIRE NOW BELAUSE SHE SAW A ROST ON FACEBOOK WHICH STATED THAT THE TERTHIMS TO | ABLE' |
| B 6 Relevant Tests/Laboratory Data, Including Dates (continued) B 7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pragnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) | | | |
| B.6. Relevant Tests/Laboratory Data, Including Dates (continued) B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepetic/renal dysfunction, etc.) (continued) | 3 | | |
| B 6 Relevant Tests/Laboratory Data, Including Dates (continued) B 7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergias, race, pregnancy, smoking and alcohol use, hepetic/renal dysfunction, etc.) (continued) | E. | | |
| B6 Relevant Tests/Laboratory Data, Including Dates (continued) B7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatichenal dysfunction, etc.) (continued) | 0 156 | | |
| B 6 Relevant Tests/Laboratory Data, Including Dates (continued) B 7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hapaticheral dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude healiment of event) (For continuation of C 10 and/or D 11, please distinguish) DSS OCT 1 7 2014 | , | | |
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| B 7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C 10 and/or D 11, please distinguish) DSS OCT 1 7 2014 | | | |
| B7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 1.7 2014 | | | |
| B7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 1.7 2014 | | | |
| B7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 1.7 2014 | | | |
| B.7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | l | | |
| B.7 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | l | B.6. Relevant Tests/Laboratory Data Including Dates (continued) | |
| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | ı | Dates (Continued) | |
| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | ١ | | |
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| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | ı | | |
| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | I | | |
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| Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) DSS OCT 17 2014 | ŀ | B.7. Other Relevant History, Including Pressisting Medical Conditions (e.g. allemine see | |
| DSS 0CT 17 2014 | l | (continued by the conti | inued) |
| DSS 0CT 17 2014 | ı | | • |
| DSS 0CT 17 2014 | l | | . • |
| DSS 0CT 17 2014 | l | | |
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| DSS 0CT 17 2014 | ŀ | Concomitant Medical Products and Therapy Dates (Eyellydo trootgoet of avert) (Eyellydo trootgoet of avert) | |
| OCT 1 7 2014 | ŀ | PSC (Exclude freatment of event) (For continuation of C.10 and/or D.11; please distinguish) | 2 |
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| | | OCT 17 | 2014 |
| Other Remarks OCT 1 6 2016 | | | |
| Other Remarks OCT 1 6 2016 | | | |
| Other Remarks OCT 1 6 2014 | | | |
| Other Remarks OCT 16 2016 | | | |
| Other Remarks | Ļ | OCT 1 e 201 | £. |
| | ١ | Other Remarks | 7 |
| | | | |
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Individual Case Safety Report

OMPLAINT RECORD



| 10529055-01-00-04 | COMPLAINT #: 2574 |
|---|---|
| PRODUCT: BARY TEETHING TABLET | DATE OF COMPLAINT: 09/29/14 |
| SIZE: UNKNOWN | S ITEM CODE: BTET |
| (b) (6) | LOT NO.: UNKNOWN |
| ADDRESS: | |
| ADDRESS. | |
| CITY: | STATE: (b) (6) |
| COUNTRY: USA | ZIP CODE: |
| PHONE #: (b) (6) | |
| E-MAIL: | DAUGHTER, BEGAN TAKING "BABY TEETHING TABLETS" WHEN SHE WAS ABOUT 4 MONTHS |
| DAUGHTER ANY KIND OF MEDICATION OR SUPPLEMEN SYMPTOMS WERE PRESENT. THE REPORTER STATED REPORTER STATED THAT HER DAUGHTER HAD HER FILL HAD 5 MORE SEIZURES AND WAS DIAGNOSED WITH EP WAVES ON A "BRAIN SCAN". PER THE REPORTER, THE BECAUSE THEY LAST FOR 3 MINUTES; PER THE REPORTER STATED THAT HER DAUGHTER WAS NOUSING THE "BABY TEETHING TABLETS" WHEN HER DAUGHTER WAS NOT HAVING SEIZURES IMMEDIA'NOBODY CORRELATED THE SEIZURES WITH THE "BABY POST ON FACEBOOK WHICH STATED THAT THE TEETHING THAT THE TEETHING TO THE THE THE THE THE THE THE THE THE THE | ER STATED THAT SHE GAVE THE TABLETS AS DIRECTED ON THE BOTTLE, 1 TABLET BY CAREFUL ABOUT THE DOSING BECAUSE SHE WAS VERY WARY ABOUT GIVING HER T. PER THE REPORTER, THE "BABY TEETHING TABLETS" WERE ONLY GIVEN WHEN THAT SHE HAD ALSO BEEN GIVING HER DAUGHTER "ORAJEL" FOR HER TEETHING. THE RST SEIZURE WHEN SHE WAS 6 MONTHS OLD. PER THE REPORTER, SINCE THEN SHE HAS PLEPSY ABOUT 2 WEEKS AGO. THE REPORTER STATED THAT SHE HAD ABNORMAL BRAIN DOCTOR STATED THAT THESE SEIZURES ARE NOT CONSIDERED TO BE "GRAND MAL" TITER, THE DOCTOR STATED THAT "GRAND MAL" SEIZURES LAST FOR 5 OR MORE MINUTES. DW TAKING MEDICATION FOR THE SEIZURES. SHE STATED THAT SHE DISCONTINUED IGHTER STOPPED TEETHING, AT AROUND THE AGE OF 12 MONTHS. PER THE REPORTER, TELY FOLLOWING ANY OF HER DOSES OF "BABY TEETHING TABLETS". PER THE REPORTER, TELY FOLLOWING ANY OF HER DOSES OF "BABY TEETHING TABLETS". PER THE REPORTER, TELY FOLLOWING ANY OF HER DOSES OF "BABY TEETHING TABLETS". PER SAW A NG TABLETS CAUSED SEIZURES. THE REPORTER STATED THAT SHE WAS AT WORK AND THAT I WOULD RETURN HER CALL IF I DIDN'T HEAR FROM HER, THE REPORTER SAID, "OH, WE GETS OFF OF WORK AT 3:30 PM EST. |
| FOR ADDITIONAL SPA | CE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET |
| | - STATE OF A STATE STREET |
| PRODUCT RECEIVED FOR Y INSPECTION: (CIRCLE ON | PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) |
| | DATE REQUESTED PRODUCT BE RETURNED: |
| | UPS CALL TAG ISSUED: (CIRCLE ONE) |
| | DATE PRODUCT RECEIVED: |
| SECTION II: INVESTIGATION | |
| INVESTIGATION: PLEASE SEE ATTACHED INVE | STIGATION REPORT. |
| | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE | FOR EVALUATION ON |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE | |
| SECTION III: CORRECTIVE ACTION: | - |
| | DSS |
| | OCT 1 7 2014 |
| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: ADVERSE EVENT REPORTS | |
| | AE #: |
| ADVERSE EVENT SERIOUS: | OCT 1 6 2014 |
| ADVERSE EVENT REPORTED ON: 09/29/14 | BY: (b) (6) |
| SECTION V: | DIL |
| REVIEWED BY MANAGEMENT BY: | PWW DATE: 10-07-14 |
| BY: 9 HUA 7 | Bau DATE: 10-07-14 |
| QA / QC DIRECTOR | DATE: 10-01-19 |

cc: QA / QC Packaging

Production Shipping / Receiving 10 0 1 1

CaseID: 10529055



10529055-01-00-05



ous Adverse Event SAE-0041-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

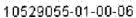
10/6/14

Date

DSS 0CT 1 7 2014

OCT 1 6 2014





RSE EVENT DATA FORM



| AE #: | 1564 | COMPLANTA |
|-------------|--|--|
| | | COMPLAINT #: 2574 |
| SECTION | PATIENT INFORMATION (IF DI | FFERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS | | |
| | | |
| CITY: | | STATE: (b) (6) |
| COUNTRY | | ZIP CODE: |
| PHONE #: | (b) (6) | |
| E-MAIL; | | |
| SECTION I | PACKAGING INFORMATION: | |
| | | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY |
| | | PANELS) |
| | Techning Tablette of the control of | |
| | and the second s | |
| | | Teething Tablets |
| | | And the second s |
| | | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 |
| | have the reverse to report his member and the control of the contr | |
| | The control of the co | \$ 1 & 1 |
| | Company of the Control of the Contro | |
| | | |
| SECTION III | CORRECTIVE ACTION: | |
| | | D00 |
| | | DSS |
| | | OCT 1 7 2014 |
| CORRECTIV | E ACTION(S) COMPLETED BY: | DATE: |
| | | |
| SECTION IV | <u>. </u> | OCT 16 2014 |
| REVIEWED | BY MANAGEMENT BY: | Nat DATE: 10-07-14 |
| BY: | GHIA B | RUU DATE: 10-07-14 |
| | QA / QC DIRECTOR | DATE: 10 07 / 1 |

CaseID: 10530766

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

se by user-facilities, tributors and manufacture JDATORY reporting

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| EDA | Hen | Only |
|-----|-----|------|

| FORM FDA 350 | 0A (2/13) | | | Page |
|---|---|---|--|--------------|
| A. PATIENT INF | ORMATION | and a secretary | Satisfies at the s | |
| 1. Patient Identifier | 2. Age at Time | BOTH SERVICE OF MANAGEMENT | 3. Sex | 4. Weight |
| (b) (6) | of Event: | Months | | |
| | or | | Female | |
| In confidence | Date of Birth: | | ✓ Male | or |
| B. ADVERSE EV | VENT OR PRODU | CT PROBLE | M response a surface and | k |
| | | | Mark Control of the C | |
| 1. Adverse Event | | oduct Problem (e | .g., defects/malfu | unctions) |
| 2. Outcomes Attribut (Check all that apply | ed to Adverse Event | | | |
| Death: | | Disability o | r Permanent Dar | mane |
| ✓ Life-threatenin | (mm/dd/yyyy) | | | |
| | - initial or prolonged | *************************************** | Anomaly/Birth Dous (Important M | |
| | vention to Prevent Perm | | | |
| 3. Date of Event (mm | | | | |
| | 3/2012 | | Report (mm/dd/ | (уууу) |
| 5. Describe Event or | | | 10/01/2014 | |
| CHILD HAD AN A | ACCIDENT ON (b) (6 |) | BAR | Y WAS 7 |
| MONTHS OLD HOL | DING ON TO AN | OTTOMAN ANI | HE LANDE | ON HIS |
| HEAD ON A CONC | RETE / MARBLE | FLOOR AND T | THIS CAUSE | DIRECT |
| | WENT TO THE HO E TO THIS INJU | SPITAL AND | HAD SURGER | RY FOR A |
| REMOVED TO REL | JEVE BRAIN SWE | LLING. 5 I | DAYS LATED | THE |
| DOCTORS FOUND | ANOTHER OLDER | BRAIN BLEED | . HE WAS | |
| DIAGNOSED WITH | SHAKEN BABY S | YNDROME BUT | HAD NO BE | ROKEN |
| (LAG ON RIGHT | SIGNS OF INJU SIDE WHEN HE W | RY. BABY H | IAS CEREBRA | AL PALSY |
| SIDE, AND RETI | NAL HEMORRHAGI | NG WHICH MA | DE HIM BLI | IGHT |
| ONE EYE (NONE | OF THIS PRESEN | T BEFORE HE | FELL D | DUE TO |
| HEAD INJURY). | DOCTORS ALSO | FOUND MULTI | PLE LAYERS | OF OLD |
| INJURY. MOTHE | L HEMORRHAGE U R WANTS TO KNO | PON EVALUAT | ION OF THE | HEAD |
| FOUND WAS DUE | TO BABY TEETHI | NG TABLETS | BECAUSE DO | CTORS |
| THOUGHT THAT O | LDER RETINAL B | LEED WAS DU | E TO SHAKE | N BABY |
| SYNDROME. STA | RTED GIVING BA | BY TEETHING | TABLETS W | HEN THE |
| CHILD WAS 5 MOI | NIHS OLD. | | | |
| | | | | |
| | | | | |
| | | | | |
| 6. Relevant Tests/Labo | oratory Data Including | Deter | (Continue on | page 3) |
| HOSPITALIZED AN | | | M DIEEN | E DAVC |
| LATER DOCTORS H | FOUND ANOTHER (| DLDER BRAIN | BLEED. | 5 DAIS |
| DIAGNOSED WITH | SHAKEN BABY ST | INDROME. | | |
| | | g _{max} | RECE | VE |
| | | | er severe deta, typica | r fi W Bloom |
| | | | OCT 1 | 7 2044 |
| | | | OCT 1 | 1 ZU14 |
| | | | | |
| | | (| Continue on | page 3) |
| 7. Other Relevant Histo | ory, Including Preexist king and alcohol use, he | ing Modical Cons | ditions to a sta | rgies, |
| ON (p) (o) | 7 MONTH O | LD CHILD WA | S HOLDING | ON TO |
| AN OTTOMAN AND | HE LANDED ON H | IS HEAD ON | A CONCRETE | 2 / |
| MARBLE FLOOR AN | D THIS CAUSED | DIRECT SEIZ | URES. | |
| CHILD HAS CEREB RETINAL HEMORRH | AGING DOCTOR | WEAK ON THE S ALSO FOUN | RIGHT SID | E, AND |
| AYERS OF OLD A | | HEMORRHAGE | UPON EVAT | HATTON |
| OF THE HEAD INJ | URY. | | | OTILION |
| CHILD BORN PREM | ATURE DUE TO M | OTHER'S PRE | ECLAMPSIA. | |
| | | | | 1 |
| | | ((| Continue on p | age 3) |

PLEASE TYPE OR USE BLACK INK

| ser-facilities, | Mfr Report # | | See OMB sta | tement on reverse. |
|--------------------------------------|---|-----------------------------|-------------------------------------|--------------------|
| s and manufacture | TS | 54973 | | |
| ORY reporting | UF/Importer F | Report # | | |
| of 5 | | | | |
| C. SUSPECT PR | | | alexander inches | FDA Use Only |
| 1. Name (Give labeled | strength & mfr/labeler, ABY TEETHING T | | | |
| | IDI TEBIHING I | ABLE12 | | |
| #2 | | 1- | | |
| 2. Dose, Frequency & | | 3. Therapy E from/to (or | Dates (If unknowr best estimate) | n, g ive duration) |
| #1 1/2TABSLQ6- | 8HRS;1TABSL | #1 | | |
| #2 | | #2 | | |
| 4. Diagnosis for Use (| | | Event Abated As Stopped or Dos | |
| #1 TEMP RELIEF | TEETHING PAIN | #1 | Yes VN | o Doesn't |
| #2 | | #0 | | Apply Doesn't |
| 6. Lot # | 7. Exp. Date | #2 | | O Apply |
| #1 | #1 | | Event Reappear Reintroduction? | ed After |
| #2 | #2 | #1 | Yes N | o Doesn't |
| 9. NDC# or Unique ID 54973-3127-3 | | #2 | □Yes □N | Doesn't |
| 10. Concomitant Medic | cal Products and The | | | L Apply |
| consomitant medit | ar Froducts and The | apy Dates (Ex | crude treatment (| or event) |
| | | | | |
| | | | | |
| * | | | (Continue o | on page 3) |
| D. SUSPECT MEI | DICAL DEVICE | | | |
| Brand Name | | | | |
| Common Device Nar | ne | | 2b. Procode | |
| 3. Manufacturer Name, | City and State | | | |
| | | | | |
| 4. Model# | Lot# | | 5 Operate | or of Device |
| | | | | th Professional |
| Catalog # | Expiration | Date (mm/dd/yy | (YY) | Jser/Patient |
| Serial# | Unique Ide | ntifier (UDI) # | Othe | 1 |
| | | (02.) | | |
| 6. If Implanted, Give Da | te (mm/dd/yyyy) | 7. If Explanted | d, Give Date (mn | n/dd/yyyy) |
| B. Is this a Single-use D | evice that was Repri | ocessed and Re | eused on a Pati | ent? |
| Yes No | | | | ant. |
| . If Yes to Item No. 8, E | nter Name and Addr | ess of Reproce | essor | DSS |
| | | | | 000 |
| | | | (0) | T 2 0 2014 |
| 0. Device Available for | Evaluation? (Do not | send to FDA) | TU (| 00 00 00 |
| Yes No | Returned to Ma | anufacturer on:_ | /m / 17 | an and |
| 1. Concomitant Medica | I Products and There | apy Dates (Exc | (mm/dd/y Jude treatment o | |
| | | | | |
| | | | /C=-#- | |
| E. INITIAL REPOR | TER | Control Committee Control | (Continue of | page 3) |
| Name and Address | La Libraria de Sala Maria (C. 1900) | | | |
| o) (6) | | | u. | |
| 0) 0) USA | | | OCT 1 | 7 2014 |
| | | | | |
| hone # o) (6) | Email | Address | | |
|)) (O) | (b) (6) | | | |
| Health Professional? | 3. Occupation | | 4. Initial Report Report to FD | ter Also Sent |
| Vec Class | RIA | | Port to ru | |

NA

Yes No V Unk.

☐ Yes ✓ No

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.



Importer

User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate

Age of Device

11. Report Sent to FDA?

Yes

No

Yes

No

6. Date User Facility or

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

F. FOR USE BY USER FACILITY THINFORTER (DEVICES UTILY)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Facility

Other:

Outpatient Treatment

Home

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

age 2 o

| | FDA USE ONLY |
|--|---|
| of 5 | - CAROLONEI |
| | |
| H. DEVICE MANUFACTURERS ONL | |
| Type of Reportable Event Death | 2. If Follow-up, What Type? |
| Serious Injury | Correction Additional Information |
| Malfunction | Response to FDA Reques |
| | Device Evaluation |
| Device Evaluated by Manufacturer? | Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | Yes No |
| 6 Event Broken and Full vision in the | |
| 6. Event Problem and Evaluation Codes (Refer to | coding manual) |
| Code | - |
| Device Code | - |
| | |
| Method | |
| Results - | |
| Constraine | |
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse Unknown |
| Replace Patient Monitoring Relabeling Modification/ | 9. If action reported to FDA under |
| Adjustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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CaseID: 10530766

G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number 310-768-0700 EDYTA FRACKIEWICZ Report Source (Check all that apply) Address Foreign HYLAND'S, INC. 154 W. 131ST STREET Study LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM Date Received by Manufacturer (mm/dd/yyyy) User Facility (A)NDA# Company Representative 39/29/2014 IND# Distributor 6. If IND, Give Protocol # Other:, BLA# PMA/ 7. Type of Report 510(k)# (Check all that apply) Combination 30-day 5-day Product Yes 7-day Periodic Pre-1938 Yes 10-day ✓ Initial OTC Product √ Yes ✓ 15-day Follow-up # 9. Manufacturer Report Number 8. Adverse Event Term(s) BRAIN AND RETINAL HEMORRHAGE, 54973 AE # 1563 SEIZURE, HEAD INJURY, CEREBRAL PALSY, RIGHT SIDED WEAKNESS, BLIND This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Please DO NOT RETURN this form to the above PRA Staff email address.

OCT 2 0 2014 OCT 1 7 2014

Individual Case Salety Report

COMPLAINT RECORD



| DATE OF COMPLAINT: PRODUCT: | E S |
|--|------------|
| SIZE: 135 TABLETS LOT NO: NOT AVAILABLE REPORTER ADDRESS: CITY: STATE: (D)(6) COUNTRY: USA ZIP CODE: PHONE #: (D)(6) E-MAIL: CHILD HAD AN ACCIDENT ON (D)(6) BABEY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HE LANDED ON HIS HEAD ON A CONCRETE! MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FLOOR AND READ ON A CONCRETE! MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FLOOR AND HIS HEAD ON A CONCRETE! MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HEAST 2 YEARS. BABY IS WITH HUSBAND'S PABENTS. BAY WE SERVICES TOOK THE BABY ANY AND PARASHES HAVE NOT HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PABENTS. BAY WE SERVICES TOOK THE BABY ANY AND PARASHES HAVE NOT HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PABENTS. BAY WE SERVICES TOOK THE BABY ANY AND PARASHES HAVE NOT HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PABENTS. BAY WE SERVICES TOOK THE BABY ANY AND PARASHES HAVE NOT HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PABENTS. BAY WE SERVICES TOOK THE BABY ANY AND PARASHES HAVE NOT TO HEAD INJURY. DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMOFRADGE WHEN HE HEAD HE FELL - DUE TO HEAD INJURY. DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMOFRADGE WHEN HE HEAD HE HE WENT TO THE BECAUSE DOCTORS THOUGHT THAT OLDER RETINAL BLEED THAT FOLION DAYS BUT TO THE HOSPITAL (AT 6 MONTH'S INCERESED DOSE BY GIVING HIM A FULL TABLET). MOTHER IS TRYING TO GET HER BABY BACK AND LAYING OUT ALL CHILD WAS SO MORTHS. GAVE 'S TABLET IN HIS MOUTH EVERY 6 - 8 HOURS AS NEEDED X ZOHN BACK AND LAYING OUT ALL PROPERTINAL BLEED THAT TO GET HER BABY BACK AND LAYING OUT ALL PROPERTINAL BALD THAT TO GET HER BABY BACK AND LAYING OUT ALL PROPERTINAL FABLE IS FROM WALMART IN (D) (G) HAND YOU HAD ANY COMPLICATIONS IN 2012. I STARTED GIVING THEM TO MY SON JUDICHING E-MAIL ON 09/24/14. HELLO; IN WAS WONDERING IF HOUSE WENT OF THE PROPERTINAL FABLETS FROM WALMART IN (D) (G) (CIRCLE | E S |
| REPORTER: (D)(6) ADDRESS: CITY: COUNTRY: USA ZIP CODE: PHONE #: (D)(6) E-MAIL: NATURE OF COMPLAINT: AND HE LANDED ON HIS HEAD ON A CONCRETE I MARBLE FLOOR AND THIS CAUSED DIRECT SEZURES. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME SWELL WAS REMOVED TO RELIEVE BRAIN NO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICED. HE WAS DIAGNOSED WITH SHARED BAY SYNDROME SIZE OF INJURY. DOCTOR'S ALSO FOUND MULTIFLE LAYERS OF OLD AND NEW TENNESS. SHARED BAY SYNDROME SHE HE WALKS, WEAK ON'T HOUSE THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD AND NEW TENNESS. SHARED SYNDROME STATED GIVING WHITH THE ADDITIONAL STATED GIVING PROTECTIVE SERVICED. TO SHAKEN BARS YSNDROMES STATED GIVING WHITH THIN OTHER WANTS TO KNOW IF OLD AND NEW TENNESS TO SHAKEN BARS YSNDROMES STATED GIVING HOUSE THE OWN STATED GIVING BOY STATED GIVING THE MAY SOLD WHEN THE CHILD WAS 5 MONTHS. GAVE IS TABLET IN HIS MOUTH EVERY 6 - 8 HOURS AS NEEDED X 2MONTHS LIVE OF WEST THE FIRST TO GETTER BARS BAY BAKE AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3" CUSTOMER SENT THE FOLLOWING E-MAIL ON 09/24/14. HELLO, INVAS WONDERNOSE TO A BRAND HE STATED GIVING THE THIN THE THE DOCTORS ON JURIESULY OF 2012 AND IN 16/14 HE HAD AND ALCONEDATION OF THE ADD HEAD ADD HEAD ADD HEAD ADD HEAD ADDRESS OF THE SHARED GIVE STATED GIVEN STATED GIVEN STORMS THEM TOW | E S |
| CITY: COUNTRY: USA ZIP CODE HONE #: (b) (6) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN ATURE OF COMPLAINT: AND HE LANDED ON HIS HEAD ON A CONCRETE / MARRIE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY. PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN NO BROKEN BONES OR OTHER SUCTION A POTHER PART OF HIS PROPERTY. AND PARENTS HAVE NOT HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HOLD PROTECTIVE SERVICES TOOK THE BABY WAD PARENTS HAVE NOT HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HEAD HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HEAD HAD CUSTOR FOR THE LAST 2 YEARS. BABY IS WITH HEAD HAD CUSTOR RIGHT SIDE. AND RETINAL HEMORRHAGING WHICH MARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON T RIGHT SIDE. AND RETINAL HEMORRHAGING WHICH MARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WEAT TO THE FOR THE LAST 2 YEARS. BABY IS WITH HE LAYERS OF OUR BILLING IN ONE EYE (NOW) OF THIS PRESENT BEFORE HE FELL. DUE TO HEAD HOUSPITAL, FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF CLD RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WENT TO THE BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS. GAVE 'S TABLET IN HIS MOUTH EVERY 5 — BEQUING STARTED DIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS. GAVE 'S TABLET IN HIS MOUTH EVERY 5 — BEQUING STARTED DIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS. GAVE 'S TABLET IN HIS MOUTH EVERY 5 — BEQUING SHAPE WITH HEAD AND THE PROPERTY OF THE P | E S |
| COUNTRY: USA ZIP CODE: COUNTRY: USA ZIP CODE: CHILD HAD AN ACCIDENT ON (b) (c) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HELANDED ON HIS HEAD ON A CONCRETE / MARRIE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY. PART OF HIS SKULL WAS REMOVED TO RELEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTOR'S FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HOS BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE BABY WAND PARENTS HAVE NOT HAD CUSTOD FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ONT RIGHT SIDE. AND RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WENT TO THE HOSPITAL FOR THE HEAD HUJBLY. MOTHER WANTS TO KNOW IF COLD RETINAL BLEED THEY POUND WHEN HE WENT TO THE HOSPITAL FOR THE HEAD HONDIES. YE THE HEAD HAS DEED AND RETINAL BLEED WAS DUE TO BABY TEETHING THABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO BABY TEETHING THABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAY WONTHS LAVING TO THE HEAD HAS DUE TO BABY TEETHING THABLETS BECAUSE DOSE BY GIVING HIM A FULL TABLET). MOTHER IS TRYING TO GET HER BABY BACK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3° CUSTOMER SENT THE FOLLOWING E-MAIN ONTHIS LINKCEASED DOSE BY GIVING HIM A FULL TABLET). MOTHER IS TRYING TO GET HER BABY BACK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3° CUSTOMER SENT THE FOLLOWING E-MAIL (LIND WENT TO THE HOSPITAL (LIND WAS TOT TO THE THE TOWN THE MENT HER TOWN THE THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN 10) (6) THANK YOU FOR ANY HELP! PRODUCT RECEIVED FOR Y REPLIED HAS BLEED AND THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN 10) (6) THANK YOU FOR ANY HELP! PRODUCT RECEIVED FOR BY ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR WY AND THE THEY TOOK MY SON OFF OF ME. WE BOUGHT | E S |
| COUNTRY: USA ZIP CODE: PHONE #: E-MAIL: CHILD HAD AN ACCIDENT ON (b) (c) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HEL LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY - PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTOR'S FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY CHILD PROTECTIVE SERVICES TOOK THE BABY AND ARBENTS HAVE NOT HAD CUSTOC FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON T INJURY). DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGES WHICH WERE FOUND WHEN HE WEAK SO. TO THE HOSPITAL FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD RETINAL BLEED WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS. GAVE 5 TABLET IN HIS MOUTH EVERY 6 – 8 HOURS AS NEEDED X 2 MONTHS UNTIL CHILD WENT TO THE HOSPITAL ATC 6 MONTHS INCREASED DOSS BY GIVING THAM THAT THE FOLLOWING E-MAIL ON GRIZARIA: HELLO, I WAS WONDERING IF CYOLIN AND CONTROL OF THE PART OF THE HEAD INJURY. IN THE BLEED AND THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN DIG IN THANK YOU FOR ANY HELP! FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR Y CICRCLE ONE) DATE PRODUCT BE RETURNED: DATE PRODUCT RECEIVED: SECTION!: INVESTIGATION INVESTIGATION LIVESTIGATION BABY WAS 7 MONTHS OUT TO AN OTTOWN THE OUT TO THE CONTROL OF THE THANK YOU FOR ANY HELP! FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR Y CICRCLE ONE) DATE PRODUCT BE RETURNED: DATE PRODUCT RECEIVED: | E S |
| COUNTRY: USA ZIP CODE: PHONE #: E-MAIL: CHILD HAD AN ACCIDENT ON (**) (**) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HEL LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY - PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTOR'S FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HNO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE BABY AND ARBITS HAVE NOT HAD CUSTOC FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON T INJURY.) DOCTOR'S ALSO FOUND MULTIFLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WEAK ON TO HEAD SHITLE FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD RETINAL BLEED WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS. GAVE 5/1 TABLET IN HIS MOUTH EVERY 6 - 8 HOURS AS NEEDED X DONTHS UNTIL CHILD WENT TO THE HOSPITAL AT 6 MONTHS INCREASED DOSS BY GIVING HIM A FULL TABLET. MOTHER IS TRYING TO GET HER BABY BACK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3 ⁽⁵⁾ CUSTOMER SENT THE FOLLOWING E-MAIL ON 09/24/14: HELLO, I WAS WONDERING IF YOU HAD ANY COMPLICATIONS IN 2012. I STARTED GIVING THEM TO MY SON JUNE/JULY OF 2012 AND IM (0) (6) HE HAD AN ACCIDENT AND HAD A BRAIN BLEED AND THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN (CIRCLE ONE) PRODUCT RECEIVED FOR Y PRODUCT BEING RETURNED FOR INSPECTION: Y NOT THE NEED AND THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN (CIRCLE ONE) DATE PRODUCT RECEIVED FOR INSPECTION: Y NOT THE PRODUCT RECEIVED: DATE PRODUCT RECEIVED FOR INSPECTION: Y NOT THE PRODUCT RECEIVED: | E S |
| PHONE #: E-MAIL: CHILD HAD AN ACCIDENT ON (6) (6) BABY WAS 7 MONTHS OLD HOLDING ON TO AN OTTOMAN AND HE LANDED ON HIS HEAD ON A CONCRETE MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY - PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN NO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE MAS DIA WAY AND PARENTS HAVE NOT HAD LUSTOF FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON T INJURY). DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGING WHICH MADE HIM BLIND IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FELL - DUE TO HEAD HOSPITAL FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD ARD NEW RETINAL BLEED HEY FOUND WAS DUE TO BABY TEETHING TABLE TO HE HOSPITAL (AT 6 MONTHS INCREASED DOS DOS BY STABLET IN HIS MOUTH EVERY 6 - 8 HOURS AS NEEDED X MONTHS UNTIL CHILD WENT TO THE HOSPITAL (AT 6 MONTHS INCREASED DOS BY STABLET IN HIS MOUTH EVERY 6 - 8 HOURS AS NEEDED X MONTHS UNTIL CHILD WENT TO THE HOSPITAL (AT 6 MONTHS INCREASED DOS BY STABLET IN HIS MOUTH EVERY 6 - 8 HOURS AS NEEDED X MONTHS UNTIL CHILD WENT TO THE HOSPITAL (AT 6 MONTHS INCREASED DOS BY GIVING HIM A PULL TABLET). MOTHER IS TRUTTED GIVING BABY TEETHING TABLE HOSPITAL (AT 6 MONTHS INCREASED DOS BY GIVING HIM A PULL TABLET. MOTHER WAS AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3 ¹⁰ . CUSTOMER SENT THE FOLLOWING E-MAIL ON 09/24/14; HELLO, I WAS WONDERING IF TO HEAD AND THE PULL TABLET. MOTHER WAS AND THE ARBY BECT AND AN ACCIDENT AND HAD A DECIDENT AND HAD BEED AND THEY TOOK MY SON OFF OF ME. WE BOUGHT THE TABLETS FROM WALMART IN (1) (GIRCLE ONE) PRODUCT RECEIVED FOR MY CLIPPED TO ME AND THE PRODUCT BE RETURNED: DATE PRODUCT RECEIVED FOR MY CIPCLE ONE) PRODUCT RECEIVED FOR MY CIPCLE ONE) DATE PRODUCT RECEIVED. | E S |
| E-MAIL: CHILD HAD AN ACCIDENT ON (b) (6) NATURE OF COMPLAINT: AND HE LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY - PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING, 5 DAYS LATER THE DOCTOR'S FOUND ANOTHER DLOER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT H NO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE BABY AWAY AND PARENTS HAVE NOT HAD CUSTOD FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAD PLASY. (AG ON RIGHT SIDE WHEN HE WALKS), WEAK ON T RIGHT SIDE, AND RETINAL HEMORRHAGING WHICH MADE HIM BLIND IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FELL - DUE TO HEAD INJURY). DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF LOLD AND NEW RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WENT TO THE BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLE WHEN THE CHILD WAS 5 MONTHS. GAVE 'S TABLET IN HIS MOUTH EVERY 6 - BHOURS AS NEEDED X 2 MONTHS UNTIL CHILD WANT TO THE HOSPITAL (AT 6 MONTHS INCREASED DOSE BY GIVING HIM A FULL TABLET). MOTHER IS TRYING TO GET HER BABY BACK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3°C. CUSTOMER SENT THE FOLLOWING E-MAIL ON 09/24/14. HELLO, I WAS WONDERING IF YOU HAD ANY COMPLICATIONS IN 2012. I STARTED GIVING THE MTO MY SON JUNE/JULY OF 2012 AND I'M (D) (6) THANK YOU FOR ANY HELP! PRODUCT RECEIVED FOR INSPECTION: DATE PRODUCT BE RETURNED: DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION LINES OF THE PRODUCT RECEIVED: DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION | E S |
| NATURE OF COMPLAINT: CHILD HAD AN ACCIDENT ON (6) (6) AND HE LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY. PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTOR'S FOUND ANDTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HON BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE BABY AWAY AND PARENTS HAVE NOT HAD CUSTOD. FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WARA ON TRIGHT SIDE. AND RETINAL HEMORRHAGING WHICH MADE HIM BUILD IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FELL – DUE TO HEAD INJURY). DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WENT TO THE HOSPITAL FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD RETINAL BLEED THEY FOUND WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLE WHEN THE CHILD WAS 5 MONTHS. GAVE 'S TABLET IN HIS MOUTH EVERY 6 – 8 HOURS AS NEEDED X 2 MONTHS UNTIL CHILD WENT TO THE HOSPITAL (AT 6 MONTHS INCREASED DOSE BY GIVING HAM FULL TABLET). MOTHER IS TRYING TO GET HER BABY BAK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3'® CUSTOMER SENT THE FOLLOWING BABY THE BABY BAK AND LAYING OUT ALL ACTIONS. HER FIRST COURT HEARING IS NOVEMBER 3'® CUSTOMER SENT THE FOLLOWING E-MAIL ON 097/41/4. HELLO, I WAS WONDERING IF A BRAIN BLEED L I CAN NOT EXPLAIN THE BLEED AND THEY TOOK MY SON JUNEJULY OF 2012 AND TIM 10 10 10 10 10 10 10 10 10 10 10 10 10 | E S |
| MATURE OF COMPLAINT: AND HE LANDED ON HIS HEAD ON A CONCRETE / MARBLE FLOOR AND THIS CAUSED DIRECT SEIZURES. HE WENT TO THE HOSPITAL AND HAD SURGERY FOR A BRAIN BLEED DUE TO THIS INJURY. PART OF HIS SKULL WAS REMOVED TO RELIEVE BRAIN SWELLING. 5 DAYS LATER THE DOCTOR'S FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT H NO BROKEN BONES OR OTHER SIGNS OF INJURY. CHILD PROTECTIVE SERVICES TOOK THE BABY AWAY AND PARENTS HAVE NOT HAD CUSTOF FOR THE LAST 2 YEARS. BABY IS WITH HUSBAND'S PARENTS. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON T RIGHT SIDE, AND RETINAL HEMORRHAGING WHICH MADE HIM BLIND IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FERL. DUE TO HEAD INJURY.) DOCTOR'S ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE WHICH WERE FOUND WHEN HE WENT TO THE HOSPITAL FOR THE HEAD INJURY. MOTHER WANTS TO KNOW IF OLD RETINAL BLEED THEY FOUND WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS BECAUSE DOCTOR'S THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. HEAD AND SHAMEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS ON THE WASHING TO SHAMEN BABY SYNDROME. TO SHAMEN BABY SHAMEN BABY SYNDROME. ON THE WASHING THE WALKEN BA | E S |
| PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE) DATE REQUESTED PRODUCT BE RETURNED: UPS CALL TAG ISSUED: OCIRCLE ONE) DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION |) |
| DATE REQUESTED PRODUCT BE RETURNED: UPS CALL TAG ISSUED: OCIRCLE ONE) DATE PRODUCT RECEIVED: DATE PRODUCT RECEIVED: |) |
| UPS CALL TAG ISSUED: Y N (CIRCLE ONE) DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION | / |
| DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION UPS CALL TAG ISSUED: (CIRCLE ONE) | |
| SECTION II: INVESTIGATION |) |
| | |
| INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. | |
| | |
| | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/29/14 | |
| VOLUME | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ | - |
| SECTION III: CORRECTIVE ACTION: | |
| | |
| CORRECTIVE ACTION(S) COMPLETED BY: | 000 |
| DATE: | DSS |
| SECTION IV: ADVERSE EVENT REPORTS AE #: 1563 | T-2 0 201 |
| ADVEDOS EVENT OFFICIAL | - 20 U ZUI |
| ADVERSE EVENT REPORTED ON | |
| SECTION V: BY: EDYTA FRACKIEWICZ | |
| REVIEWED BY MANAGEMENT BY: DATE: 10-07-19 | a agar. |
| BY: Que Bun DATE: 10-07-14 | r 2014 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0040-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of (1) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/6/14

Date

DSS OCT 2 0 2014

OCT 1 7 2016

CaseID: 10530766



CaseID: 10530766

RSE EVENT DATA FORM

| AE #:1563 | 3 | COMPLAINT #: 2573 | |
|--|--|--|------------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFEREN | IT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | | |
| ADDRESS: | | | |
| CITY: | | CTATE (b) (6) | |
| COUNTRY: | USA | ZIP CODE: | |
| PHONE #: | (b) (6) | ZIP CODE: | |
| E-MAIL: | | 2 | |
| | | | |
| SECTION II: | PACKAGING INFORMATION: | | |
| AFF | FIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| Indications: Improving making in a control of control of larger in process and was control to the control of th | And Section 1997 See that we were different and the section of the | Teething Tablets White the same of the sa | |
| | | The control of the co | |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| | | | D0 |
| CORRECTIVE AC | TION(S) COMPLETED BY: | DATE: | — DS _0ct 2 0 |
| SECTION IV: | | . / | |
| REVIEWED BY MA | ANAGEMENT BY: | DATE: 10-07-14 OC | T 1 7 2011 |

DATE: 10-07-14

by user-facilities, ibutors and manufacturers DATORY reporting

CaseID: 10530771

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015

| | See OMB statement on rever |
|---------------------|----------------------------|
| Report # 54973 | |
| F/Importer Report # | |

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| AN W RE SHEET MADE . WE SEE | | | | |
|---|---|--|--|--|
| FORM FDA 350 | 0A (2/13) | | | Page |
| A. PATIENT INF 1. Patient Identifier (b) (6) | ORMATION 2. Age at Time of Event: or9 | Months | 3. Sex | 4. Weight |
| In confidence | Date of Birth: | | ✓ Male | or |
| | ENT OR PRODU | CT PROBLE | - | kgs |
| 1. Adverse Even | | | | |
| 2. Outcomes Attribut | | duct Problem (e | .g., detects/malti | Inctions) |
| (Check all that appl) | y) | | | |
| Death: | (mm/dd/yyyy) | _ Disability o | r Permanent Dar | nage |
| ✓ Life-threatenin | | | Anomaly/Birth D | |
| | - initial or prolonged | - | ous (Important M | |
| | vention to Prevent Perma | | | |
| Date of Event (mm) 02/00/2013 | & 04/00/2013 | ı | Report (mm/dd/ 10/01/2014 | (yyyy) |
| 5. Describe Event or | | | 10/01/2014 | |
| AUGUST 2012. MOTHER SWITCHE MEDICATION WAS TO GET FEVERS THE PARENTS CA TYLENOL AND IE MOTHER CONTINU TEETH EMERGED TEETH QUICKLY" WORKUP, EEG, E "COMPLEX FEBRI CURIOUS THAT T WAS PRESCRIBED HAD NONE SINCE FEVER BUT HE A PHASES. MOTHE ABOUT TEETHING | SINCE THE SEIZ REFULLY MONITO UPROFEN ALTERN. ED TO GIVE TEE IN JANUARY 201 . AT THE HOSP PILEPTIC STRES LE SEIZURES". HERE WAS NO FAI DIAZEPAM IF HI | (GAS) AT (HE WAS BET CURRENT HEZ URES, ONCE R HIS FEVE R HIS FEVE ATELY WHEN ITHING TABLE 4. SHE SAI ITAL THEY I S TEST, ANI MOTHER SAI MILY HISTOF E HAS ANOTH O TEETHING R DURING HI READING AN ONDERED IF S SEIZURES | DNE MONTH (TTER. NO ALTH: HE I A MONTH, (RS AND GIVE FEVER OCCU ETS UNTIL H ID HE "GOT DID NEUROLO DIAGNOSEL D DOCTOR W RY OF IT. HER SEIZURE DID NOT CA S TEETHIN PO THAT COULT | DLD, IS PRONE DR TWO. E URS. HIS LAST HIS DGICAL D IT AS WAS BABY E. HAS WUSE GOST |
| 6. Relevant Tests/Labo | oratory Data, Including | Dates | (Continue on | page 3) |
| NEUROLOGICAL WO | ORKUP, EEG, EPI AGNOSED AS "COM | LEPTIC STR | ESS TEST LE SEIZURE | S". |
| | | | (Continue on | nage 31 |
| Other Relevant Historian | ory, Including Preexisti | ng Medical Con | (Continue on publications (e.g., alle | rgies, |
| race, pregnancy, sino | king and alcohol use, he PRY OF SEIZURES | patic/renal dystui | ECE | |
| | | | | - |
| | | | OCT 17 | 2014 |
| | | | CD | R |

| OKT Teporting | L. Timportoi | rioport ii | | | |
|--|-------------------|-----------------|--------------|---------------------|----------------------------|
| of <u>5</u> | | | | | |
| C. SUSPECT PRO | | er) | | | FDA Use On |
| #1 HYLAND'S BAB | | | | | |
| #2 | | | | | - |
| 2. Dose, Frequency & R | loute Used | 3. Therap | y Dates (If | unknown, g | rive duration |
| #1 | | #1 | (or best est | imate) | |
| #2 | * | #2 | | | |
| 4. Diagnosis for Use (In | | IN | Stopped | or Dose R | |
| #2 | | | #1 Yes | s No | Apply |
| 6. Lot # | 7. Exp. Date | | #2 Yes | s No | Doesn Apply |
| #1 | #1 | | 8. Event Re | eappeared | After |
| #2 | #2 | | #1 Yes | grown . | Doesn |
| 9. NDC# or Unique ID 54973-3127-3 | | | #2 Yes | s No | Apply |
| 10. Concomitant Medica | Products and Th | nerapy Dates (| Exclude tre | eatment of e | Apply event) |
| TYLENOL AND IBUI | | | | ntinue on | |
| D. SUSPECT MED | ICAL DEVICE | | | | |
| Brand Name | | | | | |
| 2. Common Device Nam | e | | 2b. Pro | code | |
| 3. Manufacturer Name, (| ity and State | | | | |
| 4. Model# | Lot# | | 5. | Operator | of Device |
| Catalog # | Expiration | n Date (mm/do | d/yyyy) | | Professional er/Patient |
| Serial# | Unique Id | lentifier (UDI) | # [| Other: | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explan | nted, Give I | Date (mm/d | d/yyyy) |
| 8. Is this a Single-use De | vice that was Rep | processed and | Reused o | n a Patient | 1? |
| 9. If Yes to Item No. 8, En | nter Name and Ad | dress of Repr | ocessor | | |
| | | | | | |
| 10. Device Available for E | valuation? (Do no | ot send to FDA |) | | ce |
| Yes No | Returned to N | | | (m m ldelsav | 100 100 |
| 11. Concomitant Medical | Products and The | erapy Dates (| Exclude trea | atment of e | 2.0 201 |
| | | | (Con | tinue on p | page 3) |
| E. INITIAL REPORT 1. Name and Address | ER | | | | |
| (b) (6) | | 00 | 17 | 2014 | |
| (b) (6) USA | | | | | |
| Phone # | Ema | ail Address | • | 1 start and | |
| b) (6) | | | | | |
| | 3. Occupation NA | | Rep | ort to FDA | Also Sent |
| Yes ✓ No | INM | | 1 1 | Yes No | / / Unk |

(Continue on page 3) Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. FDA USE ONLY

| 10: | 530771- | 01-00-0 | 2 | ige | 2 of 5 | | | | |
|--|--------------|------------------------|---------------------|--|---------|-------------------------------|-----------------------------|------------|---|
| F. FUR USE BY | USEK FAC | ILITY/IMPO | ORTER (D | evices Only) | H. C | DEVICE MANU | FACTURERS C | NLY | |
| 1. Check One | | 2. (| JF/Importer F | Report Number | 1. Ty | pe of Reportable B | ent | | 2. If Follow-up, What Type? |
| User Facility | Import | | | | | Death | | | Correction |
| 3. User Facility or Imp | orter Name/A | ddress | | | | Serious Injury | | | Additional Information |
| | | | | | | Malfunction | | | Response to FDA Request |
| | | | | | | | | | Device Evaluation |
| | | | | | 3. De | vice Evaluated by | Manufacturer? | | 4. Device Manufacture D ate |
| | | | | | | Not Returned to | Manufacturer | | (mm/yyyy) |
| 4. Contact Person | | | 5. Phone N | umber | | Yes Eval | uation Summary Attac | ched | |
| | | | | | | No (Attach page provide code: | e to explain why not) o |)r | 5. Labeled for Single Use? |
| Date User Facility o Importer Became | 1 | Type of Repo | ort | 8. Date of This Report (mm/dd/yyyy) | | provide code. | | | Yes No |
| Aware of Event (mm | r/dd/yyyy) [| Initial | | | C Fu | ant Broblem and E | industing Codes (C | afau ta aa | dia a manuali |
| |] [| Follow-up # | | | 0. EV | ent Problem and t Patient | Evaluation Codes (R | erer to co | oing manuai) |
| Approximate Age of Device | 10. Event Pr | oblem Codes | (Refer to codi | ng manual) | 11 | Code | - | - | |
| 1.90 0, 201.00 | Patient | | _ | | | Device | | - | - |
| | Code | | | | | Code | | | |
| | Code | | - | | | Method | | | |
| 11. Report Sent to FDA | 4? | 12. Location V | Where Event | Occurred | 11 | Results | | | |
| Yes | | ☐ Hospit | al | Outpatient Diagnostic Facility | | resons | | | |
| No (mm/dd | (yyyy) | Home | | Ambulatory | | Conclusions | | | |
| 13. Report Sent to Man | nufacturer? | | g Home | Surgical Facility | 7. If R | Remedial Action In | itiated, Check Type | 8. 1 | Usage of Device |
| Yes | (annual) | Facility | tient Treatmer / | п | | Recall | Notification | | Initial Use of Device |
| No (mm/dd/ | (УУУУ) | Other: | | (Specify) | . [| Repair | Inspection | | Reuse |
| 14. Manufacturer Name | e/Address | | | (Specily) | | Replace | Patient Monitoring | _ | Unknown |
| | | | | | | Relabeling | Modification/ Adjustment | 1 2 | If action reported to FDA under 21 USC 360i(f), list correction/ |
| | | | | | 11 - | Other: | , | , | removal reporting number: |
| | | | | | 11 ' | | | | |
| | | | | | 10. [| Additional Man | ufacturer Narrative | 20/ | d / or 11. Corrected Data |
| G. ALL MANUFA | CTURERS | | | |] 10 | _ Additional man | diacturer (variative | arro | 1701 TI. Corrected Data |
| Contact Office (and | | | rices) | 2. Phone Number | ٩ ا | | | | |
| Name | | | | 310-768-0700 | | | | | |
| EDYTA FRACKIEWI Address | CZ | | | 3. Report Source (Check all that apply) | 11 | | | | |
| Address | | | | Foreign | | | | | |
| HYLAND'S, INC. 154 W. 131ST ST | PDPPP | | | Study | | | | | |
| LOS ANGELES, CA | | | | Literature | | | | | |
| 5 3.11 | | | | Consumer | | | | | |
| Email Address STANDARD@HYLAND | OS.COM | | | Health Professional | | | | | |
| 4. Date Received by | | 5. | | User Facility | | | | | |
| Manufacturer (mm/de | | (A)NDA # | | Company Representative | | | | | |
| 39/29/20 | | IND# | | Distributor | | | | | Dec |
| 6. If IND, Give Protocol | 1# | BLA# | | Other: | | | | | D33 |
| | | PMA/ | | | | | | | DSS 10CT 2 0 201 |
| 7. Type of Report (Check all that apply) | | 510(k) # | | | | | | | 1001 & U ZU |
| 5-day 30-da | 1 | Combination Product | Yes | | | | | | |
| 7-day Period | | Pre-1938 | Yes | | | | | | * |
| ☐ 10-day 🗸 Initial | | OTC Product | ✓ Yes | | | | | | |
| | v-up # | | | | | | | | OCT 1 7 2014 |
| 9. Manufacturer Report | t Number | 8. Adverse Ev | rent Term(s) | | | | | | 001 1 7 8014 |
| 54973 AE # 156 | 51 | SEIZURES | | | | | | | |
| | , | | | | | | | | * |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

COMPLAINT RECORD

| 8 | aseID: 1053077 | 71 |
|---|----------------|----|
| | guarus) | |

| Individual | case sale | y keport |
|------------|------------|----------|
| | | |
| 3.00 | 20774 04 0 | 0.00 |

| 10530771-01-00-03 | | COMPLAINT #; | 2571 | |
|--|---|---|--|-----|
| | | DATE OF COMPLAINT: | 09/29/14 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT40 | |
| SIZE: | 40 TABLETS | LOT NO.: | THREW BOTTLES OUT | |
| REPORTER:(b | 0 (6) | | | |
| ADDRESS: | | | | |
| - | 1 | | | |
| CITY: | | STATE: (b) (6) | - | |
| | SA | ZIP CODE: | | |
| PHONE #: | (6) | | | |
| E-MAIL: | SON HAD 3 SEIZURES LAST YEAR IN 201 | | | |
| AUGUST 2012. CHILD I- PRESCRIBED. CURREN MONITOR HIS FEVERS TABLETS UNTIL HIS LAS NEUROLOGICAL WORK CURIOUS THAT THERE DOCTORS SAID TEETHI | T: FEVER OF 103.7°F AFTER SEIZURE AND ABLETS AT THE TIME. FIRST SEIZURE WAS IN FEBRIHE HOSPITAL THAT SAME DAY, HE HAD A THIRD SEIZ IAD GERD (GAS) AT ONE MONTH OLD, MOTHER SWIT IT HEALTH: HE IS PRONE TO GET FEVERS SINCE THIAND GIVE TYLENOL AND IBUPROFEN ALTERNATELY STEETH EMERGED IN JANUARY 2014. SHE SAID HE UP, EEG, EPILEPTIC STRESS TEST, AND DIAGNOSED WAS NO FAMILY HISTORY OF IT. BABY WAS PRESCRING DID NOT CAUSE FEVER BUT HE ALWAYS HAD FEDST ABOUT TEETHING TABLETS AND WONDERED IF FOR ADDITIONAL SPACE PLEASE USE REV | JARY 2013. (HE WAS BORN IN (b) (6) LURE. BABY STARTED USING TEETHI CHED FORMULAS AND HE WAS BETT E SEIZURES, ONCE A MONTH, OR TW. WHEN FEVER OCCURS. MOTHER CO "GOT HIS TEETH QUICKLY". AT THE I IT AS "COMPLEX FEBRILE SEIZURES" RIBED DIAZEPAM IF HE HAS ANOTHER VER DURING HIS TEETHING PHASES. THAT COULD EXPLAIN THE CAUSE OF | D. SECOND SEIZURE WAS IN NG TABLETS AT 3 MONTHS OLD IN ER. NO MEDICATION WAS O. THE PARENTS CAREFULLY NTINUED TO GIVE TEETHING HOSPITAL THEY DID TO THEY DID SELURE. HAS HAD NONE SINCE. MOTHER CALLED AFTER HER SON'S SEIZURES. | |
| PRODUCT RECEIVED FO | OR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR I | NSPECTION: Y N (CIRCLE ONET | |
| | | DATE REQUESTED PRODUCT BE | , | |
| | | | TAG ISSUED: (CIRCLE ONE) | |
| | | DATE PRODUC | T RECEIVED: | |
| SECTION II: | INVESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT | <u> </u> | | |
| | | | | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST / NURSE FOR EVALUATION | ON: 09/29/14 | 1 | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST / NURSE FOR EVALUATION | BY: TUTTI GO | LD . | |
| SECTION III: | CORRECTIVE ACTION: | | | |
| | | | | |
| | | | DSS | 4 |
| | | | | |
| CORRECTIVE ACTION(S | COMPLETED BY: | DATE: | OCT 2 0 2 | 014 |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: | 1561 | |
| ADVERSE EVENT SERIO | US: Y/N | | | |
| ADVERSE EVENT REPOR | RTED ON: 09/29/14 | BY: TUTTI GOULD | | |
| SECTION V: | | . 1 / | OCT 1 7 20 | 14 |
| REVIEWED BY MANAGE! | MENT BY: | DATE: | | |
| BY: | QUIC Burn | DATE: | 10-07-14 | |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 10530771

Serious Adverse Event SAE-0038-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prenared by

10/6/14

Date

DSS OCT 2 0 2014

OCT 1 7 2014



RSE EVENT DATA FORM



| AE #: 156 | 1 | COMPLAINT #: 2571 | |
|----------------------|--|--|--------------|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FRO | OM REPORTER ON FORM VD1) | |
| ADDRESS: | | | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: PHONE #: | USA (b) (6) | ZIP CODE: | |
| E-MAIL: | , , | 3 | |
| SECTION II: | PACKAGING INFORMATION: | | |
| AFF | TAX PACKAGING LABEL HERE THE STATE OF THE S | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Teething Tablets Teething Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething T | Y |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | DSS |
| CORRECTIVE AC | TION(S) COMPLETED BY: | DATE: | OCT 2 0 2014 |
| SECTION IV: | ~ 1 | | |
| REVIEWED BY MA | ANAGEMENT BY: | DATE: 10-07-14 | |
| BY: | QAYQC DIRECTOR | DATE: 10-07-14 | |
| | art acontector | OCT | 1 7 2014 |



se by user-facilities, tributors and manufactured NDATORY reporting

| | CaseID: 10530789 |
|-------|---|
| ~ | Form Approved: OMB No. 0910-0291, Expires: 6/30/201 See OMB statement on reverse |
| Repor | 1# |

| A. PATIENT INF | ORMATION | | | |
|------------------------------------|---|---------------------|---------------------------------------|--|
| Patient Identifier | 2. Age at Time | | 3. Sex | 4. We |
| (b) (6) | of Event: 35 | Months | | |
| | Or | | Female | |
| In confidence | Date of Birth: | | ✓ Male | |
| B. ADVERSE.E | VENT OR PRODU | CT PROBLE | M | Constitution of the Consti |
| 1 Adverse Even | and/or De | adust Problem (s | and defects (medi- | Maria Maria |
| Adverse Even Outcomes Attribut | | oduct Problem (e | y., delects/mant | inction |
| (Check all that appl | | | | |
| Death: | Imm/dd/s | Disability o | or Permanent Dar | mage |
| Life-threatenin | (mm/dd/yyyy) g | Congenita | Anomaly/Birth D |)efect |
| Hospitalization | - initial or prolonged | | ous (Important M | |
| | vention to Prevent Pern | | | |
| Date of Event (mn) | | | Report (mm/dd | |
| | 00/00/2006 | | 10/01/2014 | |
| 5. Describe Event or | Problem | 1 | | |
| | OF 6 MONTHS TO | | | |
| EPILEPSY. HE | ARS 11 MONTHS HAD FOUR DIFF BODY; ABSENCE RING SPELLS. | ERENT KINDS | ED SEIZURE : GRAND M DROP ATTAC | S ANI AL W H |
| V., U. | | | | |
| | | | | |
| | | | | |
| | H | DECE | . I A A Down Ben | 8 |
| | | RECE | IVLL | B |
| | | | | |
| | | OCT 1 | 7 2014 | |
| | | | | |
| | | CD | P | |
| | | This Red | P 6 | |
| | | | | |
| | | | (Continue on | 0000 |
| 6. Relevant Tests/Lab | oratory Data, Includin | g Dates | (Continue on | page |
| | | | | |
| UNKNOWN TESTS | | | | |
| DEVELOPED SETZ | URES AND EPILE | DSY AT 2 VI | SARS 11 MON | THE |
| OLD. | the second | 11 | - Francis (4) 40 F05021 | |
| | | | | |
| | | | | |
| | | | | |
| | | | (Continue | |
| Other Relevant Hist | ory, Including Preexis | ting Medical Cor | (Continue on | |
| race, pregnancy, smo | ory, Including Preexist oking and alcohol use, HAT HE WOULD H | hepatic/renal dysft | unction. etc.) | - 9-00 |
| | HAI HE WOULD H S NO SEIZURES | | O INE REST | OF. |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| of 5 | | | | | | -D. H. O. |
|-----------------------------------|--|-------------|--|------------|--|------------------|
| C. SUSPECT F | RODUCT(S | j) | *1 | de Care | | FDA Use On |
| 1. Name (Give label | | | District Constitution of the Constitution of t | | The state of the s | |
| #1 HYLAND'S | TEETHING T | 'ABLETS | | | | |
| #2 | | | | | | |
| 2. Dose, Frequency | & Route Used | | | oy Dates | (lf unknown, g estimate) | rive duration |
| #1 UNKNOWN DO | DSE X 6 MO | S | #1 | | | |
| #2 | | | #2 | | | |
| 4. Diagnosis for Us | e (Indication) | | - | | Abated Afte | |
| #1 TEMP RELIE | SF TEETHIN | G PAIN | | | Yes No | Doesn |
| #2 | | | | | | Apply Doesn |
| 6. Lot # | 7. Exp. | Date | | | Yes No | L Apply |
| #1 | #1 | | ************ | | Reappeared oduction? | After |
| #2 | #2 | | | #1 🗍 ነ | Yes No | ✓ Doesn Apply |
| 9. NDC# or Unique | | | | #2 🗆 | Yes No | Doesn |
| 54973-7504- 10. Concomitant Me | | and Thor | any Dates | | | ☐ Apply |
| 10. Concomitant me | raicai r roducis | and men | apy bates | Exclude | ireaiment di | eveni) |
| | | | | | | |
| | | | | | | |
| | | | | (0 | Continue or | page 3) |
| D. SUSPECT N | EDICAL DE | VICE | | | | |
| Brand Name | | | | | | |
| 2. Common Device | Name | | | 2b. F | rocode | |
| 3. Manufacturer Nar | me, City and St | ate | | | | - 10 |
| | | | | | | |
| 4. Model # | Lo | ot # | 9 | | 5. Operator | of Device |
| | | | | | Health | Professiona |
| Catalog # | E | cpiration D | Date (mm/c | dd/yyyy) | Lay Us | ser/Patient |
| Serial# | Ur | nique Iden | tifier (UDI |) # | Other: | |
| | | | | | L | |
| 3. If Implanted, Give | Date (mm/dd/y | yyy) | /. If Expla | anted, Giv | ve Date (mm/ | dd/yyyy) |
| 3. Is this a Single-us | se Device that v | was Repro | cessed ar | nd Reuse | d on a Patier | nt? |
| | 10 | | | | | |
| B. If Yes to Item No. | 8, Enter Name | and Addre | ess of Rep | rocessor | | |
| | | | | | | |
| | | | _ | | | |
| Device Available | | | | | | |
| Yes N | o [] Retur | med to Ma | nufacturer | on: | (mm/dd/y) | (yy) |
| 1. Concomitant Me | dical Products | and Thera | apy Dates | (Exclude | treatment of | event) |
| | | | | | | |
| | | | | (C | ontinue on | page 3) |
| E. INITIAL REP | THE RESERVE OF THE PERSON NAMED AND PARTY. | - | | 1 | | |
| . Name and Addres b) (6) | S | D29 | 5 | | | |
| | 00 | T 0 A | 201/ | (| OCT 17 | 301F. |
| b) USA | UL | T 2 0 | 2014 | | 101 11 | en te |
| | | | | | | |
| Phone # | | Email | Address | | | |
| | 12 2 0 | 4: | | 14.16 | nitial Banast | or Alon Cont |
| Health Profession Yes No | al? 3. Occupa | ition | | | Report to FD | Α |
| | 1 | | | | Yes 🗸 N | Vo Unk. |

Importer |

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment

Home

Other:

12. Location Where Event Occurred

Initial Follow-up#

3. User Facility or Importer Name/Address

2. UF/Importer Report Number

Phone Number

Date of This Report (mm/dd/yyyy)

Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Literature √ Consumer

User Facility

Company

Distributor

Other:

Study

Report Source
 (Check all that apply)

Health Professional

Representative

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

No

Address

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

09/30/2014

30-day

Periodic

✓ Initial

✓ 15-day Follow-up # 9. Manufacturer Report Number

54973 AE # 1566

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

Type of Report

5-day

7-day

10-day

HYLAND'S, INC.

Email Address

Contact Office (and Manufacturing Site for Devices)

Page 2 d

| of 5 | |
|---|--|
| H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| Death Serious Injury Malfunction | Correction Additional Information Response to FDA Request Device Evaluation |
| 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: | 4. Device Manufacture D ate (mm/yyyy) 5. Labeled for Single Use? Yes No |
| 6. Event Problem and Evaluation Codes (Refer to co | ding manual) - |
| Recall Notification Repair Inspection Replace Patient Monitoring Relabeling Modification/ Adjustment | Jsage of Device Initial Use of Device Reuse Unknown I action reported to FDA under 11 USC 360i(f), list correction/ emoval reporting number: |
| 10. Additional Manufacturer Narrative and | / or 11. Corrected Data |
| | |
| DSS 0CT 2 0 2 01 | OCT 1 7 2014 |

CaseID: 10530789

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA

510(k)#

Product

Pre-1938

Combination

OTC Product

8. Adverse Event Term(s) SEIZURES, EPILEPSY

Yes

Yes

√ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Please DO NOT RETURN this form to the above PRA Staff email address.

R COMPLAINT RECORD



| 10530789-01-00-03 | COMPLAINT#: 2576 |
|---|--|
| | DATE OF COMPLAINT: 09/30/14 |
| PRODUCT: HYLAND'S TEETHING TABLETS | ITEM CODE: TEETT125 |
| SIZE: 125 TABLETS | LOT NO.: N/A |
| REPORTER: (b) (6) | |
| ADDRESS: | |
| | |
| CITY: | STATE: (b) (6) |
| COUNTRY: USA | ZIP CODE: |
| PHONE #: (b) (6) | |
| E-MAIL: | y |
| ED SEIZURES AND EPILEPSY, DOCTOR'S SAID THAT HE WOULD HAV | OUT SEIZURES. FROM THE AGE OF 6 MONTHS TO 1 YEAR OLD CHILD WAS USING CHILD IS CURRENTLY 11 YEARS OLD. AT 2 YEARS 11 MONTHS OLD DEVELOP- VE SEIZURES THE REST OF HIS LIFE BUT HE HAS NO SEIZURES NOW. HE HAD ABSENCE SEIZURES; DROP ATTACH SEIZURES; STARING SPELLS. RESOLVED WAS BORN. DOCTORS CAN'T EXPLAIN HOW SEIZURES RESOLVED. |
| FOR ADDITIONAL SPACE PLEASE U | USE REVERSE OR ATTACH A SEPARATE SHEET |
| | |
| PRODUCT RECEIVED FOR Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) |
| | DATE REQUESTED PRODUCT BE RETURNED: |
| | UPS CALL TAG ISSUED: (CIRCLE ONE) |
| | DATE PRODUCT RECEIVED: |
| SECTION II: INVESTIGATION | |
| INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION F | REPORT. |
| ADVEDOS SVENT SORIALABAS | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALU | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALU | JATION BY: EDYTA FRACKIEWICZ |
| SECTION III: CORRECTIVE ACTION: | |
| | DSS |
| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: OCT 2 0 2014 |
| ECTION IV: ADVERSE EVENT REPORTS | AE#:1566 |
| DVERSE EVENT SERIOUS: | |
| DVERSE EVENT REPORTED ON: 09/30/14 | BY: EDYTA FRACKIEWICZ |
| ECTION V: | OCT 17 2 |
| REVIEWED BY MANAGEMENT BY: | NULT DATE: 10-07-14 |
| Y: GUL Baui | DATE: 10-07-14 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0038-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and four (104) Adverse Events (AE) which also included twenty-four (24) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/6/14

Date

DSS

CaseID: 10530789

DSS 2014

OCT 2 0 2014

OCT 1 7 2016





ISE EVENT DATA FORM

| AE #:156 | 66 | COMPLAINT #: 2576 | |
|---|--|---|--|
| SECTION I: | 8 | ERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | | |
| ADDRESS: | - | | |
| CITY; | | STATE: (b) (6) | |
| COUNTRY: | USA | ZIP CODE: | Will Dispusse, or |
| PHONE #: | (b) (6) | | All the same of th |
| E-MAIL: | | | |
| SECTION II: | PACKAGING INFORMATION: | | |
| AFF | IX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| land and extended | The first part of the control of the | Teething Tablets Tabletas para la Dentición Sympomis Relet Trerbagio Châten Pething Tablets Tabletas para la Dentición Sympomis Relet Tabletas para la Dentición Pething Tablets Tabletas para la Dentición Sympomis Relet ha Teching Inchilina No Nabe Jillon - Noro Namal Nota Table Disobs Insanti TETRISTA FARTIS | |
| SECTION III: | CORRECTIVE ACTION: | | DSS |
| | | | OCT 2 0 2014 |
| CORRECTIVE ACTI | ON(S) COMPLETED BY: | DATE: | |
| SECTION IV: | | / | |
| REVIEWED BY MAN | AGEMENT BY: | Jate: 10-07-14 | |
| BY: | Gue Bain | DATE: 10-07-14 | |
| | an / ac birector | | oct i y mai |

se vuser-facilities, ributors and manufacturers NDATORY reporting

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used #1 UNKNOWN DOSE IN WATER

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

| (|
|---|
| |

FDA Use Only

| Form Approved: OMB | No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
|--------------------|--|
| ort# | |

Therapy Dates (If unknown, grive duration) from/to (or best estimate)

5. Event Abated After Use Stopped or Dose Reduced?

| Mfr Report # 54973 | |
|----------------------|--|
| UF/Importer Report # | |
| | |

| A. PATIENT IN | FORMATION | | | |
|--|---------------------------------------|-------------------------------|-------------------------|------------|
| 1. Patient Identifier | | | 3. Sex | 4. Weight |
| (b) (6) | of Event: | Months | □ 5 | lbs |
| | or | | ☐ Female | or los |
| In confidence | of Birth: | ŀ | ✓ Male | kgs |
| B. ADVERSE E | VENT OR PRODU | CT PROBLEM | | |
| 1. 🕢 Adverse Ever | nt and/or Pr | oduct Problem (e.g | ., defects/malfu | unctions) |
| 2. Outcomes Attribu (Check all that app | ited to Adverse Event | | | |
| Death: | 37 | Disability or | Permanent Dar | mage |
| ☐ Life-threateni | (mm/dd/yyyy) na | Congenital A | nomaly/Birth D | efect |
| | n - initial or prolonged | | is (Important M | |
| | rvention to Prevent Pern | | , . | |
| 3. Date of Event (mi | | 4. Date of This R | | |
| 10/00/201 | 3 PRESENT | 1 | 0/06/2014 | |
| 5. Describe Event or | r Problem | | | |
| CHILD DEVELOR | ED SEIZURES AR | OUND THE AGE | OF 3 MON | THS WHEN |
| | D GIVING HIM T | | | |
| | REALLY BADLY, I | | | TO 113177 |
| AN EEG ON OCT | ON HE HAS THE SI | EIZURE. HE . ILD HAD A FEV | IS GOING ' VER OF 99 | |
| THE LAST SHAK | | HAT HE HAS H | | |
| • | WOULD ALSO SHAP | | A HISTORY | |
| HAVING HIGH F SEIZURES TO T | EVERS. DOCTOR | DOES NOT ATT | TRIBUTE T | HE |
| 122201120 10 1 | _ | | | |
| | Rece | eived | | |
| | | RIACK | | |
| | OCT 6 | 9 2044 | | |
| | UCT 2 | 3 2014 | | |
| | A - | Sa Men | | |
| | GI | DP | | |
| | | | | |
| | | | | |
| | | 1 | Continue on | page 3) |
| 6. Relevant Tests/La | boratory Data, Includin | | | , - g - 0) |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | C | Continu e on | page 3) |
| 7. Other Relevant His | story, Including Preexis | sting Medical Cond | litions (e.g., all | |
| race, pregnancy, sr HISTORY OF HI | moking and alcohol use, GH FEVERS. | nepauc/renal dysfun | ction, etc.) | |
| 1111 | | | | |
| NO FAMILY HIS | TORY OF SEIZURE | S. | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| #1 IEMP RELIEF | IEEIHING | J FAIN | #1 | □ Y | es 🗌 No | Doesn't |
|---|----------------|-------------|-----------------------------|----------|---------------------------------|--------------|
| #2 | | | #2 | Пү | es \square No | F Doesn't |
| 6. Lot # | 7. Exp. | Date | | | | ☐ Apply |
| #1A519C | #1 | | | | Reappeared oduction? | After |
| #2 | #2 | | #1 | Y | es No | Doesn't |
| NDC# or Unique ID 54973-3127-1 | | | #2 | П | es No | Doesn'i |
| 10. Concomitant Medi | cal Products | and Therag | y Dates (Ex | clude t | reatment of e | |
| | | | , | | | ,,,,, |
| | | | | | | |
| | | | | | | |
| | | | | (C | ontinue on | page 3) |
| D. SUSPECT ME | DICAL DE | VICE | | | | |
| 1. Brand Name | | | | | | |
| 2. Common Device Na | ıme | | | 2b. P | rocode | |
| 3. Manufacturer Name | , City and Sta | ate | | <u> </u> | | |
| | | • | | | | |
| 4. Model # | 17. | ot # | | | 5 Operator | of Daviss |
| 4. MOGEL# | 100 | ot# | | | 5. Operator | |
| Catalog # | Ex | piration Da | te (mm/dd/y | yyy) | | Professional |
| | | · | | | Lay Us | er/Patiênt |
| Serial # | Un | ique Identi | fier (UDI) # | | Other: | |
| 6. If Implanted, Give D | ate (mm/dd/y | yyy) [7 | If Explante | ed, Giv | e Date (mm/c | dd/yyyy) |
| | | | • | | | |
| 8. Is this a Single-use | Device that w | vas Reproc | essed and f | Reuseo | on a Patien | t? |
| 9. If Yes to Item No. 8, | Enter Name | and Addres | s of Repro | cessor | | |
| | | | 4 | | | ^ |
| | | | | | DS | 5 |
| 10.0 | . | 2/2 | 44 554 | | OCT 24 | 2014 |
| 10. Device Available fo | | | nd to FDA) ufacturer on: | | 001203 | LUIT |
| | | | | | (mm/dd/yy | |
| 11. Concomitant Medic | cal Products | and Therap | y Dates (E. | xclude | treatment of e | event) |
| | | | | | | |
| | | | | (C | ontinue on | page 3) |
| E. INITIAL REPO | RTER | | | | | |
| 1. Name and Address | | | | | | |
| b) (6) | | | | | | |
| | | | | | | |
| | | | | | | |
| Phone # | | Email A | ddress | | | |
| (b) (6) | | (b) (6) | | | | |
| 2. Health Professional | 1 | tion | | 4. Ir | nitial Reporte Report to FDA | er Also Sent |
| Yes No | NA C | CT as | 2014 | | Yes N | lo 🕢 Unk. |
| | | 41 24 | CUIT | | | |
| | | | | | | |

Individual case safety Report

10542710-01-00-02

Importer

7. Type of Report

Initial
Follow-up #

10. Event Problem Codes (Refer to coding manual)

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

Date of This Report (mm/dd/yyyy)

Outpatient Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Study

Literature
Consumer

User Facility
Company
Representative

Distributor

Other:

3. Report Source (Check all that apply)

Health Professional

F. FUR USE BY USEN PAGIETY PHINE

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Date User Facility or Importer Became

11. Report Sent to FDA?

Yes

No

☐ No

Address

Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

5-day 30-day

☐ 10-day 🗸 Initial

54973 AE # 1569

✓ 15-day Follow-up #____ 9. Manufacturer Report Number

7. Type of Report

7-day

29/29/2014

Periodic

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

³age 2 of ⁵

| | | FDA USE ONLY |
|---|------------------------|---|
| ., | | • |
| of 5 | | |
| H. DEVICE MANUFAC | TURERS ONLY | |
| Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death | | Correction |
| Serious Injury | | Additional Information |
| Malfunction | | Response to FDA Request |
| | | Device Evaluation |
| 3. Device Evaluated by Manuf | acturer? | 4. Device Manufacture D ate (mm/yyyy) |
| Not Returned to Manuf | | |
| | Summary Attached | E Labeled for Circle Us = 0 |
| No (Attach page to exp provide code: | lain why not) or | 5. Labeled for Single Use? |
| | | Yes No |
| 6. Event Problem and Evaluat | ion Codes (Refer to | coding manual) |
| Patient | 1_[| |
| Code | | |
| Device Code | |]-[] |
| Method | | |
| Metrod | | |
| Results | - | - - |
| Gthi | | |
| Conclusions | | |
| 7. If Remedial Action Initiated | , Check Type | 8. Usage of Device |
| Recall No | tification | Initial Use of Device |
| | pection | Reuse |
| 1 = - = | ient Monitoring | 9. If action reported to FDA under |
| | dification/ ustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | removal reporting manner : |
| | | |
| 10. Additional Manufactur | er Narrative | and / or 11. Corrected Data |
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This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Product

Pre-1938

Combination

OTC Product Yes

8. Adverse Event Term(s) SEIZURES, FEVERS

Yes

☐ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 10542710



COMPLAINT RECORD



10542710-01-00-03 COMPLAINT #: 2579 TAKEN BY: **EDYTA FRACKIEWICZ** DATE OF COMPLAINT: 09/29/14 PRODUCT: HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET---T135 SIZE: 135 TABLETS LOT NO.: A519C (PER CUSTOMER) REPORTER ADDRESS: (b) (6) STATE: (b) (6) CITY: COUNTRY: USA ZIP CODE: (b) (6) PHONE #: E-MAIL: CUSTOMER SENT THE FOLLOWING E-MAIL ON SEPTEMBER 29: SINCE I HAVE BEEN GIVING THE TEETHING NATURE OF COMPLAINT:

TABLETS TO MY SON HE KNOW HAS SEIZURES BECAUSE OF THE PRODUCT. I SEEN ALL OVER FACEBOOK
THAT YOU GUYS HAD A RECALL OUT FOR IT. I SPOKE WITH CUSTOMER ON SEPTEMBER 30TM. SHE REPORTED THAT SHE STARTED GIVING HER
CHILD BABY TEETHING TABLETS AT 3 MONTHS AND AROUND THAT TIME HE DEVELOPED SEIZURES. SHE WAS GIVING THEM IN WATER AND
PUTTING THEM ON THE BABY'S GUMS. USING THEM EVERY OTHER DAY X 11 MONTHS. SHE IS UNSURE OF WHAT TYPE OF SEIZURES HER CHILD
HAS BUT HE SHAKES REALLY BADLY, ESPECIALLY WHEN HE IS SLEEPING. HE IS GOING TO HAVE AN EEG ON OCTOBER 16TM. SHE PROVIDED A LOT # OF A519C WHICH SHE READ OFF THE BOTTOM OF THE BOTTLE. I TOLD HER THAT IT'S NOT A HYLAND'S LOT # AND TO LOOK AT THE SIDE OF THE LABEL, AND SHE SAID THAT SHE COULD NOT SEE A LOT # THERE. CALLED CUSTOMER AGAIN ON 10/01/14 FOR FOLLOW-UP INFORMATION: MOTHER STATED THAT THERE IS NO FAMILY HISTORY OF SEIZURES. BABY HAD A FEVER WITH THE LAST SHAKING 99.8°F. BEFORE THAT HE HAD FEVERS OF 101 AND 102°F AND WOULD ALSO SHAKE. HE HAS A HISTORY OF HAVING HIGH FEVERS. DOCTOR SAID TO HER THAT THESE FEVERS ARE NORMAL IN A CHILD AND DID NOT ATTRIBUTE THE SEIZURES TO THE FEVERS. DOCTOR SAID THAT FEVERS COULD HAVE BEEN CAUSED BY CHANGING ENVIRONMENTS BECAUSE MOTHER WAS LIVING FROM HOTEL TO HOTEL. SHE THREW THE BOTTLE AWAY. STOP USING BABY TEETHING TBALETS AND CONSULT YOUR PHYSICIAN REGARDING YOUR CHILD'S SYMPTOMS. FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR PRODUCT BEING RETURNED FOR INSPECTION: INSPECTION: DATE REQUESTED PRODUCT BE RETURNED: (CIRCLE ONE UPS CALL TAG ISSUED: DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/29/14 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: DATE: SECTION IV: ADVERSE EVENT REPORTS AE #: __1569 ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED ON 09/29/14 EDYTA FRACKIEWICZ OCT 28 2014 SECTION V: REVIEWED BY MANAGEMENT BY: BY: OA / OC DIREC

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 10542710

Serious Adverse Event SAE-0045-2014

Product in Inventory:

The lot number provided by the customer for the Hyland's Baby Teething Tablets (BTET) lot # A519C but after a search of our systems it was determined that it does not exist.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

DSS Oct 24 ₂₀₁₄



RSE EVENT DATA FORM

| CasaID: 10542710 | |
|------------------|--|
| Hylands | |
| | |

| AE #: | 1569 COMPLAINT #: _2579 | |
|---|--|---|
| SECTION | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS | | |
| CITY: | (b) (6) STATE: (b) (6) | |
| COUNTRY | USA ZIP CODE: | |
| PHONE #: E-MAIL: | | |
| | | |
| SECTION I | PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CART (INCLUDE DRUG FACTS AND PRINC PANELS) | |
| The Strategic is a time green in the plant | MCC 54973-31271 MCC 54 | sething biblets Bably sething biblets Committee of the committee of the |
| SECTION II | CORRECTIVE ACTION: | |
| : | | |
| | | r |
| CORRECTIV | E ACTION(S) COMPLETED BY: DATE: | DSS |
| SECTION IV | | OCT 2 4 2014 |
| REVIEWED | Y MANAGEMENT BY: POLITY DATE: / | 10-10-14 |
| 3Y: | | 0-10-14 |



ibutors and manufacturers DATORY reporting

#2

#2

#2

6. Lot#

9. NDC# or Unique ID

1. Brand Name

4. Model#

Catalog #

2. Common Device Name

54973-7504-1

C. SUSPECT PRODUCT(S) Name (Give labeled strength & mfr/labeler) #1 HYLAND'S TEETHING TABLETS

2. Dose, Frequency & Route Used #1 AS DIRECTED ON LABEL

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

D. SUSPECT MEDICAL DEVICE

3. Manufacturer Name, City and State

7. Exp. Date

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

#1

| Case | ID: | 10 | 542 | 735 |
|------|-----|----|-----|-----|
| | | | | |

Form Approved: OMB No. 0910-0291, Exp-ires: 6/30/2015

Therapy Dates (If unknown, give duration) from/to (or best estimate)

5. Event Abated After Use Stopped or Dose Reduced?

#1 Yes ✓ No

#2 Yes No

#1 Yes No

#2 Yes No

2b. Procode

8. Event Reappeared After Reintroduction?

(Continue on page 3)

5. Operator of Device Health Professional

Doesn't Apply

Doesn't Apply

Doesn't Apply

Doesn't

| | See OMB statem ent on reverse |
|----------------------|-------------------------------|
| Mfr Report # 54973 | |
| UF/Importer Report # | |
| | F≃DA Use Only |

#2

| FORM FDA | 3500A | (2/13) |
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|----------|-------|--------|

PLEASE TYPE OR USE BLACK INK

| FORM FDA 350 | 0A (2/13) | | | Page 1 c |
|---|--|-------------------------------------|--|--------------------|
| A. PATIENT INF | | | | |
| Patient Identifier b) (6) | 2. Age at Time of Event: | Years | 3. Sex | 4. Weight |
| | or | | ✓ Female | or lbs |
| In confidence | of Birth: | | Male | kgs |
| B. ADVERSE EV | VENT OR PROD | UCT PROBLE | М | |
| Adverse Even Outcomes Attribut | | Product Problem (| e.g., defects/malf | unctions) |
| (Check all that appl | | | | |
| Death: | (mm/dd/yyyy) | | or Permanent Da | • |
| Life-threatenin | ng n - initial or prolonged | | il Anomaly/Birth D ious (Important M | 1 |
| | rvention to Prevent Pe | 653 | | |
| 3. Date of Event (mn | n/dd/yyyy) | 4. Date of This | Report (mm/do | Vyyyy) |
| | 09 - PRESENT | | 10/08/2014 | |
| 5. Describe Event or | | | | |
| MOTHER POSTED MOTOR FUNCTION AN INFANT. D | | | THING TABL | ETS AS |
| ONLY SPOKE 40 | WORDS AT THE | TIME. | | 1 |
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| | | | (Continue or | page 3) |
| 6. Relevant Tests/Lat | boratory Data, Includ | ling Dates | 1 | |
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| | | | (Continue or | 1 nage 21 |
| 7. Other Relevant His race, pregnancy, sn NO HISTORY OF BROTHER ALSO H | noking and alcohol us DEVELOPMENTAI | e, hepatic/renal dys L DELAYS IN | onditions (e.g., a function, etc.) PARENTS | llergies, OLDER |
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| | | | (Continue or | page 3) |

| Serial # | 1 | | Lay User/Patient |
|--|----------------------|------------------------|--|
| | Unique Ide | entifier (UDI) # | Other: |
| 6. If Implanted, Give Date | e (mm/dd/yyyy) | 7. If Explanted, Given | ve Date (mm/cld/yyyy) |
| 8. Is this a Single-use De | evice that was Repr | ocessed and Reuse | d on a Patient? |
| 9. If Yes to Item No. 8, Er | nter Name and Add | ress of Reprocesso | 7 |
| | | | |
| 10. Device Available for I | Evaluation? (Do no | t send to FDA) | |
| Yes No | Returned to M | lanufacturer on: | (mm/dd/yyyy) |
| 11. Concomitant Medical | Products and The | rapy Dates (Exclude | treatment of event) |
| | | | |
| | | | |
| | | (0 | continue on page 3) |
| E. INITIAL REPOR | TER | (C | Continue on page 3) |
| 1. Name and Address | TER | (0 | |
| | TER | (C | |
| 1. Name and Address b) (6) | TER | (C | |
| 1. Name and Address | TER | (C | DSS 0CT 2 4 2014 |
| 1. Name and Address (b) (6) | | (C | |
| 1. Name and Address (b) (6) | | nil Address | DSS OCT 2 4 2014 |
| 1. Name and Address (b) (6) USA Phone # | Ema 3. Occupation | nil Address | DSS OCT 2 4 2014 |
| 1. Name and Address (b) (6) USA Phone # | 3. Occupation | nii Address | DSS OCT 2 4 2014 Initial Reporter Also Sent Report to FDA Yes \(\) No \(\) Unk. |
| 1. Name and Address (b) (6) USA Phone # 2. Health Professional? | 3. Occupation | nii Address | DSS OCT 2 4 2014 Initial Reporter Also Sent Report to FDA Yes \(\) No \(\) Unk. |
| 1. Name and Address (b) (6) USA Phone # 2. Health Professional? | 3. Occupation | nil Address | DSS OCT 2 4 2014 Initial Reporter Also Sent Report to FDA Yes \(\) No \(\) Unk. |

Lot #

Expiration Date (mm/dd/yyyy)

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| THAT AT GRAFT | case parecy | reborc |
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| | | |

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

Importer

3. User Facility or Importer Name/Address

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Study

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

Report Source (Check all that apply)

Health Professional

1. Check One

User Facility

4. Contact Person

9. Approximate

Yes

☐ No

Yes

☐ No

Name

Address

Age of Device

11. Report Sent to FDA?

Date User Facility or Importer Became

Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

10/04/2014

30-day

Periodic

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

10-day 🗸 Initial

15-day Follow-up# 9. Manufacturer Report Number

54973 AE # 1573

7. Type of Report

5-day

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

| ge 2 | of | 6 |
|------|----|---|
|------|----|---|

| f <u>6</u> | |
|--|--|
| H. DEVICE MANUFACTURERS ONLY | 1 |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Inform ation |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date (mm/yyyy) |
| Not Returned to Manufacturer | , |
| Yes Evaluation Summary Attached | 5 Labeled for Single Up 2 |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| | Yes No |
| Event Problem and Evaluation Codes (Refer to | coding manual) |
| Patient Code | - |
| Device | |
| Code | |
| Method - | |
| Barrier | |
| Results | |
| Conclusions - | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ Adjustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Product

Pre-1938

Combination

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

SPEECH AND MOTOR FUNCTION DELAYS

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

CaseID: 10542735

FDA USE ONLY

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| AINT RECORD | Sylvands 542735 |
|-------------|-----------------|
| | 71 120 ME |

10542735-01-00-03 COMPLAINT #: 2583 DATE OF COMPLAINT: 10/04/14 IONLIS DI EDITA FRAUNEWICK PRODUCT: HYLAND'S TEETHING TABLETS ITEM CODE: TEET LOT NO .: UNKNOWN SIZE: UNKNOWN REPORTER: ADDRESS: CITY: STATE: USA COUNTRY ZIP CODE: PHONE #: E-MAIL: ON (b) (6) I JUST FOUND OUT THAT THESE TABLETS CUSTOMER POSTED THE FOLLOWING ON (b) (6) WERE VOLUNTARILY RECALLED BY THE HYLAND'S COMPANY IN 2010. THEN AFTER THEY PUT A CHILD RESIS NATURE OF COMPLAINT: TANT LID ON THEIR PRODUCT PUT IT BACK ON THE SHELVES. THIS PRODUCT CONTAINS AN INGREDIENT CALLED BELLADONNA. NOW TO THOSE OF YOU WHO DO NOT KNOW WHAT BELLADONNA IS HERE IS A DESCRIPTION CEN.M.WIKIPEDIA.ORG/WIKI/ATROPA_BELLADONNA. IT IS THE MOST TOXIC PLANT IN THE NORTHERN HEMISPHERE. AND YET WE HAVE BEEN GIVING THIS TO OUR BABIES!!! I DON'T BELIEVE EVERYTHING I SEE ONLINE BUT THIS ONE I FOUND I NEEDED TO RESEARCH. MMY SON WAS BORN IN 2004 I WAS TOLD ABOUT THESE AMAZING TEETHING TABLETS FROM A FRIEND. I USED THEM FOR ALL 3 OF MY KIDS. NOW MY 2 OLDER CHILDREN NOW AGES 10 AND 6 BOTH HAVE THE SAME EXACT MOTOR FUNCTION DELAYS. BOTH SPEECH AND OT. BOTH HAVING TO DO WITH THE BRAIN. NOW I AM NOT SAYING THAT THESE TABLETS ARE DEFINITELY THE CAUSE OF THEIR DELAYS BUT IT SEEMS PRETTY ODD THAT THEY WERE BORN COMPLETELY HEALTHY AND NEVER HAD ANY PROBLEMS UNTIL AFTER THEIR FIRST BIRTHDAYS. MY OLDER DAUGHTER DID NOT TALK UNTIL SHE WAS 3 AND EVEN THEN SHE ONLY HAD AROUND 40 WORDS IF THAT. MY SON HAS BEEN STRUGGLING WITH SPEECH, OT, READING, ATTENTION SPAN, MEMORY AND A LOT MORE. THE THING THAT GETS ME IS THAT THEY HAVE THE SAME EXACT SYMPTOMS. WHAT ARE THE ODDS?? I USED THESE TABLETS AS DIRECTED FOR BOTH OF THEM EVERYDAY WHILE THEY WERE TEETHING. FOR MONTHS AT A TIME. THEY SEEMED TO WORK GREAT!! I NEVER THOUGHT THAT THERE WOULD BE PROBLEMS LATER ON. THE BOTTLE SAYS HOMEOPATHIC. THAT'S GOOD RIGHT? WRONG. HOMEOPATHIC DOES NOT MEAN SAFE! I KNOW THAT NOW. MY SON IS 10 AND IS A SPECIAL EDUCATION CLASS. HE STRUGGLES CONSTANTLY WITH EVERYTHING. HE HAD THESE TABLETS ON A DAILY BASIS FROM THE AGE OF 9 (CONTINUED ON NEXT PAGE) FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR PRODUCT BEING RETURNED FOR INSPECTION: INSPECTION: DATE REQUESTED PRODUCT BE RETURNED UPS CALL TAG ISSUED: (CIRCLE ONE DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION INVESTIGATION Please see attached Investigation Report. ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/04/14 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: DATE: SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1573 ADVERSE EVENT SERIOUS: OCT 24 2014 ADVERSE EVENT REPORTED ON 10/04/14 BY: EDYTA FRACKIEWICZ SECTION V: REVIEWED BY MANAGEMENT BY BY:

cc: QA/QC Packaging

Production Shipping / Receiving





とつもっ COMPLAINT #2582:

PAGE 2

NATURE OF COMPLAINT (CONT):

MONTHS UNTIL HE WAS FINISHED TEETHING. HE WAS MY FIRST BABY. AND ANYONE WHO HAS MORE THAN ONE CHILD KNOWS HOW PARANOID YOU ARE WITH YOUR FIRST. I WAS SCARED TO USE THE TABLETS AT FIRST. BUT MY HUSBAND TRIED THEM WHEN I WAS NOT HOME AND THEY WORKED. THEY MADE A SCREAMING BABY CALM DOWN AND BE PAIN FREE. LEARNING ALL OF THE NEW NEWS I'M HEARING ABOUT THESE TABLETS IS REALLY SCARING ME. ESPECIALLY WITH THE WAY MY CHILDREN ARE. NO KNOWN CAUSE. DOESN'T RUN IN THE FAMILY. PARENTS NEVER HAD DELAYS OR ANY PROBLEMS GROWING UP. I WANT TO REACH OUT TO OTHER PARENTS WHO HAVE USED THESE TABLETS. I WANT TO KNOW ABOUT YOUR CHILDREN'S SYMPTOMS IF ANY. ANY INFORMATION WILL HELP ME MAKE A POSSIBLE CASE AGAINST THIS COMPANY AND TO WARN POISONOUS PLANT EXTRACTS IN THE WORLD. PLEASE RE-THINK GIVING YOUR BABIES THESE TABLETS. I WISH I KNEW ALL THIS INFORMATION YEARS AGO. IT WOULD HAVE SAVED ME COUNTLESS YEARS OF ANGUISH. PLEASE COMMENT IF YOU HAVE SEEN ANY SYMPTOMS IN YOUR BABY OR CHILDREN. I WILL BE MAKING A FB PAGE AND WILL POST THE LINK HERE IF YOU WOULD LIKE TO JOIN TO BE UPDATED OF ANY FINDINGS.

HYLAND'S POSTED ON FACEBOOK ON 10/06/14: HYLAND'S IS COMMITTED TO FOLLOWING UP ON REPORTS OF ADVERSE EVENTS AND WOULD ASK YOU TO PLEASE CONTACT OUR PRODUCT INFORMATION SERVICE AS SOON AS POSSIBLE AT 1-800-624-9659 EXT. 4117 TO DISCUSS WHAT HAPPENED WITH YOUR CHILD AND FOR MORE INFORMATION ABOUT THE PRODUCT. AS A GENERAL GUIDELINE, WE ENCOURAGE ALL CONSUMERS TO CONTACT COMPANIES BY PHONE AT THE NUMBER PROVIDED RATHER THAN POSTING ON WHEN THEY ARE CONCERNED ABOUT A REACTION TO A MEDICINE SO THAT ANY ISSUES CAN BE PROPERLY ADDRESSED. PLEASE KNOW THAT HYLAND'S BABY TEETHING TABLETS HAVE A VERY WIDE MARGIN OF SAFETY, AS DO ALL HOMEOPATHICALLY-PREPARED MEDICINES.

DSS OCT 2 4 2014



FANDARD EOPATHIC THE USA SINGE 1903

CaseID: 10542735

Serious Adverse Event SAE-0050-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

10/10/14

DSS DCT **2** 4 2014



Hylands 10542735

RSE EVENT DATA FORM

| AE #: | 1573 | COMPLAINT #: | |
|--------------------------------|-------------|---|----------------|
| SECTION I | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: ADDRESS | : | (b) (6) | |
| CITY: COUNTRY PHONE #: E-MAIL: | | USA STATE: ZiP CODE: | |
| SECTION I | <u>II:</u> | PACKAGING INFORMATION: | |
| | AFFI | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Tabletas paralla Dentición Tabletas paral la Dentición Tabletas paral la Dentición AND AND AND AND AND AND AND AND AND AND | |
| SECTION I | <u>III:</u> | CORRECTIVE ACTION: | |
| CORRECT | IVE ACT | CTION(S) COMPLETED BY: DATE: OCT | 988 24 2014 |
| REVIEWED BY: | | ANAGEMENT BY: POUL DATE: 10-14-14 QA/QC DIRECTOR DATE: 10-14-14 | |

OCT 22 2014

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FORM FDA 3500A (2/13)

CaseID: 10542775 Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statem ent on reverse.

Mfr Report # se by user-facilities, 54973 tributors and manufactu NDATORY reactions UF/Importer Report # Page 1 o

| 111 | | | | | - |
|---|--------------------------------------|--------------|----------------|------------------------|---------------|
| | | - | | | =DA Use Only |
| C. SUSPECT PROD 1. Name (Give labeled street | | | | | |
| #1 HYLAND'S BABY | | BLETS | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Rou | ite Used | | | | ive duration) |
| #1 2-3 TABS ONCE | A WEEK | #1 | (or best e | sumate) | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (India | cation) | J | | Abated After | |
| #1 TEMP RELIEF TE | ETHING PAIN | | Stoppe #1 Y | ed or Dose R es ∏No | Doesn't |
| #2 | | | | | Apply Doesn't |
| 6. Lot# | 7. Exp. Date | | #2 Y | | L⊈ Apply |
| #1A05014 | #1 | | | Reappeared oduction? | |
| #2 | #2 | | #1 🗌 Y | es No | Doesn't Apply |
| 9. NDC# or Unique ID 54973-3127-3 | | ; | #2 🗌 Y | es No | Doesn't |
| 10. Concomitant Medical F | Products and The | apy Dates | (Exclude I | reatment of e | |
| | | | | | |
| | | | | | |
| | | | (C | ontinue on | nage 31 |
| D. SUSPECT MEDIC | CAL DEVICE | | (0 | - minus VII | page 3) |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 2b. P | rocode | |
| 3. Manufacturer Name, Cit | ty and State | | | | |
| | | | | | |
| 4. Model # | Lot# | | | 5. Operator | of Device |
| Catalog # | Expiration | Date (mm) | dd/ywwl | Health | Professional |
| Juliuog " | Expiration | -316 (11111) | | | er/Patient |
| Serial # | Unique Ide | ntifier (UD |)# | Other: | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Expl | anted, Giv | e Date (mm/ | dd/yyyy) |
| 8. Is this a Single-use Dev | ice that was Ron- | ocessed a | nd Rouse | l on a Pation | 112 |
| Yes No | ov mat was repr | ocesseu a | na neuset | | |
| 9. If Yes to Item No. 8, Ent | er Name and Add | ess of Re | processor | DS | SS |
| | | 921 | | OCT 9 | 4 2014 |
| | | | | | - 2017 |
| 10. Device Available for Ev | /aluation? (Do not Returned to Ma | | • | | |
| | | | | (mm/dd/yy | |
| 11. Concomitant Medical F | roducts and Ther | apy Dates | (Exclude | treatment of | event) |
| | | | | | |
| E. INITIAL REPORT | ER | | (C | ontinue on | page 3) |
| 1. Name and Address | | | | | |
| (b) (6) | | | 007 | | |
| (b) (6) USA | | | UCI | 23 20 | 14 |
| | | | | | . |
| Phone # (b) (6) | Emai | Address | | | |
| 2: Health Professional? 3 | Occupation | | | | er Also Sent |
| l_ | | | 1 8 | Report to FD | Α . |

NA

Yes No V Unk

Yes

√ No

A. PATIENT INFORMATION 4. Weight 1. Patient Identifier 2. Age at Time Sex of Event: Months 22 Female lb: or Date ✓ Male In confidence of Birth: kgs **B. ADVERSE EVENT OR PRODUCT PROBLEM** ✓ Adverse Event and/or Product Problem (e.g., defects/malfunctions) 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) ✓ Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 09/19/2014 10/07/2014 5. Describe Event or Problem 9 MONTH OLD BABY HAD A SEIZURE ON (b)(6) AFTER BEING ON TEETHING TABLETS FOR 4 - 5 WEEKS. IT CAME ON AFTER HIS BATH AS MOTHER WAS RUBBING LOTION ON HIS LEGS. SHE SAID IT WAS AS THOUGH HE WAS SHIVERING. HIS LEGS THEN RHYTHMICALLY TIGHTENED AND LOOSENED. THIS SHAKING SPREAD TO THE REST OF HIS BODY AND LASTED 20 MINUTES. 911 WAS CALLED AND THE POLICE AND AMBULANCE ARRIVED; BABY'S TONGUE WAS HELD DOWN BY A TONGUE DEPRESSOR AND WAS TRANSFERRED TO THE CHILDREN'S HOSPITAL WHERE HE WAS BI OBSERVED FOR 4 DAYS. MOTHER SAID THAT SHE HAD GIVEN THE PLEASE TYPE OR USE BABY 3 TABLETS OF TEETHING PRODUCT THE DAY BEFORE THE SEIZURE. (Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates A 36-HOUR EEG TEST SHOWE RECEIVED F UNKNOWN ORIGIN. ALL OTHER TESTS WERE NORMAL (MRI, CAT SCAN AND BLOOD WORK). DOCTORS PRESCRIBED PHENOBARBITAL UNTIL OCTOBER 15TH WHEN ANOTHER FOR WISLES 2000 NE. CDR (Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) THERE IS NO HISTORY OF EVER HAVING ANY COLDS, FEVERS OR RASHES. HIS LAST IMMUNIZATION WAS JUNE 10TH, 2014; HE HAS ALSO RECEIVED REGULAR FLU SHOTS. (Continue on page 3) Submission of a report does not constitute an admission that medical

personnel, user facility, importer, distributor, manufacturer or product

caused or contributed to the event.

Importer

7. Type of Report

Initial Follow-up # 10. Event Problem Codes (Refer to coding manual)

3. User Facility or Importer Name/Address

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

8. Date of This Report

Outpatient Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Literature ✓ Consumer

User Facility

Company

Distributor

Other:

Study

3. Report Source (Check all that apply)

Health Professional

Representative

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

☐ No

Name

Address

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

10/02/2014

Periodic

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

5-day 30-day

☐ 10-day 📝 Initial

54973 AE # 1571

✓ 15-day Follow-up # 9. Manufacturer Report Number

7. Type of Report

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

age 2 c

| | | FDA USE ONLY |
|-------------------------------------|---------------------------|---|
| of ⁵ | | |
| | | |
| H. DEVICE MANUFAC | TURERS ON | |
| Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death Serious Injury | | Correction Additional Inform ation |
| Malfunction | | Response to FDA Request |
| | | Device Evaluation |
| | | |
| 3. Device Evaluated by Manu | | Device Manufacture Date (mm/yyyy) |
| Not Returned to Manu | | |
| | Summary Attach | 5 1 -1 -1 -1 - 0 - 1 - 1 - 0 |
| No (Attach page to ex provide code: | piain why not) of | |
| | | Yes No |
| 6. Event Problem and Evalua | tion Codes (Refe | fer to coding manual) |
| Patient | | |
| Code | | |
| Device Code | | |
| Name of T | | |
| Method | | |
| Results | - | - |
| | | |
| Conclusions | | |
| 7. If Remedial Action Initiated | d, Check Type | 8. Usage of Device |
| Recall No | otification | Initial Use of Device |
| Repair In: | spection | Reuse |
| | atient Monitoring | Unknown |
| | odification/ djustment | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | | removal reporting number: |
| | | |
| 10. Additional Manufactu | rer Narrative | and / or 11. Corrected Data |
| | | Li company |
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| | | OCT 23 2014 |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# **PMA/**

510(k)#

Product

Pre-1938

SEIZURE

Combination

8. Adverse Event Term(s)

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.

CaseID: 10542775



Individual case Salety Report

COMPLAINT RECORD



| 10542775-0 | 11-00-03 | COMPLAINT #: | 2581 |
|---|--|--|--|
| | | DATE OF COMPLAINT: | 10/02/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | ВТЕТ |
| SłZE: | UNKNOWN | LOT NO.: | A05014 |
| REPORTER: (b) (6) |) | | |
| ADDRESS: | | | |
| | The state of the s | | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: USA | The state of the s | ZIP CODE: | |
| PHONE #: (b) (6 |) | | |
| E-MAIL: | 9 MONTH OLD BABY HAD A SEIZURE ON (| 0) (6) | EETHING TABLETS FOR 4 – 5 |
| 20 MINUTES. 911 WAS CA WAS TRANSFERRED TO T ORIGIN. ALL OTHER TEST WHEN ANOTHER EEG WIL SEIZURE, PLAYING WITH | RING, HIS LEGS THEN RHYTHMICALLY TIGHTENED AT ALLED AND THE POLICE AND AMBULANCE ARRIVED; THE CHILDREN'S HOSPITAL AND STAYED FOR 4 DAY TS WERE NORMAL (MRI, CAT SCAN AND BLOOD WOF LL BE DONE. BABY HAS BEEN ON FORMULA AND HA HIS BOUNCER AND WALKER. THERE IS NO HISTORY ALSO RECEIVED REGULAR FLU SHOTS. MOTHER SA | ND LOOSENED. THIS SPREAD TO TH BABY'S TONGUE WAS HELD DOWN S. A 36-HOUR EEG TEST SHOWED A RK). DOCTORS PRESCRIBED PHEN D. THE SAME ROUTINE AND DIET IN Y ANY COLDS FEVERS OR RASHES | IE REST OF HIS BODY AND LASTED BY A TONGUE DEPRESSOR. BABY "SMALL SPIKE" OF UNKNOWN "DBARBITAL UNTIL OCTOBER 15 TH THE 24 HOURS PRIOR TO THE HIS I AST IMMUNIZATION WAS |
| | FOR ADDITIONAL SPACE PLEASE USE REVE | RSE OR ATTACH A SEPARATE SHE | ET |
| | | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (N) | PRODUCT BEING RETURNED FOR I | NSPECTION: Y (N) (CIRCLE ONE) |
| 11431 23 11014. | (CINCLE ONE) | DATE REQUESTED PRODUCT BE | ,- |
| | | DATE REQUESTED PRODUCT BE | RETORNED. |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| | | DATE PRODUC | FRECEIVED: |
| SECTION II: | NVESTIGATION | | |
| IND/FOTION TION | 5.5.05.055.055.050.050.050.050.050.050. | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| | | | |
| | | | |
| ADVERSE EVENT FORWAR | RDED TO PHARMACIST / NURSE FOR EVALUATION C | ON: 10/02/14 | |
| ADVERSE EVENT FORWAR | RDED TO PHARMACIST / NURSE FOR EVALUATION B | Y: TUTTI GO | ULD |
| SECTION III: | CORRECTIVE ACTION: | | |
| • | | | |
| | | | |
| | | | - |
| CORRECTIVE ACTION(S) | COMPLETED BY: | DATE: | Doo |
| SECTION IV: AD | OVERSE EVENT REPORTS | ^ F# | 522 |
| CECTIONIV. | OVERSE EVENT REPORTS | AE #: _ | OCT 2 4 2014 |
| ADVERSE EVENT SERIOUS | S: (Y)/ N | | - |
| ADVERSE EVENT REPORT | ED ON: 10/02/14 | BY: TUTTI GOULD | |
| SECTION V: | | 1 | |
| REVIEWED BY MANAGEME | ENT BY: MAJON Y | f nate | 10-10-14 |
| | C. M. M. | DATE: I | 10-10-14 |
| BY: | QA / QC DIRECTOR | _ DATE: | 10-10-14 |

cc: QA / QC Packaging Production Shipping / Receiving

OCT 23 -2014





Serious Adverse Event SAE-0048-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/8/14

Date

DSS OCT 2.4 2014

CaseID: 10542775

CC-0792-2014 AE-0469-2014 06F-2-3-201L



RSE EVENT DATA FORM



| AE #: | 1571 COMPLAINT #: 2581 | |
|---------------------|--|-------------|
| SECTION | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | _ |
| ADDRESS | | <u>-</u> |
| CITY: | STATE: (b) (6) | - |
| COUNTRY PHONE #: | USA ZIP CODE: | - |
| E-MAIL: | | - |
| SECTION | PACKAGING INFORMATION: | |
| | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Testing Tables To thing To thing To the control of the con | |
| SECTION | : CORRECTIVE ACTION: | |
| | /E ACTION(S) COMPLETED BY: DATE: | DSS |
| REVIEWED | BY MANAGEMENT BY: DATE: 10-10-14 | OCT 24 2014 |
| BY: | QA/QC DIRECTOR DATE: 10-10-14 | - - |

e by user-facilities ributors and manufacturers IDATORY reporting

| Case | ID: 10 | 542937 |
|----------------|-----------|-------------------|
| round: OHP No. | 0010 0001 | Evenimos COOMO 46 |

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

| Mfr Report # | 54973 | |
|---------------|----------|--|
| UF/Importer F | Report # | |

1 of ⁶

| | FORM FDA 350 | 0A (2/13) | | | Page |
|------------------------------|--|---|---|--|---|
| | A. PATIENT INF | FORMATION | | | |
| | Patient Identifier (b) (6) | 2. Age at Time of Event: | | 3. Sex | 4. Weight |
| | (2) (-) | or10 | Months | Female | lb: |
| | In confidence | Date of Birth: | | ✓ Male | or ka: |
| | | VENT OR PRODUC | CT PROBLE | | kg: |
| | 1. Adverse Even | | oduct Problem (e | | diane) |
| | 2. Outcomes Attribut | ted to Adverse Event | Auge From | .g., delect | Unicaona, |
| | (Check all that appl | | ☐ Disability c | or Permanent Dar | mage |
| | Life-threatenin | (<i>mm/dd/yyyy</i>) ng | | l Anomaly/Birth D | |
| | ' | n - initial or prolonged | | ious (Important M | |
| | | rvention to Prevent Perma | , | | ···· |
| | 3. Date of Event (mn 08/0 | n/dd/yyyy) 00/2014 | 1 | Report (mm/dd 10/06/2014 | |
| | 5. Describe Event or | | | | |
| PLEASE TYPE OR USE BLACK INK | WONDERED IF IT SYMPTOMS. THE MONTH, SOMETIN SHE SAYS THAT AROUSE; HE IS FOR THE LAST ? TAKING TEETHIN TAKE TEETHING 6 MONTHS OF ACTIVE THE SON HAD SEBEEN ON MYSTATINFECTIONS, COMPICE SAYS HE WAS TEETHIN THOUGHT HE HALFREQUENTLY DESHAVING ACID RESAYS HAVING ACI | T WAS RELATED T E SYMPTOMS SEEM MES WHEN HE WAS HE SLEEPS DEEP SLOW TO RESPON 2 MONTHS; DURIN | TO HER SON'S TO OCCUR TO OCCUR TO OCCUR TO OCCUR TO OCCUR TO AWAY FROM THE HAS TO THIS TIME THIS TIME THIS OLD, SO THAVING "FOR THE MOT TO A "BRAIN FOR THE STOM THE STOM THE STOM TO SYSTEM THE SYSTEM THE THE THANGES, AND TOLD THAT TO | S SEIZURE- 4 - 5 TIME: MOTHER'S I DIFFICULT' BEEN HAVII IE HE HAS NO YEAR OLD, ING EPISODI HE JUST USI RGOTTEN" AI THER REPOR' BLEED". HI HRUSH, EAR ACH INFECT: T 6 MONTHS. HING TABLE: HE ALSO D WAS DIAGO THERE WAS I | LIKE S A HOME. TO NG THEM OT BEEN AND DID ES FROM ED BOUT THE TED THAT E HAS IONS", WHEN TS. SHE VOMITED NOSED AS NOTHING |
| | = 4-1-1 | | | (Continue on | page 3) |
| | | boratory Data, Including HEDULED AN MRI | • | (10/22/14) | 1 |
| | BLOOD TEST FOR | HEDULED AN MRI : | TECH WAS NORMA | Pivad | , |
| | transcent = | C Inc. | DA= - | , red | , |
| | | | OCT 23 | 3 2014 | |
| | | | CDR | ~017 | |
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| | 7 Other Delevant His | 1 - 1 - dina Prantis | | (Continue on | |
| | race, pregnancy, sm | itory, Including Preexist noking and alcohol use, h | ting Medical Con epatic/renal dysft | nditions (e.g., au unction, etc.) | ergies, |
| | GERD; ACID REF | LUX; | | | |
| | HISTORY OF BAC FREQUENT COLDS | TERIAL STOMACH | INFECTIONS | , EAR INFE | CTIONS, |
| | CHILD IS PRONE IMMUNICATION S | TO FEVERS AND | DEVELOPS T | HEM AFTER | |
| | 4 | | | | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

(Continue on page 3)

| of <u>0</u> | | | # FDA Use Only | |
|--|-------------------|-----------------|---|--|
| C. SUSPECT PROD | | | | |
| Name (Give labeled stren | | | | |
| #1 HYLAND'S BABY | TEETHING TA | ABLETS | | |
| #2 | | | | |
| Dose, Frequency & Rou #1 AS PER LABEL/A | | | ites (If unknown, grive duration) lest estimate) | |
| | | | | |
| #2 4. Diagnosis for Use (Indic | ation) | #2 5, E | vent Abated After Use | |
| #1 TEMP RELIEF OF | • | PAIN | topped or Dose Reduced? | |
| #2 | | #1 | Yes No Doesn't | |
| 6. Lot # | 7. Exp. Date | #2 | Yes No Doesn't | |
| #1 | #1 | | vent Reappeared After | |
| #2 | #2 | R | eintroduction? ☐ Yes ☐ No ☐ Doesn't | |
| 9. NDC# or Unique ID | | | Apply | |
| 54973-3127-3 | | #2 | Yes No Doesn't | |
| 10. Concomitant Medical P | | | | |
| NYSTATIN, AMOXICI | LLIN, TYLEN | OL, AND MC | TKIN | |
| | | | | |
| | | | (Continue on page 3) | |
| D. SUSPECT MEDIC | AL DEVICE | | (Continue on page 3) | |
| 1. Brand Name | | | | |
| 2. Common Device Name | | 1 | 2b. Procode | |
| | | | | |
| 3. Manufacturer Name, City | y and State | | | |
| | | | | |
| 4. Model # | Lot# | | 5. Operator of Device | |
| Catalog # | Expiration | Date (mm/dd/yy | Health Professional | |
| | | , | Lay User/Patient | |
| Serial # | Unique Ide | ntifier (UDI) # | Other: | |
| 6. If Implanted, Give Date (| mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/dd/yyyy) | |
| , | | | | |
| 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No | | | | |
| 9. If Yes to Item No. 8, Ente | r Name and Add | ress of Reproce | ssor | |
| , | | | | |
| | | | | |
| 10. Device Available for Ev | aluation? (Do act | send to EDA1 | 704 - 5 - 66 | |
| Yes No [| _ | anufacturer on: | OCT 23 20 | |
| | | | (mm/dd/yyyy) | |
| 11. Concomitant Medical Pr | roducts and Ther | apy Dates (Exc | uae treatment of event) | |
| | | | _ | |
| F 1007141 | | | (Control of the ge 3) | |
| E. INITIAL REPORTE 1. Name and Address | :R | | | |
| (b) (6) | | | OCT 2 4 2014 | |
| (b) (6) USA | | | } | |
| USA | | | | |
| Dhama # | | | | |
| Phone # (b) (6) | Emai | Address | | |
| 2. Health Professional? 3. | Occupation | | 4. Initial Reporter Also Sent | |
| ☐ Yes ☑ No N | • | | Report to FDA | |

Importer

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Study

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

3. Report Source (Check all that apply)

Health Professional

F. FUR USE OF USER FASIER

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

☐ No

Yes

☐ No

Name

Address

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

10/01/2014

30-day

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

☐ 10-day
✓ Initial

✓ 15-day ☐ Follow-up # 9. Manufacturer Report Number

7. Type of Report

5-day

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

age 2 o

| | FDA USE ONLY |
|--|--|
| f 6 | |
| | |
| H. DEVICE MANUFACTURERS ON | |
| 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury Malfunction | Additional Information |
| maidriction | Response to FDA Request Device Evaluation |
| | |
| 3. Device Evaluated by Manufacturer? | Device Manufacture D ate (mm/yyyy) |
| Not Returned to Manufacturer | |
| Yes Evaluation Summary Attache | |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| | Yes No |
| 6. Event Problem and Evaluation Codes (Refe | er to coding manual) |
| Patient | |
| Code | |
| Device Code | [-] |
| , | |
| Method | |
| Results |]-[|
| | |
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| 10. Additional Manufacturer Narrative | |
| io. [] Additional manufacturer Narrative | and / or 11. Corrected Data |
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| | OCT 23 2014 |

54973 AE # 1567 This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k) #

Product

Pre-1938

Combination

OTC Product | Yes

8. Adverse Event Term(s)

Yes

Yes

SEIZURE LIKE SYMPTOMS, DEEP SLEEP

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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CaseID: 10542937



NTINUATION PAGE) e by user-facilities, ributors, and manufacturers for MANDATORY reporting

CaseID: 10542937

ITIEU YY A I CH

| | FORM FDA 3500A (2/13) (continued) | Page 3 of | |
|-------------------------------------|--|---|---|
| | B.5. Describe Event or Problem (continued) | | |
| | OF FEVERS WITH TEETHING". THE HIGH TABLETS, HE WAS ALSO GIVEN TYLENOL, CHILD HAS BEEN SLEEPING MORE OFTEN HAS BEEN HAVING 4 NAPS A DAY AND ON | AND LATER MOTRIN FOR FEVER. (MOTE THAN USUAL. HIS REGULAR NAPS TEND | RIN WHEN HE WAS OLD ENOUGH.) |
| | | | |
| B.5 | i | | |
| Back to Item | | | |
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| | B.6. Relevant Tests/Laboratory Data, Including Dates (cor | ntinuad) | |
| | , Julia, Illustrating 24:05 (con | , and a second | |
| 9.6 | | | |
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| Back to Item | | | |
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| | B.7. Other Relevant History, Including Preexisting Medica | Conditions (e.g., allergies, race, pregnancy, smoking and | alcohol use, hepatic/renal dysfunction, etc.) (continued) |
| | | | |
| B.7 | | | |
| Back to Item B.7 | | · · | |
| <u>5</u> | | | |
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| Ξ. | .] | | |
| 6 | Concernitant Medical Products and Therese Dates (Early) | 14.4.4.4.5 | |
| E | Concomitant Medical Products and Therapy Dates (Exclude | ie treatment or event) (For continuation of C.10 and/or D.11; | please distinguish) |
| e te | | | _ |
| ç | | | DSS |
| 8 | | | |
| 5 | | | OCT 24.2014 |
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| <u></u> | | • | |
| Back to Item D.11 Back to Item C.10 | Other Remarks | | OCT 28 2014 |
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COMPLAINT RECORD



| 105429 | 937-01-00-04 | COMPLAINT #: | 2577 | |
|--|--|--|--|---|
| | | DATE OF COMPLAINT: | 10/01/14 | ,, |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE; | BTET | |
| SIZE: | UNKNOWN | LOT NO.: | THREW BOT | TLE AWAY |
| REPORTER: | (b) (6) | | | |
| ADDRESS: | | | | |
| | | (b) (6) | | |
| CITY: | The state of the s | STATE: | | |
| COUNTRY: | USA | ZIP CODE: | | |
| PHONE #: | (b) (6) | Means and some form of the Mean of the State | | |
| E-MAIL: | A MOTHER CALLED AFTER READING ABO | | | |
| BEING CALLED OR BEEN TAKING TEET MONTHS OF AGE UT ABLETS. ON THE BUT SHE DID NOT I AND "BACTERIAL S USING TEETHING T CHANGES, AND WACHILD HAS A HISTOFTABLETS, HE WAS A FOR OCTOBER 22 ^M . THAN USUAL. HIS RI | MOTHER'S HOME. SHE SAYS THAT HE SLEEPS DEEPLY AR & MOTHER WAVING HER ARMS AROUND. HE HAS BEEN HA' ITHING TABLETS. HER SON IS 1 YEAR OLD, AND DID TAKE: UNTIL 10 MONTHS OLD. AT 10 MONTHS OLD, SHE JUST USI E PHONE MESSAGE, THE MOTHER REPORTED THAT HER SO MENTION THIS ON THE PHONE CALL. HE HAS BEEN ON NY STOMACH INFECTIONS', WHICH SHE SAYS SEEMS TO HAVE TABLETS. SHE THOUGHT HE HAD A LOWERED IMMUNE SY AS DIAGNOSED AS HAVING ACID REFLUX. SHE WAS TOLD RY OF 'LOTS OF FEVERS WITH TEETHING'. THE HIGHEST FEVE ALSO GIVEN TYLENOL AND LATER MOTRIN FOR FEVER. (MOTRI) . HIS LAST IMMUNIZATION WAS SEPTEMBER 2. HE DEVELOPS INTERCORD TO BE 15 MINUTES, BUT LATELY HE HAD BE IVED TO DATE WAS A BLOOD TEST FOR IRON, WHICH WAS NOR FOR ADDITIONAL SPACE PLEASE USE REVE TED FOR | VING THEM FOR THE LAST 2 MONTH TEETHING TABLETS DURING HIS TEE DETETHING RINGS TO HELP HIM, HON HAD SEIZURES AND DOCTOR HAY STATIN AND AMOXICILLIN FOR THRESTATION AND AMOXICILLIN FOR THRESTATED AT 6 MONTHS, WHEN HE STEM. HE ALSO VOMITED FREQUEN THAT THERE WAS NOTHING THAT CRIP HE ELICITS IS 102°F. DURING THE TIME WHEN HE WAS OLD ENOUGH.) THE DEVENS AFTER THE SHOTS. HE ALSO HEELD HAVING 4 NAPS A DAY AND ONE DEMAND. | S; DURING THIS ETHING EPISOD HAVING "FORGG D CALLED THE USH, EAR INFE WAS TEETHING WITLY DESPITE OULD BE DON ME HE WAS GIVE DOCTOR HAS SC HAS BEEN SLEEI DAY SLEPT FOR 4 | S TIME HE HAS NOT DES FROM 6 DITTEN" ABOUT THE M "BRAIN BLEEDS". CTIONS, COLDS, 3 AND STARTED FORMULA E FOR IT. TEETHING HIDDIED AN MRI PING MORE OFTEN |
| | | DATE REQUESTED PRODUCT BE | RETURNED; | |
| | | UPS CALL | TAG ISSUED: | Y (CIRCLE ONE) |
| | | DATE PRODUC | T RECEIVED: | |
| SECTION II: | INVESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | TECHOLOGIC AT MORED INVESTIGATION RELIGION. | | | |
| | | | | , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| ADVERSE EVENT F | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION (| ON: 10/01/14 | | |
| ADVERSE EVENT F | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION E | BY: TUTTI GO | ULD | |
| SECTION III: | CORRECTIVE ACTION: | | | |
| | | | | |
| | | | | Dec |
| 000000000000000000000000000000000000000 | 0.1/0.00101.5777.01 | | | 200 |
| CORRECTIVE ACTIO | ON(S) COMPLETED BY: | DATE: | | OCT 24 2 |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: | 1567 | |
| | · | • | | |
| ADVERSE EVENT SI | \mathbf{O} | | | |
| ADVERSË EVENT RI | REPORTED ON: 10/01/14 | BY: TUTTI GOULD | | |
| SECTION V: | 77 | . 11 | | u/ |
| REVIEWED BY MAN | NAGEMENT BY:KU | DATE: | 10-10- | 14 OCT 28 201 |
| | Quela Barre | | 18-10 | <u> </u> |
| BY: | QA / QC DIRECTOR | DATE: | 10-10- | 19 |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0044-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

10/8/14

Date

DSS OCT **2** 4 2014

OCT 23 2014

CaseID: 10542937



RSE EVENT DATA FORM



| AE #: | 1567 | COMPLAINT #: 2577 | |
|-----------|--|--|---|
| SECTION | PATIENT INFORMATION (I | F DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | | |
| ADDRESS | : | | |
| | - | | |
| CITY: | | STATE: (b) (6) | MANUFACTURE AND ADDRESS OF THE PARTY OF THE |
| COUNTRY | : USA (b) (6) | ZIP CODE: | |
| PHONE #: | (0) (0) | | |
| E-MAIL: | | | |
| SECTION | E PACKAGING INFORMATIO | <u>N:</u> | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE | |
| | Transporter Comments of the Co | (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| | Teething Tablets Teething Tablets | | |
| | A the second sec | | |
| | | (eething fablets | |
| | | Tablets The same of the same | |
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| SECTION I | II: CORRECTIVE ACTION: | | |
| | | | Management |
| | | | |
| | | | DSS |
| CORRECTI | VE ACTION(S) COMPLETED BY: | DATE: | |
| | | Ŋ | OCT 2 4 2014 |
| SECTION I | <u>V:</u> | Q1.11 | |
| REVIEWED | BY MANAGEMENT BY: | MUOUT DATE: (U-10-14 | |
| BY: | Euc M | DATE: 10-10-14 O | CT 23 2012 |
| | QA / QC DIRECTOR | | |



e by user-facilities, ributors and manufacturers DATORY reporting

CaseID: 10542971

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015

| | See OMB statement on revers |
|---------------------|-----------------------------|
| ffr Report # 54973 | |
| F/Importer Report # | |
| | |

| A. PATIENT IN | ORMAT |
|--------------------------------|------------------------|
| Patient Identifier (b) (6) | 2. Age at 1 of Even |
| | or |
| | Date |

PLEASE TYPE OR USE BLACK INK

| FORM FDA 350 | 0A (2/13) | | | | Pag | ge ' |
|--|----------------------------|-----------------|--------------------|--------------------|----------------------------|-------|
| A. PATIENT INF | ORMATION | | | | | |
| Patient Identifier (b) (6) | 2. Age at Time of Event: | | | 3. Sex | 4. Weigh | nt |
| | or | 9 | Months | √ Female | | lbs |
| to conserv | Date | | | Male | or | |
| In confidence B. ADVERSE EV | of Birth: | ODUC | T DRAPI E |] | | kgs |
| B. ADVERSE E | VENT OR PR | | TPROBLE | VI | | |
| 1. Adverse Even | | | luct Problem (e. | .g., defects/malfu | inctions) | |
| Outcomes Attribut (Check all that appl | | vent | | | | |
| Death: | | | Disability o | r Permanent Dar | nage | |
| | (mm/dd/yyyy) ig | | Congenital | Anomaly/Birth D | efect | |
| Hospitalization | n - initial or prolong | ged | Other Serie | ous (Important M | edical Eve | ents) |
| Required Inter | vention to Prevent | t Perma | nent Impairment | /Damage (Device | es) | |
| 3. Date of Event (mn | √dd/yyyy) | T | 4. Date of This | Report (mm/dd | <i>(</i> УУУУ) | |
| 05/00/2014 | & 09/22/20 | 14 | | 10/09/2014 | | |
| 5. Describe Event or Problem MOTHER CALLED CONCERNED ABOUT HER 1 YEARS OLD DAUGHTER WHO HAS BEEN TAKING TEETHING TABLETS AS NEEDED FROM MARCH UNTIL SEPTEMBER 5, 2014. HER DAUGHTER DEVELOPED SYMPTOMS IN MAY (HEAD SWELLING) AND SEPT. 22 (FEBRILE SEIZURE). SHE IS WONDERING IF THEY ARE RELATED TO THE TEETHING TABLETS. THE CT SCAN IN MAY IDENTIFIED THE SWELLING AS "BLEEDING BETWEEN THE SKIN AND SKULL". THERE WAS ANOTHER SWELLING A MONTH OR SO LATER ON ANOTHER PART OF HER HEAD. ALSO, WHEN SHE WAS TEETHING. THE CHILD HAS HAD "WEIRD EPISODES" THAT ARE OUT OF CHARACTER TO HER SUCH AS SCREAMING ON WAKING (AS OF SEPT. 29TH), BANGING AND HOLDING HER HEAD. SHE WAS INTRODUCED TO COW'S MILK ON THE 24TH. ON SEPT. 19TH (OR 22ND AS PER CUSTOMER) CHILD WAS DIAGNOSED WITH A VIRUS AND GIVEN AMOXICILLIN. SHE VOMITTED THAT NIGHT, AND ROLLED HER EYES, WENT STIFF AND STOPPED BREATHING BRIEFLY. THE DOCTOR WHO SAW THE CHILD SEVERAL DAYS LATER DIAGNOSED IT AS FEBRILE SEIZURE. | | | | | | |
| 6. Relevant Tests/Lab | oratory Data, Inc | cluding | Dates | (Continue on | page 3 | _ |
| CT SCAN ~- MAY PENDING. ALL | 2014, UIT NEGATIVE SO | | ceive [2 3 201 | | TEST : | IS |
| | | UL | D OF LUI | • | | |
| | | (| CDR | | | |
| 7 Other Belandaria | tone features = | | | (Continue on | | |
| 7. Other Relevant His race, pregnancy, sm EAR INFECTION AMOXICILLIN (S SEIZURE (SEPT. | (SEPT. 2, 2 EPT.), KAWA | 2014), ASAKI | , FUNGAL I | NFECTION F | ergies, `ROM `EBRILE | |
| LAST IMMUNIZAT | ION: AUGUS | ST 10, | , 2014 | | | |
| SPRAYED THE GA | RAGE FOR TE | RMITE | ES IN SEPT | EMBER 2014 | | |
| | | | | (Continue on | nama 31 | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| KI Tepor | ting | Ľ | , mporta re | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | |
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| #2 2 Dose Fr | - Tuesday & D | to lk | d | To Thoran | - Detac | /// |
| | equency & R | | 3ea | | | (If unknown, give duration estimate) |
| #2 | | | | #2 | | |
| | is for Use (Inc | dication | <u> </u> | | 5 Event | Abated After Use |
| _ | RELIEF 1 | | | | | ed or Dose Reduced? |
| #2 | | | | | | Apply Apply |
| 6. Lot# | | 7. E | xp. Date | | #2 🔲 \ | res ☐ No ☐ Does Apply |
| #1A1001 | 4 | #1 | | | | Reappeared After |
| #2 | | #2 | E * - 1 | | | roduction? |
| 9. NDC# or | Unique ID | | | | " , | Apply |
| 54973- | -3127-1 | | | | #2 \ | — — Арріу |
| | | | | | | treatment of event) |
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| SEIZURE | | | ,,,, | | 2. 0. | TO THE TELL |
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| D GIIGE | ECT MED | ICAL | DEVICE | | (0 | Continue on page 3) |
| 1. Brand Na | ECT MED | ICAL | DEVICE | ···· | | |
| | | | | | | |
| 2. Common | Device Nam | е | | | 2b. F | rocode |
| 3. Manufac | turer Name, (| City and | d State | | 1 | |
| | | | | | | |
| 4. Model# | | | Lot# | | | 5. Operator of Device |
| | | | | | | Health Profession |
| Catalog # | ‡ | | Expiration i | Date (mm/d | d/yyyy) | Lay User/Patient |
| Serial # | | | Unique Ider | ntifier (UDI) | # | Other: |
| | | | | , | | |
| 6. If Implant | ted, Give Date | e (mm/c | fd/yyyy) | 7. If Expla | nted, Giv | ve Date (mm/cld/yyyy) |
| 8. Is this a s | Single-use De | evice th | at was Repro | cessed an | d Reuse | d on a Patient? |
| Yes | ☐ No | | | | | |
| 9. If Yes to | item No. 8, Er | nter Na | me and Addr | ess of Rep | rocesso | |
| | | | | | | |
| | | | | | | |
| 10. Device A | Available for I | Evaluat | ion? (Do not | send to FDA | 1) | |
| Yes | No | □R | leturned to Ma | enufacturer o | on: | net og 2018 |
| | | | | | | U Walin (disp) yy LUTT |
| 11. Concom | itant Medical | Produ | cts and Ther | apy Dates | (Exclude | treatment of event) |
| | | | | | | |
| | | | | | (0 | continue on page 3) |
| E. INITIA | L REPOR | TER | | | | |
| 1. Name and | d Address | | - | 100 | | |
| (b) (6) | | | L | SS | | |
| (b) | | | nct | 242 | 014 | |
| (b) (6) USA | | | | | | |
| Phone # b) (6) | | | Email (b) (6) | Address | | |
| . Health Pr | ofessional? | 3. O cc | upation | | | nitial Reporter Also Ser Report to FDA |
| Yes | √ No | NA | | | | Yes No V Unk |



Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

No

Name

Address

11. Report Sent to FDA?

Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

10/03/2014

30-day

Periodic

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

☐ 10-day 📝 Initial

54973 AE # 1574

√ 15-day Follow-up # 9. Manufacturer Report Number

7. Type of Report

5-day

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other: _

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Literature √ Consumer

User Facility

Company

Distributor

Other:

Study

Report Source (Check all that apply)

Health Professional

Representative

age 2 c

| of 5 | |
|---|--|
| H. DEVICE MANUFACTURERS ONL | Y |
| 1. Type of Reportable Event Death Serious Injury Malfunction | 2. If Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation |
| 3. Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached | 4. Device Manufacture Date (mm/yyyy) |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? Yes No |
| 6. Event Problem and Evaluation Codes (Refer t Patient Code Device Code Method Results | o coding manual) - |
| 7. If Remedial Action Initiated, Check Type Recall Notification Repair Inspection Replace Patient Monitoring | 8. Usage of Device Initial Use of Device Reuse Unknown |
| Relabeling Modification/ Adjustment Other: | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
| DSS 0CT 2 4 20 | OCT 23 2014 |

CaseID: 10542971

FDA USE ONLY

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Combination

OTC Product Y Yes

8. Adverse Event Term(s) SWELLING AND SEIZURE

Pre-1938

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@tda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

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COMPLAINT RECORD



| | 1-00-03 | COMPLAINT #: | 2584 | |
|---|--|--|---|------|
| IANEN DI. | TO THE GOODED | DATE OF COMPLAINT: | 10/03/14 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 | |
| SIZE: | 135 TABLETS | LOT NO.: | A10014 BOTTLE A10114 BOX | |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | | | | |
| | | *************************************** | 7.1.2 | |
| CITY: | | STATE: (b) (6) | | |
| COUNTRY: USA | | ZIP CODE: | | |
| PHONE #:(b) (6) | | | | |
| E-MAIL: | | | | |
| SCAN IN MAY IDENTIFIED TH LATER ON ANOTHER PART (CHARACTER TO HER SUCH 22 ^{NO} AS PER CUSTOMER) CH WENT STIFF AND STOPPED SEIZURE. THE MOTHER CO | MOTHER CALLED CONCERNED ABOUT HE TABLETS AS NEEDED FROM MARCH UNTIL DISEPTEMBER 22 (FEBRILE SEIZURE). SHE IS WON HE SWELLING AS "BLEEDING BETWEEN THE SKIN / OF HER HEAD, ALSO WHEN SHE WAS TEETHING. I AS SCREAMING ON WAKING (AS OF SEPTEMBER 2 HILD WAS DIAGNOSED WITH A VIRUS AND GIVEN A DEACHTHING BRIEFLY. THE DOCTOR WHO ONLY SOMMENTED THAT HER OLDER SON HAD SIMILAR SYNIZATION. SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS AS A SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS A SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS AS A SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS AS AS A SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS AS A SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS AS A SEPTEMBER 24, 2014 THE CHILD WAS GIVEN AS AS AS AS AS AS AS AS AS AS AS AS AS | L SEPTEMBER 5, 2014. HER DAUGH IDERING IF THEY ARE RELATED TO AND SKULL". THERE WAS ANOTHEF THE CHILD HAS HAD "WEIRD EPISO 29 TH), BANGING AND HOLDING HER AMOXICILLIN. SHE VOMITTED THAT GAW THE CHILD SEVERAL DAYS LAT GAW THOMS AND IT WAS DIAGNOSED | TER DEVELOPED SYMPTOMS IN THE TEETHING TABLETS. THE CT R SWELLING A MONTH OR SO DES' THAT ARE OUT OF HEAD. ON SEPTEMBER 19 [™] (OR NIGHT, AND ROLLED HER EYES, FER DIAGNOSED IT AS FERRILE | |
| | FOR ADDITIONAL SPACE PLEASE USE REVE | RSE OR ATTACH A SEPARATE SHE | EET | |
| | | | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (N) (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | | |
| mor Echon. | (CINCLE ONE) | DATE REQUESTED PRODUCT BE | (CIRCLE ONE) | |
| | | | Y | |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) | |
| | | DATE PRODUC | T RECEIVED: | |
| SECTION II: INV | /ESTIGATION | 5/1121110500 | THEOLIVED. | |
| | | | | |
| INVESTIGATION: P | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | | | | |
| | | | | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION O | N: 10/03/14 | | |
| ADVERSE EVENT FORWARD | DED TO PHARMACIST / NURSE FOR EVALUATION B | Y: TUTTI GO | ULD | |
| | | | V-10 | |
| | | | | |
| | | | | |
| | | The state of the s | | |
| CORRECTIVE ACTION(S) COI | MPLETED BY: | DATE: | DSS | • |
| SECTION IV: ADVI | FRSE EVENT REPORTS | A.F | | |
| ADVE | COLUMN REPORTS | AE #: , | 13/4 001 24 | ZU14 |
| ADVERSE EVENT SERIOUS: | (Y)/ N | | | |
| ADVERSE EVENT REPORTED | D ON: | BY: TUTTI GOULD | | |
| SECTION V: | x 4 | 1 | | |
| REVIEWED BY MANAGEMENT | пву: | DATE: | 16-16 - 14 OCT 23 | 201F |
| BY: | Cour Baun | DATE: | 10-15-14 | |
| ADVERSE EVENT FORWARD ADVERSE EVENT FORWARD SECTION III: CORRECTIVE ACTION(S) CORSECTION IV: ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED SECTION V: REVIEWED BY MANAGEMENT | DED TO PHARMACIST / NURSE FOR EVALUATION OF DED TO PHARMACIST / NURSE FOR EVALUATION BY CORRECTIVE ACTION: DIMPLETED BY: DERSE EVENT REPORTS DO ON: 10/03/14 | DATE PRODUC N: 10/03/14 Y: TUTTI GO DATE: AE #: DATE: | DSS 1574 OCT 24 | 2014 |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

4

18





Serious Adverse Event SAE-0051-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lots # A10014 or A10114, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lots' (b) (4) and units respectively have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lots # A10014 and A10114 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lots # A10014 and A10114. Both lots are from the same bulk lot # 122523, which was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(b)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0280-2014) has been received for Hyland's Baby Teething Tablets lot # A10014. The complaints were reviewed and the complaints do not appear to be related. No other complaints have been reported related to Hyland's Baby Teething Tablets lot # A100114. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

10/14/14

Date

DSS OCT 2 4 2014

CaseID: 10542971

OCT 28 2014





RSE EVENT DATA FORM

| AE #:1 | 1574 | COMPLAINT #:2584 |
|--|--|---|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT | T FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| | | (b) (6) |
| CITY: | | STATE: (5/6) |
| COUNTRY: | USA | ZIP CODE: |
| PHONE #: | (b) (6) - | |
| E-MAIL: | | · · · · · · · · · · · · · · · · · · · |
| SECTION II: | PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| Indications in community of the control of the cont | The transport of the tr | Teething Tablets Feating Tablets Teething Tablets Teething Tablets |
| | | |
| SECTION III: | CORRECTIVE ACTION: | |
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| CORRECTIV | E ACTION(S) COMPLETED BY: | DSS OCT 24 20 |
| SECTION IV: | | 1 |
| | BY MANAGEMENT BY: | DATE: 10-15-14 |
| BY: | ON OCCUPECTOR | DATE: 10-15-14 |

OCT 28 2014



se by the facilities, trigators and manufacturers NDATORY reporting

| CaseID: | 10543066 |
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| OMB No. 0910-0 | 291. Expires: 6/30/20 |

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| pproved: | OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
| | |

| | See OMB statement on reverse |
|----------------------|------------------------------|
| Mfr Report # 54973 | |
| UF/Importer Report # | |
| | |

| Δ | PATIENT INF | ORMATION | | | |
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| (b) (6) | | of Event: 5 | Months | | |
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| l Ir | confidence | Date of Birth: | | ☐ Male | k |
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| | itcomes Attribui heck all that appl | ted to Adverse Event | | | |
| | Death: | | Disability o | r Permanent Da | mage |
| | Life-threatening | (mm/dd/yyyy) na | Congenital | Anomaly/Birth D | Defect |
| | _ | n - initial or prolonged | L | ous (Important M | |
| | _ | rvention to Prevent Perm | \Box | , - | |
| 3. D: | te of Event (mr | | | Report (mm/do | |
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| 5. De | scribe Event or | · | 1 | | |
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| | | ~ D I | TR. | (Continue of | n page 3) |
| 6. Re | levant Tests/La | boratory Data, Includir | ng Dates | | , |
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| THE R | P HOLATA | | | | |
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| 7. 0 | her Relevant Hi | story, Including Preexi | sting Medical Co | (Continue or | |
| rac | ce, pregnancy, sr | moking and alcohol use, | hepatic/renal dys | function, etc.) | |
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Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

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| | D. T. COM (2) | | |
| TEETHING TA | BLETS | | |
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| Y,2-3 DAYS | #1 | | |
| | #2 | | |
| ation) | | | Abated After Use ed or Dose Reduced? |
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| 7. Exp. Date | | #2 Y | es No Apply |
| #1 | | | Reappeared After oduction? |
| #2 | | | es No Doesn't |
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| AL DEVICE | | - (- | , |
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| y and State | | | |
| Lot# | | | 5. Operator of Device |
| | | | Health Professional |
| Expiration | Date (mm/ | dd/yyyy) | Lay User/Patient |
| Unique Ide | ntifier (UDI | n # | Other: |
| | , | | |
| mm/dd/yyyy) | 7. If Expl | anted, Giv | e Date (mm/dd/yyyy) |
| ce that was Renr | ocessed a | nd Reuse | d on a Patient? |
| ou that has hop | | | on a Patient? |
| er Name and Add | ress of Re | processor | |
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| aluation? (Do not | send to FL | DA) | |
| Returned to M | anufacture | r on: | |
| roducts and The | rany Dates | (Exclude | (mm/dd/yyyy) |
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| | iil Address | [4.1 | DSS |
| | re Used (1, 2-3 DAYS ation) ETHING PAIN (7. Exp. Date #1 #2 roducts and Ther (8, 3 DIFFER AL DEVICE y and State Lot # Expiration Unique Ide mm/dd/yyyy) ce that was Repr or Name and Add aluation? (Do not) Returned to M | gth & mfr/labeler) TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS #1 #2 #2 #1 #2 #2 #1 #2 #2 #4 #2 #4 #4 #5 #6 #6 #6 #6 #6 #6 #6 #6 #6 | gth & mfr/labeler) TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING TABLETS TEETHING PAIN TETHING PAIN TO Stoppe #1 |



Importer

3. User Facility or Importer Name/Address

1. Check One User Facility

4. Contact Person

Approximate Age of Device

11. Report Sent to FDA?

Yes

No.

Yes

No

Address

6. Date User Facility or

Importer Became
Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

10/01/2014

30-day

Periodic

4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

☐ 10-day 📝 Initial

54973 AE # 1568

15-day Follow-up# 9. Manufacturer Report Number

7. Type of Report

5-day

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPURTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Literature √ Consumer

User Facility

Distributor

Other:

Company Representative

Study

3. Report Source (Check all that apply)

Health Professional

(mm/dd/yyyy)

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| | FDA USE ONLY |
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| | |
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Inform ation |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | 1 |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | ☐ Yes ☐ No |
| | ☐ Tes ☐ NO |
| Event Problem and Evaluation Codes (Refer to | coding manual) |
| Patient | |
| Code | |
| Device Code | - |
| Code | |
| Method | |
| Davids . | |
| Results | |
| Conclusions | |
| If Remedial Action Initiated, Check Type | N. Hagge of Daviso |
| | 8. Usage of Device |
| Recall Notification | ☐ Initial Use of Device ☐ Reuse |
| Repair Inspection | Unknown |
| Replace Patient Monitoring | |
| Relabeling Modification/ Adjustment | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
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| Additional Manufacturer Narrative | and / or 11. Corrected Data |
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CaseID: 10543066

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k) #

Product

Pre-1938

SEIZURE

Combination

OTC Product

8. Adverse Event Term(s)

Yes

Yes

✓ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@ida.hhs.gov valid OMB control number

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



COMPLAINT RECORD



10543066-01-00-03 COMPLAINT #: 2578 DATE OF COMPLAINT: 10/01/14 IMPEN DI TOT IT GOULD HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET----T135 PRODUCT: SIZE: 135 TABLETS LOT NO.: A44514 (b) (6) REPORTER: ADDRESS: (b) (6) CITY: STATE: USA ZIP CODE: COUNTRY: (b) (6) PHONE #: E-MAIL: ON AUGUST 10, 5 MONTH OLD BABY STARTED USING TEETHING TABLETS. (b) (6) THE MOTHER TOOK NATURE OF COMPLAINT: THE BABY TO THE HOSPITAL BECAUSE SHE WAS NOT HER USUALLY HAPPY SELF, SHE WAS NOT SMILING AND WAS DROOLING, AND HAD A FEVER OF 102.5°F. THE DIAGNOSIS WAS "VIRAL SYNDROME". (b) (6) MOTHER CALLED WAS DROULING, AND HAD A FEVER OF 1025 F. THE DIAGNOSIS WAS VIRAL SYNDROME. 105.0°F, SHALLOW BREATHING, PALE FACE, ALTERED STATE, HEART RATE OF 240. SHE WAS TRANSFERRED TO THE PEDIATRIC INTENSIVE CARE UNIT WHERE SHE HAD A SPINAL MENINGITIS TEST, BRAIN WAVE SCAN, EPILEPSY TEST, AND BLOOD AND URINE TESTS. THE DIAGNOSIS WAS A "URINARY TRACT INFECTION". AT THIS TIME MOTHER STOPPED GIVING TEETHING TABLETS. SHE ALSO STOPPED GIVING BANANAS AS SHE HAD INTRODUCTED THEM SHORTLY BEFORE THE SEIZURE EVEN THOUGH THE DOCTOR HAD RULED THEM OUT. BABY WAS GIVEN RECTAL TYLENOL, IV FLUIDS AND 3 DIFFERENT ANTIBIOTICS INCLUDING BACTRIM. A FEW DAYS AFTER BEING SENT HOME, MOTHER RETURNED TO THE HOSPITAL BECAUSE HER DAUGHTER STILL HAD A FEVER. SHE WAS TOLD TO KEEP USING BACTRIM AND TYLENOL. MOTHER RETURNED FOR ANOTHER HOSPITAL VISIT AS HER DAUGHTER HAD DEVELOPED A RASH ON HER WHOLE BODY AS A REACTION TO THE ANTIBIOTIC MEDICATION. THEY STOPPED THE MEDICATION AS THE URINARY INFECTION WAS RESOLVED. MOTHER HAD CALLED THE FDA ASKING IF THE TEETHING TABLETS WERE ON RECALL AFTER READING ABOUT THEM ON FACEBOOK. THEY SAID THE RECALL WAS IN 2010 AND THAT A REFORMULATED PRODUCT WAS BACK ON THE SHELVES. A REPORT WOULD BE SENT FOR HER TO FILL OUT. THE MOTHER COMMENTED THAT IF WE WERE SUBMITTING A REPORT TO THE FDA, THEN SHE WOULD NOT DUPLICATE IT BY SENDING IN ONE AS WELL. DURING THIS TIME, THE BABY HAS NOT YET ERUPTED ANY TEETH EVEN THOUGH THEY SEEM TO BE APPEARING AS WHITE MARKS ON HER GUMS. MOTHER HAS USED TEETHING TABLETS PREVIOUSLY FOR HER OLDER CHILD WITH NO ADVERSE REACTION. LAST NIGHT, THE BABY WAS GIVEN TEETHING TABLETS AGAIN, AND SLEPT THROUGH THE NIGHT. THE MOTHER WAS WORRIED AFTER READING ABOUT TEETHING TABLETS ONLINE THAT THIS MAY NOT BE A GOOD SIGN, EVEN THOUGH IT IS EXPLAINED ON THE LABEL THAT SLEEPING CAN OCCUR AS A SIGN OF RELAXATION. THE BABY RECEIVED HER LAST IMMUNIZATION SHOT IN AUGUST. MOTHER SEEMED QUITE AGITATED AND SAID SHE WOULD PURSUE LEGAL ACTION. SHE WOULD LIKE A REFUND OF \$8. FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR PRODUCT BEING RETURNED FOR INSPECTION: INSPECTION: (CIRCLE ON DATE REQUESTED PRODUCT BE RETURNED UPS CALL TAG ISSUED: (CIRCLE ONE DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/01/14 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS AE #: 1568 ADVERSE EVENT SERIOUS N ADVERSE EVENT REPORTED ON: 10/01/14 TUTTI GOULD SECTION V: Wals REVIEWED BY MANAGEMENT BY: BY

cc: QA/QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0034-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A44514, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A44514 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A44514. The Baby Teething bulk lot # 123338 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(0)}^{(0)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0641-2014) has been received for Hyland's Baby Teething Tablets lot # A44514. The complaints were reviewed and although a previous SAE has been reported related to this bulk lot the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A44514.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by Date

OCT 28 2014

CaseID: 10543066

DSS OCT 24 2014





RSE EVENT DATA FORM

| AE #: | COMPLAINT #: 2578 |
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| SECTION I: PATIENT INFORMATION (IF I | DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: (b) (6) | |
| ADDRESS: | |
| - | (b) (6) |
| CITY: | STATE: |
| COUNTRY: USA (b) (6) | ZIP CODE: |
| PHONE #: | |
| E-MAIL: | |
| SECTION II: PACKAGING INFORMATION: | |
| AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| Indications. Introduction and calculation of the Control of any section and calculation of the State of the Control of any section and calculation of the State of the Control of any section and calculation of the State of the State of the Control of the State of the Control of the State of the Control of the State of the State of the Control of the State | A dia an wins selection of the property of the |
| SECTION III: CORRECTIVE ACTION: | |
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| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: | OCT 28 2014 |
| | |
| REVIEWED BY MANAGEMENT BY: | WW DATE: 10-13-14 |
| BY: 9440 /200 | DATE: 10-10-14 DSS |
| QA/QC DIRECTOR | OCT 24 2014 |



or use by user-facilities, , distributors and manufacturers MANDATORY reporting

| Casel | D: | 10547 | 7547 |
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| Form Approved; OMB No. 0910-0291, Expires: 6/30/201 See OMB statement on reverse | 5 |
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| Mfr Report # 54973 | |
| UF/Importer Report # | |
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PLEASE TYPE OR USE BLACK INK

| FORM FDA 3500 | A (2/13) | | | Page 1 |
|------------------------------------|--------------------------|----------------------------|--------------------|-----------------|
| A. PATIENT INFO | ORMATION | | | |
| 1. Patient Identifier | | ` | 3. Sex | 4. Weight |
| (b) (6) | of Event: | | o. Sex | 4. Weight |
| | or1 | Years | Female | ibs |
| | Date | | ✓ Male | or |
| In confidence | of Birth: | | | kgs |
| B. ADVERSE EV | ENT OR PRODUC | TPROBLE | VI | |
| 1. 🕢 Adverse Event | and/or Pro | duct Problem (e | .g., defects/malfo | unctions) |
| 2. Outcomes Attribute | | | | |
| (Check all that apply) |) | | | |
| Death: | (mm/dd/yyyy) | _ 🚺 Disability o | r Permanent Dar | mage |
| Life-threatening | 1 | Congenital | Anomaly/Birth D | Defect |
| Hospitalization | - initial or prolonged | Other Serie | ous (Important M | ledical Events) |
| Required Interv | ention to Prevent Perma | ment Impairment | /Damage (Devic | es) |
| 3. Date of Event (mm/ | /dd/yyyy) | 4. Date of This | Report (mm/dd | /vvvv) |
| 1 | PRESENT | | 10/08/2014 | , |
| 5. Describe Event or F | | | 10,00,2011 | |
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| MOTHER POSTED | ON (b) (b) TH | AT 10 YEAR | OLD SON H | AS MOTOR |
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| 6. Relevant Tests/Lab | oratory Data Including | Dates | (CONTINUE OF | , page 3) |
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| 7. Other Relevant Hist | ory, Including Preexist | ing Medical Cor | nditions (e.g., al | |
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| Submission of a ro | | | (Continue on | page 3) |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

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|---|-----------------|-------------------------------------|---------------------------------|----------------------------|------------------|
| of 6 | | | | | FDA Use Only |
| C. SUSPECT PROD | | | | | |
| 1. Name (Give labeled stre | - | | | | |
| #1 HYLAND'S TEET | ning TAB | ne12 | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Ro | | from/ | apy Dates (li lo (or best es | | rive duration) |
| #1 AS DIRECTED OF | N THE LAI | BEL #1 | | | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Indi | | | | Abated After | |
| #1 TEMP RELIEF O | r TEETHI! | NG PAIN | #1 TY | | Doesn't Apply |
| #2 | -1 - | | #2 [7] | ps [] +- | Doesn't |
| 6. Lot # | 7. Exp. Da | te | #2 Ye | | L Apply |
| #1 | #1 | | Reintro | Reappeared oduction? | |
| #2 | #2 | | _ #1 □ Y6 | es No | Doesn't Apply |
| 9. NDC# or Unique ID 54973-7504-1 | | | #2 Ye | es No | Doesn't |
| 54973-7504-1 10. Concomitant Medical | Producte and | d Therany Data | | | Apply event) |
| | odd dil | _ Jpy Patt | , | | 7 |
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| n ellences | CALBE | CE. | (C | ontinue on | page 3) |
| D. SUSPECT MEDI 1. Brand Name | CAL DEVI | CE | | | |
| | - | | | | |
| 2. Common Device Name | · | | 2b. Pr | rocode | |
| 3. Manufacturer Name, C | ity and State | | | | |
| | | | | | |
| 4. Model# | Lot # | 1 | T | 5. Operator | of Device |
| Catalog # | F | ration Date (mn | Vdd/\\\ | Health | Professional |
| John January # | Expir | LIOII DATE (MI | yyyy) | | er/Patient |
| Serial # | Uniqu | ue Identifier (UI | DI) # | Other: | |
| 6. If Implanted, Give Date | (mm/dd/vinn |) [7.1f==- | planted Give | e Date (mm/c | dd/yyvv) |
| | | | | | |
|] | vice that was | Reprocessed | and Reused | on a Patien | nt? |
| 9. If Yes to Item No. 8, En | ter Name and | d Address of P | eprocessor | | |
| | ulil | 200 VI IV | | | |
| | | | | | |
| 10. Device Available for E | valuation? " | Do not soud to | -DA) | | |
| 10. Device Available for E | _ ` | Do not send to F d to Manufactur | , | | |
| | | | | (mm/dd/yy | *** |
| 11. Concomitant Medical | rroducts and | u inerapy Date | :s (Exclude l | a a arment of e | event) |
| | | | | | |
| E INITIAL EN | 'EB | | (Co | ontinue on | page 3) |
| E. INITIAL REPORT 1. Name and Address | EK | | | - | |
| 1. Name and Address (b) (6) | | | | DS | 38 |
| USA | | | | | |
| ~ w43 | | | 1 | OCT 2 | 4 2014 |
| Phone # | | Email Address | | | |
| . House # | | Linaii Address | • | | |
| 2. Health Professional? | 3. Occupatio | 'n | | | er Also Sent |
| Yes 🗸 No | NA | | | eport to FD/ | A No [∕]Unk. |

OCT 23 2014

CaseID: 10547547 Individual Case Safety Report FDA USE ONLY Page 2 of 6 H. DEVICE MANUFACTURERS ONLY 10547547-01-00-02 Type of Reportable Event 2. If Follow-up, What Ty pe? [__] Importer User Facility Death Correction 3. User Facility or Importer Name/Address Serious Injury Additional Information Malfunction Response to FD → Request Device Evaluation 3. Device Evaluated by Manufacturer? 4. Device Manufacture Date (mm/yyyy) Not Returned to Manufacturer 4. Contact Person 5. Phone Number Yes Evaluation Summary Attached 5. Labeled for Single Use? No (Attach page to explain why not) or provide code: 8. Date of This Report 6. Date User Facility or 7. Type of Report Yes □ No (mm/dd/yyyy) Aware of Event (mm/dd/yyyy) Initial 6. Event Problem and Evaluation Codes (Refer to coding manual) Follow-up # Patient Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) Code Patient Device Code Code Device Method 11. Report Sent to FDA? 12. Location Where Event Occurred Results Outpatient Diagnostic Facility Hospital Yes (mm/dd/yyyy) Home No Conclusions Ambulatory Surgical Facility Nursing Home 13. Report Sent to Manufacturer? 7. If Remedial Action Initiated, Check Type 8. Usage of Device Outpatient Treatment Facility Initial Use of Device Yes Recall Notification (mm/dd/yyyy) Reuse No Other: Repair Inspection (Specify) Unknown Replace Patient Monitoring 14. Manufacturer Name/Address If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: Modification/ Adjustment Relabeling Other: Additional Manufacturer Narrative and / or Corrected Data G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number 310-768-0700 EDYTA FRACKIEWICZ 3. Report Source (Check all that apply) Address Foreign HYLAND'S, INC. Study 154 W. 131ST STREET LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM User Facility Date Received by Manufacturer (mm/dd/yyyy) Company (A)NDA# Representative 10/04/2014 Distributor IND# 6. If IND, Give Protocol # Other: BLA# PMA/

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

510(k) #

Product

Pre-1938

DELAYS

Combination

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

DEVELOPMENTAL AND MOTOR FUNCTION

7. Type of Report

5-day

7-day

10-day

(Check all that apply)

30-day

Initial

15-day Follow-up #

54973 AE # 1572

9. Manufacturer Report Number

Periodic

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address,

DSS

OCT 24 2014

OMB Statement: "An agency may not

OCT 28 2014

conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.



| | | COMPLAINT #: | 2582 (1) (4) 7/2 |
|---|---|--|--|
| 1054 | 17547-01-00-03 | DATE OF COMPLAINT: | 10/04/14 |
| PRODUCT: | HYLANDS LEETHING LADELIG | ITEM CODE: | TEET |
| StZE: | _UNKNOWN (b) (6) | LOT NO.: | UNKNOWN |
| REPORTER: | | | |
| ADDRESS: | | | AAAA AAA AAA AAA AAAA AAAA AAAA AAAA AAAA |
| | | | de la company de |
| CITY: | | | |
| COUNTRY: | USA | ZIP CODE: | A A A A A A A A A A A A A A A A A A A |
| PHONE #: | | | |
| E-MAIL: | CUSTOMER POSTED THE FOLLOW | NG ON (b) (6) ON (b) (6) I JUST FO | UND OUT THAT THESE TABLETS |
| OF YOU WHO DO N TOXIC PLANT IN TH ONLINE BUT THIS I: FROM A FRIEND. ! FUNCTION DELAYS THE CAUSE OF THE UNTIL AFTER THEI! MY SON HAD BEEN S THE SAME EXACT SY FOR MONTHS AT A T | R PRODUCT PUT IT BACK ON THE SHELVES. THIS PENOT KNOW WHAT BELLADONNA IS HERE IS A DESCRED FOR THE NORTHERN HEMISPHERE. ANY YET WE HAVE BE IS ONE I FOUND I NEEDED TO RESEARCH. MY SON WUSED THEM FOR ALL 3 OF MY KIDS. NOW MY 2 OLD. BOTH SPEECH AND OT BOTH HAVING TO DO WITH EIR DELAYS BUT IT SEEMS PRETTY ODD THAT THEY REIRS BIRTHDAYS. MY OLD DAUGHTER DID NOT TO STRUGGLING WITH SPEECH, OT, READING, ATTENTION SYMPTOMS. WHAT ARE THE ODDS?? LUSED THESE TABLES THEY SEEMED TO WORK GREAT!!! I NEVER THOUGATS GOOD RIGHT? WRONG. HOMEOPATHIC DOES NOT | IPTION CEN.M.WIKIPEDIA.ORG/WIKI/ATRO! EN GIVING THIS TO OUR BABIES!!! I DON'T VAS BORN IN 2004 I WAS TOLD ABOUT THE ER CHILDREN NOW AGES 10 AND 6 BOTH 1 THE BRAIN. NOW I AM NOT SAYING THAT WERE BORN COMPLETELY HEALTHY AND TALK UNTIL SHE WAS 3 AND EVEN THEN SH PAN, MEMORY AND A LOT MORE. THE THING LETS AS DIRECTED FOR BOTH OF THEM EVER SHT THAT THERE WOULD BE PROBLEMS LATE | PA_BELLADONNA. IT IS THE MOST BELIEVE EVERYTHING I SEE ESE AMAZING TEETHING TABLETS HAVE THE SAME EXACT MOTOR ITHESE TABLETS ARE DEFINITELY NEVER HAD ANY PROBLEMS HE ONLY HAD AROUND 40 WORDS THAT GETS ME IS THAT THEY HAVE YDAY WHILE THEY WERE TEETHING. IR ON. THE BOTTLE SAYS |
| | GLES CONSTANTLY WITH EVERYTHING. HE HAD THESE T | | 9 (CONTINUED ON NEXT PAGE) |
| | TON ADDITIONAL STAGE PELAGE USE | The vende on all moll a departable dile | - |
| PRODUCT RECEIVE INSPECTION: | ED FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR | INSPECTION: Y N (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT BE | RETURNED: |
| | | UPS CALL | TAG ISSUED: (CIRCLE ONE) |
| | | DATE PRODUC | T RECEIVED: |
| SECTION II: | INVESTIGATION | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION RE | DORT | |
| INVESTIGATION. | FLEASE SEE ATTACHED INVESTIGATION RE | PORT. | |
| | | | |
| ADVERSE EVENT F | ORWARDED TO PHARMACIST / NURSE FOR EVALUA | TION ON : 10/04/14 | |
| ADVERSE EVENT F | ORWARDED TO PHARMACIST / NURSE FOR EVALUA | TION BY: EDYTA FE | RACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| CORRECTIVE ACTIO | ON(S) COMPLETED BY: | DATE | |
| 001111201112110111 | | DATE. | 800 |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: | 1572 USS |
| ADVERSE EVENT S | ERIOUS: Y/ N | | OCT 24 2 |
| ADVERSE EVENT R | REPORTED ON: 10/04/14 | BY: EDYTA FRACKI | EWICZ |
| SECTION V: | | \ | |
| REVIEWED BY MAN | JAGEMENT BY: | JUU DATE: | 10-14-14 |
| BY: | OM DERECTOR | DATE: | 10-14-14 |

cc: QA / QC Packaging

Production Shipping / Receiving 067 23 2014

Form # VD1



COMPLAINT # 2582

PAGE 2

NATURE OF COMPLAINT (CONT):

MONTHS UNTIL HE WAS FINISHED TEETHING. HE WAS MY FIRST BABY. AND ANYONE WHO HAS MORE THAN ONE CHILD KNOWS HOW PARANOID YOU ARE WITH YOUR FIRST. I WAS SCARED TO USE THE TABLETS AT FIRST. BUT MY HUSBAND TRIED THEM WHEN I WAS NOT HOME AND THEY WORKED. THEY MADE A SCREAMING BABY CALM DOWN AND BE PAIN FREE. LEARNING ALL OF THE NEW NEWS I'M HEARING ABOUT THESE TABLETS IS REALLY SCARING ME. ESPECIALLY WITH THE WAY MY CHILDREN ARE. NO KNOWN CAUSE. DOESN'T RUN IN THE FAMILY. PARENTS NEVER HAD DELAYS OR ANY PROBLEMS GROWING UP. I WANT TO REACH OUT TO OTHER PARENTS WHO HAVE USED THESE TABLETS. I WANT TO KNOW ABOUT YOUR CHILDREN'S SYMPTOMS IF ANY. ANY INFORMATION WILL HELP ME MAKE A POSSIBLE CASE AGAINST THIS COMPANY AND TO WARN POISONOUS PLANT EXTRACTS IN THE WORLD. PLEASE RE-THINK GIVING YOUR BABIES THESE TABLETS. I WISH I KNEW ALL THIS INFORMATION YEARS AGO. IT WOULD HAVE SAVED ME COUNTLESS YEARS OF ANGUISH. PLEASE COMMENT IF YOU HAVE SEEN ANY SYMPTOMS IN YOUR BABY OR CHILDREN. I WILL BE MAKING A FB PAGE AND WILL POST THE LINK HERE IF YOU WOULD LIKE TO JOIN TO BE UPDATED OF ANY FINDINGS.

HYLAND'S POSTED ON FACEBOOK ON 10/06/14: HYLAND'S IS COMMITTED TO FOLLOWING UP ON REPORTS OF ADVERSE EVENTS AND WOULD ASK YOU TO PLEASE CONTACT OUR PRODUCT INFORMATION SERVICE AS SOON AS POSSIBLE AT 1-800-624-9659 EXT. 4117 TO DISCUSS WHAT HAPPENED WITH YOUR CHILD AND FOR MORE INFORMATION ABOUT THE PRODUCT. AS A GENERAL GUIDELINE, WE ENCOURAGE ALL CONSUMERS TO CONTACT COMPANIES BY PHONE AT THE NUMBER PROVIDED RATHER THAN POSTING ON (6) (6) WHEN THEY ARE CONCERNED ABOUT A REACTION TO A MEDICINE SO THAT ANY ISSUES CAN BE PROPERLY ADDRESSED. PLEASE KNOW THAT HYLAND'S BABY TEETHING TABLETS HAVE A VERY WIDE MARGIN OF SAFETY, AS DO ALL HOMEOPATHICALLY-PREPARED MEDICINES.

007 23 2014 OCT 2 4 2014

CaseID: 10547547

CaseID: 10547547



10547547-01-00-05



Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (108) Adverse Events (AE) which also included twenty-eight (28) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

10/10/14

DSS OCT **24** 2014

OCT 28 2014



US ADVERSE EVENT DATA FORM



| AE #: | 1572 | 2 COMPLAINT #: 2582 | |
|---------------------|--|---|------------|
| SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | | (b) (6) - | |
| ADDRESS | : | | |
| CITY: | | STATE: | |
| COUNTRY PHONE #: | : | USA ZIP CODE: | |
| E-MAIL: | | | |
| SECTION I | <u>l:</u> | PACKAGING INFORMATION: | |
| | AFF | FIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| | Sent and sen | Manual Planetines of the Control of | |
| SECTION II | <u>li:</u> | CORRECTIVE ACTION: | |
| CORRECTI | VE ACT | TION(S) COMPLETED BY: DATE: | DSS |
| SECTION IV | <u>/:</u> | 067 88 2014 OC | T 2 4 2014 |
| REVIEWED | BY MA | ANAGEMENT BY: DATE: 10-14-14 | |
| BY: | | DATE: 10-T474 | 4 |



The FDA Salety Information and Adverse Event Reporting Program

PLEASE TYPE OR USE BLACK INK

mer Report

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

Y reporting of uct problems and **FDA USE ONLY** Triage unit sequence # product use errors Dose or Amount Frequency Route

| Dise of Birth: 1 A Honchs | A. PATIENT INFORMATION | 2. | Dose or Amount | Frequenc | Route | |
|--|--|----------|--------------------------|---|------------------|---------------------------|
| 1.4 Months 1.4 | m t cm t | t #1 | 1 | | | |
| Building | (b) (c) | lb | | | | |
| No. of the product of the product Problem (a.g. defloct/maturacions) 10 / 31 / 2014 1 | (b) (6) | | 2 | | | |
| The National Work and Provided Control Contr | Male | kg | | | | |
| Check all study | B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR | | | wn, give duration) i | | |
| | | , , | , | /31/2014 | | Yes No Doesn't |
| Collections Entrol Proteen with information and animal solution of a construction of a collection Product do Adverse Event Close at this 4-ph/s) Disability or Permanent Damage Disability or Disability or Permanent Damage Disability or Permanent Damage Disability or Permanent Damage Disability or Disability or Disability or Permanent Damage Disability or Di | | #2 | | | | Apply |
| 2. Obterona Attributed to Adverse event Concent of the Adverse Event Reappeared After Concent of the Adverse Event Reappeared After Concent of the Adverse Event Reappeared After Concentration (amototypy) Disability or Permanent Damage Percent (amototypy) Congental Anomaly(Birth Defect Defending Congental Anomaly(Birth Defect Defending Congental Anomaly(Birth Defect Percent (amototypy) A. Date of the Report (amototypy) 10 / 31 / 2014 11 / 04 / | | | Diagnosis or Reason 1 | for Use (Indication | | |
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| Life-breatening Congenital AnomalyBirth Defect Geographic Congenital AnomalyBirth Defect Geographic | ☐ Death: ☐ Disability or Permanent Damage | _ | | | | |
| Hospitalization - Initial or protonged Other Serious (Important Medical Everts) R. Lot # Manufacturer | | #2 | 2 | | #1 [| Apply |
| Required intervention to prevent Permanent Impairment/Damage (Devices) Subter of Event (mm/ddy)yyy) | | 6. L | ot# | 7. Expiration [| Date #2 [| |
| 3. Date of Event (mm/655/yyy) 10/31/2014 11/04/2014 11/04/2014 11/04/2014 1. Brand Name 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Sepiration Date (mm/655/yyy) 1 Lay User/Patient 1 Catalog # Expiration Date (mm/655/yyy) 1 Lay User/Patient 1 Cher # Control Date (mm/655/yyy) 2. If Explanted, Give Date (mm/655/yyy) 3. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allerges, race, pregnancy, smoking and accord use, inverkidney problems, etc.) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allerges, race, pregnancy, smoking and accord use, inverkidney problems, etc.) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9 c. Product names and therapy dates (exclude breatment of event) 8. Is the a Single-use Device that was Reprocessed and Reused on a Patient? 9 c. Product names and therapy dates (exclude breatment of event) 8. Is the a Single-use Device that was Reprocessed and Reused on a Patient? 9 c. Product names and therapy dates (exclude breatment of event) 1 Nov 0 5 2014 1 Name and Address 2 Common Device Name 3. Manufacturer Name, City and State 5 c. Cher # Expiration Date (mm/65/yyyy) 7. If Explanted, Give Date (mm/65/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9 c. Fround Address 1 Name and Address 1 Name and Address 2 Common Device Name 3. Manufacturer 1 Review of the second of the seco | | .veille) | | | | |
| 1. Specific Event, Problem or Product Use Error See page 2 for complete text. 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Specific Complete Lext. 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Specific Complete Lext. 5. Operator of Device Specific Complete Lext. 6. Relevant TestalLaboratory Data, including Dates 6. Relevant TestalLaboratory Data, including Dates 7. Other Relevant History, Including Preakisting Medical Conditions (e.g., allergies, race, perginaricy, smoking and advoid use, inenfoding problems, etc.) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 7. Other Relevant History, Including Preakisting Medical Conditions (e.g., allergies, race, perginaricy, smoking and advoid use, inenfoding problems, etc.) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 7. Other Relevant History, Including Preakisting Medical Conditions (e.g., allergies, race, perginaricy, smoking and advoid use, inenfoding problems, etc.) 8. In Manufacturer Name, City and State 9. It is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 7. Other Relevant History, Including Preakisting Medical Conditions (e.g., allergies, race, perginaricy, smoking and Address of Reprocessor 8. For Other (CONCOMITANT) MEDICAL PRODUCTS 9. OTHER (CONCOMITANT) MEDICAL PRODUCTS 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 1. Name and Address 2. Common Device Name 1. Name and Address 2. Common Name 3. Manufacturer 1. Health Professional? 1. Name and Address 2. Common Name 3. Manufacturer 1. Read Fermina Name 1. Name and Address 1. Name and | | #2 | | #2 | | |
| 5. Describe Event Problem or Product Use Error See page 2 for complete text. 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Superation Date (mm/dd/yyyy) Lay User/Patient Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Cother: 6. Relevant Tests/Laboratory Data, Including Dates 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) T. If Explanted, Give Date (mm/dd/yyyy) T. If | | | SUSPECT MED | ICAL DEVICE | 50000 | |
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| Catalog # Expiration Date (mm/dd/yyyy) | | 4. N | Model # | Lot# | | 5. Operator of Device |
| C. PRODUCT AVAILABILITY C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer (from product label) H. Name; ByLands teething tablets Strength: Manufacturer. Health Professional? Strength: Manufacturer. Strength: Manufacturer. Manufacturer. Manufacturer Manufacturer. Manufacturer Manufacturer. Manufacturer Manufacturer Manufacturer Manufacturer. Manufacturer Ma | | | | | | Health Professional |
| Serial # Other # 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explan | | - | Catalog # | Expiration | Date (mm/dd/y) | /yy) Lay User/Patient |
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| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) See page A for complete text. F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) NOV 5 2014 G. REPORTER (See confidentiality section on back) 1. Name and Address Name: [D] (6) Address: D. SUSPECT PRODUCT(S) 1. Name Strength, Manufacturer (from product label) #1 Name: Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Name: Strength: Manufacturer: #4 Name: Strength: Manufacturer: #5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: OTHER (CONCOMITANT) MEDICAL PRODUCTS NOV 5 2014 OTHER (CONCOMITANT) MEDICAL PRODUCTS NOV 5 2014 ON | | | Yes No | | | |
| See page | | 9. H | f Yes to Item No. 8, Ent | ter Name and Addr | ess of Reproces | isor |
| F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) NOV 5 2014 G. REPORTER (See confidentiality section on back) 1. Name and Address Name: (b) (6) Address: D. SUSPECT PRODUCT(S) 1. Name: Strength, Manufacturer (from product label) #1 Name: Hylands teething tablets Strength: Manufacturer. #2 Name: Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Strength: Manufacturer: #4 Also Reported to: #5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: #6 If you do NOT want your identity disclosed to the manufacturer. | 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., | | | | | |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: | | | | | | - |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: | See page a for complete text. | | | and the second second | | 4) |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Ves No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name: Hylands teething tablets Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Name: #4 Also Reported to: Manufacturer | | Pro | ocuct names and ther | apy dates (exclud | e treatment of 6 | 6 0111/ |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label) #1 Name: Hylands teething tablets Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Name: #4 Also Reported to: Yes No Manufacturer Manufacturer Manufacturer | CTI | | | | | MOA |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Address: D. SUSPECT PRODUCT(S) 1. Name Strength, Manufacturer (from product label) #1 Name: Hylands teething tablets Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Name: Strength: Manufacturer: #4 Also Reported to: Manufacturer | | | | | | |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes | NOV 0 5 2014 | G. | REPORTER (Se | e confidentiali | ty section o | n back) |
| Product Available for Evaluation? (Do not send product to FDA) ✓ Yes | C. DDODLICT AVAILABILITY | 1.1 | Name and Address | | | |
| Yes No Returned to Manufacturer on: (mm/dd/yyyy) | | | | | 0 | |
| D. SUSPECT PRODUCT(S) 1. Name. Strength, Manufacturer (from product label) #1 Name: Hylands teething tablets Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Name: Strength: Manufacturer: #4 Also Reported to: #5 Manufacturer #6 Manufacturer #7 Manufacturer #8 Strength: Manufacturer: #8 Distributor/Importer | | ' | address: | | 1 | |
| 1. Name: Strength, Manufacturer (from product label) #1 Name: Hylands teething tablets Strength: Manufacturer: #2 Name: Strength: Manufacturer #3 Strength: Manufacturer #4 Also Reported to: #5 Manufacturer #6 Manufacturer #7 Manufacturer #8 Strength: Manufacturer #8 Strength: Manufacturer #9 Strength: Manufacturer #1 Distributor/Importer | Tes No Returned to Manufacturer on: (mm/dd/yyyy) | | 2:4 | | Ct-t | ZID: |
| 1. Name: Strength, Manufacturer (from product label) #1 Name: Hylands teething tablets Strength: #2 Name: Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Strength: Manufacturer: #4 Also Reported to: #5 Manufacturer #6 Manufacturer #6 User Facility #7 to the manufacturer, place an "X" in this box: #6 Distributor/Importer | The state of the s | | | | | ZIP: |
| Strength: Manufacturer: #2 Name: Strength: Manufacturer: #2 Name: Strength: Manufacturer: #3 Strength: Strength: Manufacturer: #4 Also Reported to: #5 Manufacturer #6 User Facility to the manufacturer, place an "X" in this box: #6 Distributor/Importer | | Pho | one # | | | |
| Manufacturer: #2 Name: Strength: Manufacturer: #3 No | / 1 | | | | | |
| Name: Strength: Strength: Strength: Strength: User Facility User | | 2. H | Health Professional? | 3. Occupation | | |
| Strength: Manufacturer: 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: Distributor/Importer | #2 Name: | | Yes No | ii. | | |
| Wallufacturer. | Strength: | | | | | |
| | | | • | | | |

B.5. Describe Event or Problem (continued)

I gave my daughter two tablets of Hylands Teething tablets on Thursday, 10/30/14 and three on Friday 10/31. Friday evening while trick or treating she was being held and began to stare off into space for about 1-2 minutes. We called her name, rubbed her cheek, etc. but could not get her attention. We were worried and took her home immediately. The following morning, 11/1, my husband noticed another similar episode. I called the pediatrician and she is being seen this week. In the meantime she is no longer being given these tablets. She has not had an episode of possible absence seizures since Saturday morning. The only other thing that was odd is that she became very constipated this weekend.

Individual Case Safety Report

10567790-01-00-02

DSS NOV 5 2014 B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions: None

Allergies: None

Important Information: None

RX Meds: None

OTC Meds: Occasional Motrin and Tylenol for teething

Individual Case Safety Report



by user-facilities, ibutors and manufactures DATORY reporting

CaseID: 10570064 Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statem ent on reverse.

| V | | See OMB statem ent on rev |
|-----------|-------------|---------------------------|
| Mfr Repor | t# 54973 | |
| UF/Import | er Report # | |

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| /VILW VV | A | | | DA |
|--|--|--|---|-----------|
| FORM FDA 350 | | | | Page |
| A. PATIENT INF | | | | |
| (b) (6) | 2. Age at Time of Event: | Years | 3. Sex | 4. Weight |
| | or | | Female | or |
| In confidence | of Birth: | | ✓ Male | k |
| B. ADVERSE E | VENT OR PRODU | JCT PROBLE | M | |
| 1. Adverse Even | | roduct Problem (e | e.g., defects/malf | unctions) |
| (Check all that appl | ted to Adverse Event | | | |
| Death: | (mm/dd/yyyy) | Disability of | or Permanent Da | mage |
| Life-threatenin | - | | Anomaly/Birth [| |
| | - initial or prolonged | | ous (Important M | |
| 3. Date of Event (mn | vention to Prevent Perr | | Report (mm/dd | |
| | 29/2013 | 4. Date of This | 10/22/2014 | |
| 5. Describe Event or | Problem | | *************************************** | |
| THE REPORTER' | S SON BEGAN EX | PERIENCING | SEIZURES W | ITH |
| VOMITING DURI | NG THE PERIOD | OF TIME THAT | T HE WAS T | AKING |
| SEIZURES BETW | THING TABLETS" EEN (b) (6) | AND 06/201 | | NCED 4 |
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| | | REC | EIVE | -D |
| | | | CONTRACTOR OF SECTION | an and |
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| | | | | |
| | | | (Continue or | naga 21 |
| 6. Relevant Tests/Lat | poratory Data, Including | ng Dates | (Continue or | page 3) |
| (b)(6) RESULTS WERE N | ARIOUS TESTS, | INCLUDING A | AN EEG | ALL |
| | | | | |
| | EVIDENCE ON AN DIAGNOSIS WAS (| | | TUE |
| | NOT DETERMINED | | CAUSE FUR | 1110 |
| | | | | |
| | | | | |
| | | | (Continue on | |
| Other Relevant His race, pregnancy, sm | tory, Including Preexi oking and alcohol use, | sting Medical Cor hepatic/renal dysft | nditions (e.g., all unction, etc.) | lergies, |
| NO FAMILY HIST | ORY OF SEIZURE SUPPLEMENTS A | S. CHILD N | OT TAKING | IEDCE |
| | HAN THE "TEETH | | | EKSE |
| | | | | |
| | | | | |
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| | | | | |
| _ | | | (Continue on | page 3) |
| ubmission of a re | port does not cor | stitute an adn | nission that | medical |
| aused or contribu | cility, importer, disted to the event. | stributor, man | | Suct |
| | | | NOV 0 | 5 2014 |
| | | | MUA O | 0 2014 |

PLEASE TYPE OR USE BLACK INK

| DRY reporting | UF/Ir | nporter Re | port # | | | |
|--|--------------|-------------|-----------------|---------|-------------------------------|------------------|
| of 5 | | | | | | |
| C. SUSPECT PRO | DUCT(S | 5) | | | | FDA Use On |
| Name (Give labeled st | - | | | | | |
| #1 HYLAND'S BAB | Y TEETH | HING TA | BLETS | | | |
| #2 | | | | | | |
| 2. Dose, Frequency & R | loute Used | | | | (If unknown, g estimate) | we duration, |
| #1 2-3 TABLETS | BY MOUT | H QID | #1 | | | |
| #2 | | | #2 | | | |
| 4. Diagnosis for Use (In | dication) | | 5 | | Abated Afte | |
| #1 TEMP RELIEF | TEETHIN | G PAIN | # | 1 7 | | Doesn |
| #2 | | | | | | Apply Doesn |
| 6. Lot # | 7. Exp. | Date | | | Yes No | L Apply |
| #1 | #1 | | | | Reappeared roduction? | After |
| #2 | #2 | | ŧ. | 1 🗌 | Yes No | ✓ Doesn Apply |
| 9. NDC# or Unique ID | | | - | 2 🗍 | Yes No | Doesn |
| 54973-3127-1 10. Concomitant Medica | Products | and Ther | | | | Apply |
| 10. Oontomaan medica | ar i roddets | and The | apy bates (| LXCIGGE | u eatment of | event) |
| | | | | | | |
| | | | | (0 | Continue or | n page 3) |
| D. SUSPECT MED | ICAL DE | VICE | | | | |
| 1. Brand Name | | | | | | |
| 2. Common Device Nam | ne | | | 2b. I | Procode | |
| 3. Manufacturer Name, | City and St | ate | | | | |
| | , | | | | | |
| 4. Model # | Ti | ot # | | | 5. Operator | of Device |
| | | 01 11 | | | | Professional |
| Catalog # | E | xpiration l | Date (mm/dd | /уууу) | | ser/Patient |
| Serial# | U | nique Ider | ntifier (UDI) # | ŧ | Other: | |
| | | | | | | |
| 6. If Implanted, Give Dat | e (mm/dd/y | ryyy) | 7. If Explan | ted, Gi | ve Date (mm/ | 'dd/yyyy) |
| 8. Is this a Single-use D | evice that | was Repro | cessed and | Reuse | d on a Patier | nt? |
| Yes No | | | | | | |
| 9. If Yes to Item No. 8, E | nter Name | and Addr | ess of Repr | ocesso | r | |
| | | | | | | |
| | | | | | | |
| 10. Device Available for | Evaluation | ? (Do not | send to FDA | | | |
| Yes No | Retu | med to Ma | nufacturer o | n: | (mm/dd/y) | vyy) |
| 11. Concomitant Medica | I Products | and Thera | apy Dates (| Exclude | treatment of | event) |
| | | | | | | |
| | | | | (0 | Continue on | page 3) |
| E. INITIAL REPOR | TER | 1985(0) | 98.KM | | | |
| Name and Address | | | | | | |
| (b) (6) | | | | | | |
| | | | | | | |
| | | | | | | |
| Phone # (b) (6) | | Email | Address | | | |
| | 3 00000 | ation | | 14 1 | nitial Deno-t | or Alea Cart |
| 2. Health Professional? Yes ✓ No | NA | ation | | 4. | nitial Report Report to FD | A |
| ☐ .es [A] IAO | 13/3 | | | | Yes 1 | No 🔽 Unk. |

NOV 05 2014

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

Importer

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory

(Specify)

2. Phone Number 310-768-0700

Foreign

Study

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

3. Report Source (Check all that apply)

Health Professional

Surgical Facility

F. FOR USE BY USER FACILITY THINK

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

10/21/2014

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

5-day 30-day

10-day ✓ Initial

54973 AE # 1575

✓ 15-day Follow-up # 9. Manufacturer Report Number

7. Type of Report

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate

Age of Device

11. Report Sent to FDA?

Yes

No

Yes

☐ No

Address

Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

ge 2 c

| | SPECIAL REPORTS | FDA USE ONLY |
|-------------------------------------|-----------------|---|
| of 5 | | |
| H. DEVICE MANUFACTUR | RERS ONLY | , |
| Type of Reportable Event | ILNO UNL | |
| | | 2. If Follow-up, What Type? |
| Death | | Correction |
| Serious Injury | | Additional Information |
| Malfunction | | Response to FDA Request |
| | | Device Evaluation |
| | | |
| Device Evaluated by Manufactu | rer? | 4. Device Manufacture D ate (mm/yyyy) |
| Not Returned to Manufactur | rer | (|
| Yes Evaluation Sum | mary Attached | |
| No (Attach page to explain | why not) or | 5. Labeled for Single Use? |
| provide code: | , , , , , | |
| | | Yes No |
| Event Problem and Evaluation | Codes (Pofor t | |
| | codes (Neier to | cooling manuary |
| Patient Code | - | - |
| Device | | |
| Code | | - |
| | | |
| Method | | |
| | | |
| Results | | |
| Otii | | |
| Conclusions | | |
| 7. If Remedial Action Initiated, Ch | eck Type | 8. Usage of Device |
| Recall Notifica | tion | Initial Use of Device |
| | | Reuse |
| Repair Inspect | | Unknown |
| | Monitoring | |
| Relabeling Modification | | If action reported to FDA under 21 USC 360i(f), list correct ion/ |
| Other: | | removal reporting number: |
| | | |
| | | |
| 10. Additional Manufacturer N | arrative | and / or 11. Corrected Data |
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Product

Pre-1938

Combination

OTC Product Yes

8. Adverse Event Term(s) SEIZURES, VOMITING

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

CaseID: 10570064

CUSTOMER COMPLAINT RECORD



| STANDARD | CUSTOMER COMPLAINT | RECORD | Casell <i>Hula</i> | 10570064 Inds |
|------------------------------------|--|--|--|--|
| MADE IN THE USA SINCE 1903 | | | | |
| SECTION I: COMPLAINT | | COMPLAINT #: | 2585 | |
| TAKEN BY: | | DATE OF COMPLAINT: | 10/21/14 | |
| PRODUCT: HYLAND'S BA | BY TEETHING TABLETS | ITEM CODE: | BTET | |
| SIZE: UNKNOWN | | LOT NO.: | UNKNOWN | |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | | | | |
| | | (b) (6) | | |
| CITY: | | STATE: | | |
| COUNTRY: USA (b) (6) | | ZIP CODE: | _ | |
| PHONE #: | | | | |
| NATURE OF COMPLAINT: THE REP | ORTER STATED THAT SHE HAD BEEN GIVING | THE TIME THAT HE WAS TAKIN | NG THE 'TEETHING TABLET | S*. SHE |
| PRODUCT RECEIVED FOR | E WAS RUSHED TO THE HOSPITAL AND THAT Y PSPECIALIST AT THE CHILDREN'S HOSPITAL FO SENCE ON THE EEG THAT HER SON HAD HAD / ER, THE CHILD WAS NEVER GIVEN A DIAGNOS DAILY BASIS AND THAT SHE HAD USED APPR SAVE HIM 2 – 3 TABLETS PER DOSE MAINLY W RUCTIONS ON THE LABEL AND DID NOT GIVE I FOLLOWING A DOSE OF "TEETHING TABLETS", TS." SHE STATED THAT HE WAS NOT TAKING N SHE STOPPED GIVING HER SON THE "TEETT BBY TEETHING TABLETS" CAUSE SEIZURES – UCT HAS BEEN RECALLED BECAUSE IT CAUSE WOLVED BECAUSE OF ALL OF THE TIME AND ARO LID DAUGHTER, WHO IS HAVING DIFFICUL THE BOTTLE. SHE ASKED IF WE HAD ANY OTH WOULD LIKE A REFUND FOR THE BOTTLE THA" ES OCCURRED DURING THE TIME THAT CHILD ING TABLETS DURING THIS TIME. CHILD DID 10 — THE AMBULANCE TOOK THE CHILD THE 6 "VED. HIS LAST SEIZURE WAS JUNE 2013. NO ECIFIC SEIZURE TYPE GIVEN. CHILD WAS 1 ½ AT BABY TEETHING TABLETS CAUSE SEIZURE THE TABLETS OR THE SYMPTOMS COULD HA WONAL SPACE PLEASE USE REVERSE OR. Y (CIRCLE ONE) PRODUC (CIRCLE ONE) | ALL OF HIS TESTS, INCLUDING LLOWING THE EMERGENCY RASEIZURE, BUT THE DOCTOR: IS. THE REPORTER STATED TO COXIMATELY THREE BOTTLES HEN SYMPTOMS WERE PRESS: HIM MORE THAN THE RECOMM BUT THAT THEY OCCURRED ANY OTHER MEDICATIONS OF HING TABLETS.* THE REPORTER MONEY THAT THEY SPENT OF THE THIS POST WAS THE REASON IS SEIZURES. THE REPORTER MONEY THAT THEY SPENT OF THE THING, BUT SHE IS AFRE FR PAIN PRODUCTS THAT SHE FOR HER DAUD WAS TEETHING. ONLY THING OTHER DAUD WAS TEETHING. ONLY THING OF THE SEARCH STATE THE TIME OF THE SEARCH STATE SHEED THAT SHE SEARCH STATE SHEED THAT SHE SEARCH STATE SHEED THAT SHE SEARCH STATE SHEED THAT SHE SEARCH STATE SHEED THAT SHE SEARCH SHEED THE SHEED THE SEARCH SHEED THE SHEED T | SAN EEG, WERE NORMAL. OOM VISIT. PER THE REPE S WERE UNABLE TO DETER THAT SHE HAD BEEN GIVIN OF "TEETHING TABLETS" W ENT. SHE STATED THAT SH MENDED DOSE. SHE STATE DURING THE PERIOD OF TIE R SUPPLEMENTS AT THE TI RE STATED THAT SHE REC THAT SHE CALLED. SHE SE R STATED THAT SHE REC S STATED THAT IT THESE F N DOCTOR'S VISITS FOR HI ALD TO GIVE HER DAUGHTE BE COULD GIVE TO HER DAI GHTER; SHE PAID ABOUT S O DIFFERENT THE MOTHER VOMITING DURING THE SE SEIZURE) AND AFTER THAT S. WENT TO A SPECIALIST SEIZURES. I TOLD THE MO THAT HER CHILD COULD HA OF ELSE SUCH AS ILLNESS OF | PER THE ORTER, O |
| | | DATE PRODUCT | RECEIVED: | |
| SECTION II: INVESTIGATION | | | | |
| INVESTIGATION: PLEASE SEE ATTA | ACHED INVESTIGATION REPORT. | | | |
| ADVERSE EVENT FORWARDED TO PHARMAC | | 10/21/14 | | |
| ADVERSE EVENT FORWARDED TO PHARMAC | DIST / NURSE FOR EVALUATION BY: | (b) (6) | | |
| SECTION III: CORRECTIVE ACT | TION: | | | |
| CORRECTIVE ACTION(S) COMPLETED BY: | | DATE: | | |
| SECTION IV: ADVERSE EVENT RE | <u>PORTS</u> | AE #: _ | 1575 | Dec |
| ADVERSE EVENT SERIOUS: | (_Y) _{/ N} | | | D32 |
| ADVERSE EVENT REPORTED ON: | 10/21/14 | (b) (6) BY: | | DSS NOV 0.5 2014 |
| SECTION V: | 0. \111 | | | 0,6 |
| REVIEWED BY MANAGEMENT BY: | FWWY | | 0-29-14 | |
| BY: QA / QC DII | rector 12am | NOV 05: 20 | 1-29-14 | |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

CaseID: 10570064



Serious Adverse Event SAE-0052-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirteen (113) Adverse Events (AE) which also included thirty-three (33) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prenared by

10/28/14

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Individual Case Safety Report

10570064-01-00-04

DSS NOV 0 6 2014

NOV OF 2014

DSS NOV 05 2014

CC-0861-2014 AE-0512-2014

Page 1 of 1

Individual Case Safety Report

10570064-01-00-05

SERIOUS ADVERSE EVENT DATA FORM

| AE #: | 1575 | COMPLAINT #:2585 |
|--|--|--|
| SECTION | I: PATIENT INFORMATION (IF | DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS | : | |
| CITY: | | STATE: (b) (6) |
| COUNTRY | : USA | ZIP CODE: |
| PHONE #: | | |
| E-MAIL: | | |
| SECTION I | II: PACKAGING INFORMATION | <u>l:</u> |
| | AFFIN PLOW LONG LAND LAND | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| Tableton is despen- tablets and referen- directions; this is to brough it forms as to brough it forms as the green time to the wards. I starre to the and addition to the angle. Ferrongs. Ferrongs. Leaders. 44 FEE. GRACOM. | the by Backersone of the Committee of th | Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets Teething Tablets |
| | | E CANADA CONTRACTOR CO |
| SECTION II | II: CORRECTIVE ACTION: | |
| | | |
| CORRECTIV | VE ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV | <u>/:</u> | / |
| REVIEWED | BY MANAGEMENT BY: | DATE: 10-29-14 |
| BY: | QA / QC DIRECTOR | DATE: 10-29-14 |

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM MOV 0 5 2014

PLEASE TYPE OR USE BLACK INK

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

CaseID: 10576562

| 10576562-01-00-01 | orting of oblems and rs | Triage unit sequence # | AUSEONLY 7/666 |
|---|---|---|---|
| (b) (6) Male or | 2. Dose or Amount #1 #1 #1 #2 #2 | Frequency | Route |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply: 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Med 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Experiment Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 10/17/2014 5. Describe Event, Problem or Product Use Error See page 2 for complete text. | 3. Dates of Use (If unknown (or best estimate) #1 10/15/2014 - 10 #2 4. Diagnosis or Reason (#1 Tooth pain #2 //ents) 6. Lot ##1 #1 | /17/2014 for Use (Indication) 7. Expiration Date #1 #2 ICAL DEVICE | 5. Event Abated After Use Stopped or Dose Reduced? #1 |
| | 3. Manufacturer Name, C | | NOV 1 0 2014 5. Operator of Device Health Professional |
| 6. Relevant Tests/Laboratory Data, Including Dates See page 3 for complete text. | Catalog # | Expiration Date (mn | \(\text{Lay User/Patient} \) \[\text{Other:} \] |
| 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., | Yes No 9. If Yes to Item No. 8, Ente | | planted, Give Date (mm/dd/yyyy) ad and Reused on a Patient? |
| allergies, race, pregnañcy, smoking and alcohol use, liver/kidney problems, etc., See page 4 for complete text. | F. OTHER (CONCO | MITANT) MEDICAL apy dates (exclude treatme | nt of event) |
| C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) | 1. Name and Address (b) (6) | confidentiality section | SS |
| 1. Name, Strength, Manufacturer (from product label) | Phone # | E-mail | TU LUI4 |

FORM FDA 3500 (1/09)

#2 Name:

Strength:

Manufacturer:

Strength: as needed

#1 Name: hylands teething gel and tablets

Manufacturer: hylands teething gel and tablets

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Yes No

2. Health Professional? 3. Occupation

5. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

(b) (6)

4. Also Reported to:

✓ Manufacturer User Facility

Distributor/Importer

B.5. Describe Event or Problem (continued)

CaseID: 10576562

noticed a possible connection to using Hylands teething tablets and teething gel my daughter has had a couple fainting spells or seizures with the last one being classified as a seizure after using Hyland's teething tabs and teething gel 2 days in a row for tooth discomfort she was hospitalized at the (b)(6) Children's Hospital for 2 days under observation we were advised not to use those products anymore

Individual Case Safety Report

10576562-01-00-02

DSS NOV 1 0 2014

CaseID: 10576562

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

all tests were done on (b)(6) at the door and coincide the seems fine but they said some of those could have been out of her system by the time they took the lab workthey also don't check for belladonna toxicity

Individual Case Safety Report

10578582-01-00-03

CaseID: 10576562

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:Other Medical Conditions: None ------Allergies: None

Important Information: None

RX Meds: None OTC Meds; D3

Individual Case Safety Report

Individual case ballery mepole

10576562-01-00-04



ise by user-facilities, stributors and musifact NDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

Afr Report # 54973

| UF/Importer Report # | |
|----------------------|--|
| | |

| f 5 | |
|-----|---|
| | 1 |

| A. PATIENT IN | | | | _ |
|--|--|-----------------------|---------------------------------------|---------------|
| Patient Identifier | | | 3. Sex | 4. Weight |
| (b) (6) | of Event: | Years | ☐ Female | lbs |
| | Or Date | | | or |
| In confidence | of Birth: | | ✓ Male | kgs |
| B. ADVERSE E | VENT OR PROD | UCT PROBLE | M | |
| 1. Adverse Ever | | Product Problem (6 | e.g., defects/malfi | unctions) |
| Outcomes Attribution (Check all that app | ited to Adverse Even √y) | t | | |
| Death: | | Disability of | or Permanent Da | mage |
| ✓ Life-threatening | (<i>mm/dd/yyyy</i>) ng | Congenita | l Anomaly/Birth D | Defect |
| Hospitalizatio | n - initial or prolonged | Other Seri | ous (Important M | edical Events |
| Required inte | rvention to Prevent Pe | ermanent Impairmen | t/Damage (Devic | es) |
| 3. Date of Event (mi | m/dd/yyyy) | 4. Date of This | Report (mm/dd | /уууу) |
| | 00/2014 | | 11/03/2014 | |
| | ORDING OF THE | | | |
| |) "MY SON WAS IING TABLETS N | | | |
| | HES TURNING | | | |
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| | | | | |
| | | D- | 3 | |
| | | uece | eived | |
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| | | NOV 1 | 3 2014 | |
| | | | - 6017 | |
| | | CD |) E | |
| | | ₩ 🐱 | 1 6 | |
| | | | | |
| | | | | |
| | | | (Cantinua | |
| 6. Relevant Tests/La | boratory Data, Includ | ding Dates | (Continue or | page 3) |
| | | . | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| 7 Other Palarmet III | etoni lackidia P | visting Madiant A | (Continue on | |
| race, pregnancy, sr | story, Including Pree noking and alcohol us | e, hepatic/renal dyst | nuitions (e.g., al function, etc.) | rergies, |
| | | | | |
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| | | | | |
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| 1 | | | | |
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| | | | | |
| | | | (Continue on | |

| | | | | F | DA Use Only |
|---|--------------------|--------------|----------------------------|------------------------|---------------|
| C. SUSPECT PROD | | | | | |
| Name (Give labeled strer | , | D.I. DEC | | | |
| #1 HYLAND'S BABY | TEETHING TA | BLETS | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Rou | ite Used | | y Dates (la (or best es | f unknown, gi | ve duration) |
| #1 | | #1 | (or pear ea | ,ratoj | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (India | ation) | L "" | 5. Event | Abated After | Use |
| #1 TEMP RELIEF TE | | | Stoppe | d or Dose Re | educed? |
| | | | #1 Y | es 🗌 No | Doesn't Apply |
| #2 6. Lot # | 7. Exp. Date | | #2 Y | es No | Doesn't Apply |
| | · . | } | | Reappeared A | |
| #1 | #1 | | | duction? | |
| #2 | #2 | | #1 \[\text{Y} | es No | Doesn't Apply |
| 9. NDC# or Unique ID | | | #2 \ Y | es No | Doesn't |
| 54973-3127-1 | Products and The | nny Data- | | | L Apply |
| 10. Concomitant Medical F | TOUGETS and Ther | apy ∪ates | (∟xciude ti | eaument of e | veru) |
| | | | | | |
| | | | | | |
| | | | (0) | ontinue on | page 3) |
| D. SUSPECT MEDIC | AL DEVICE | | ,0, | | -344) |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | Dr B- | rocode | |
| 2. Common Device Name | | | | Jeone | |
| 3. Manufacturer Name, Cit | y and State | | | | |
| | | | | | |
| 4. Model# | Lot# | | | 5. Operator of | of Device |
| | | | | | Professional |
| Catalog # | Expiration | Date (mm/o | (d/yyyy) | | er/Patient |
| Serial # | Unique Ide | ntifier /UDN | | Other: | |
| | Sinque luel | | - | | |
| 6. If Implanted, Give Date (| (mm/dd/yyyy) | 7. If Expla | nted, Give | e Date (mm/d | d/yyyy) |
| Is this a Single-use Device that was Reprocessed and Reused on a Patient? | | | | | |
| 8. Is this a Single-use Devi | ice that was Repre | ocessed an | a Keused | on a Patient | r |
| 9. If Yes to Item No. 8, Ente | er Name and Addi | ess of Ren | rocessor | | |
| -, | | | | | |
| | | | | | |
| 40. D. | | | | | |
| 10. Device Available for Ev | | | • | r | 100 |
| YesNo | Returned to Ma | | | (mm/dd/yyy | ⇔& |
| 11. Concomitant Medical P | roducts and Ther | apy Dates | (Exclude t | reatm or te | vent) 20 |
| | | | | *40 4 | 4 4 CU |
| | | | 101 | ontinue on p | nage 31 |
| E. INITIAL REPORTS | ER | | - (00 | munu e on p | Jage 3) |
| Name and Address | | | | | |
| (b) (6) | | i | | | l |
| a a | 1 C [] | | | | |
| • 1 | | | NOV | 13 201 | 6 |
| | | | | rot | 7 |
| Phone # (b) (6) | (b) (6) | Address | | | 7 |
| 2. Health Professional? 3. | Occupation | | [4. In | itial Reporte | Also Sent |
| | IA | | R | eport to FDA | |
| | • • | | 1 | Yes No | o [⊿/∐Unk.l |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

[] Importer

3. User Facility or Importer Name/Address

Check One

User Facility

4. Contact Person

9. Approximate

Yes

☐ No

Yes

No

Address

Age of Device

11. Report Sent to FDA?

Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

5-day 30-day

10-day ✓ Initial

54973 AE # 1576

√ 15-day Follow-up # 9. Manufacturer Report Number

7. Type of Report

7-day

10/19/2014

Periodic

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up # _

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

2. Phone Number 310-768-0700

Foreign

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

Study

Report Source (Check all that apply)

Health Professional

(Specify)

age 2 of

| 5 | |
|---|--|
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury Malfunction | Additional Information |
| | Response to FDA Request Device Evaluation |
| | |
| Device Evaluated by Manufacturer? | 4. Device Manufacture D ate (mm/yyyy) |
| Not Returned to Manufacturer | |
| Yes Evaluation Summary Attached | E. Labalad for Single Up 2 |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| | Yes No |
| Event Problem and Evaluation Codes (Refer to | coding manual) |
| Patient | |
| Code | |
| Device Code | - |
| | |
| Method | J-[] |
| Results | 7- |
| | |
| Conclusions | |
| If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | removal reporting number: |
| Other: | |
| | |
| . Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
| | DSS |
| | |
| | NOV 1 4 201 |
| | NOV 18 2014 |

CaseID: 10584800

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA #

IND#

BLA# PMA/

510(k)#

Combination Product

OTC Product Yes

8. Adverse Event Term(s)

Pre-1938

Yes

Yes

TROUBLE BREATHING, PALLOR

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Please DO NOT RETURN this form to the above PRA Staff email address.



OMPLAINT RECORD



10584800-01-00-03 COMPLAINT #: 2586 TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 10/19/14 PRODUCT: HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET SIZE: UNKNOWN LOT NO .: NOT PROVIDED (b) (6) REPORTER: ADDRESS: CITY: STATE: COUNTRY: USA ZIP CODE: (b) (6) PHONE #: E-MAIL: CUSTOMER SENT THE FOLLOWING E-MAIL ON OCTOBER 19, 2014: MESSAGE: I AM WRITING TO ACTUALLY NATURE OF COMPLAINT: COMPLAINT: COMPLAIN ABOUT YOUR PRODUCT. MY SON WAS TEETHING AND I BOUGHT YOUR HYLAND'S TEETHING TABLETS NOW HE IS HAVING TROUBLE BREATHING AND HE'S TURNING PALE. I WANT A FULL REFUND. AND YOU NEED TO RE-THINK YOUR PRODUCT. CUSTOMER DID NOT RESPOND TO OUR E-MAIL. THE WOMAN ANSWERING THE PHONE NUMBER STATES THAT IT IS A WRONG NUMBER. NO CONTACT INFORMATION PROVIDED FOR REFUND. FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR PRODUCT BEING RETURNED FOR INSPECTION: INSPECTION: (CIRCLE OF (CIRCLE ON DATE REQUESTED PRODUCT BE RETURNED: UPS CALL TAG ISSUED: (CIRCLE ONE DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/19/14 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: DATE: SECTION IV: **ADVERSE EVENT REPORTS** AE#: 1576 ADVERSE EVENT SERIOUS: Ν ADVERSE EVENT REPORTED ON: 10/19/14 EDYTA FRACKIEWICZ NOV 18 2014 SECTION V: REVIEWED BY MANAGEMENT BY: BY:

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0053-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirteen (113) Adverse Events (AE) which also included thirty-three (33) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of (b) ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

NOV 1 4 2014

NOV 18 2016

CaseID: 10584800





RSE EVENT DATA FORM

| AE #: | 1576 | COMPLAINT #:2586 | |
|-------------|--|--|--------------|
| SECTION I | PATIENT INFORMATION (I | F DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | | |
| ADDRESS: | - | | |
| CITY: | - | OTATE | |
| COUNTRY: | USA | STATE: ZIP CODE: | |
| PHONE #: | (b) (6) | | - |
| E-MAIL: | | | |
| SECTION II | PACKAGING INFORMATIO | <u>'N:</u> | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY | |
| | Techning Tables and Control of Co | PANELS) Teething Tablets Estates Tablets | |
| | | The description of the control of th | |
| SECTION III | CORRECTIVE ACTION: | | |
| | | | |
| CORRECTIV | /E ACTION(S) COMPLETED BY: | DATE: | _ DSS |
| SECTION IV | <u>:</u> | 2 11 | NOV 1 4 2014 |
| REVIEWED | BY MANAGEMENT BY: | DATE: 10-29-14 | |
| BY: | Ouc Ba | DATE: 10-29-14 | |

NOV 18 2014

FORM SAE01



umer Report

6aşelD: 10589980 910-0291, Expires: 12/31/2011 See OMB statement on reverse. Form Approved: OMB

FDA USE ONLY

| \Y reporting of | |
|-------------------|--|
| auct problems and | |
| | |

| | | | uct problems and | sequence # | 2 7247 | 9 |
|---|--|---------------------------------------|---|----------------------|---------------------|--|
| Adverse Event Reporting Progra | m | product us | le errors | | | |
| A. PATIENT INFORMATION | | | 2. Dose or Amount | Freque | ncv Route | |
| . Patient identifier 2. Age at Time of Eve | nt or 3. Sex | 4. Weight | #1 1-2 dissolva | | | under the tongue |
| b) (6) Date of Birth: | Female | 20 _{lb} | pills a day | | | |
| 7 Months (b) (6) | | or | #2 | | | |
| In confidence | ✓ Male | kg | | | | |
| B. ADVERSE EVENT, PRODUC | T PROBLEM OR EF | RROR | Dates of Use (If unkr (or best estimate) | own, give duration |) from/to 5. Eve | nt Abated After Use ed or Dose Reduced? |
| Check all that apply: | | | #1 09/24/2014 - 1 | 1/01/2014 | ''' | Yes No Doesn't |
| <u> </u> | lem (e.g., defects/malfund Different Manufacturer (| , | | | | Apply |
| | | or Same Medicine | 4. Diagnosis or Reaso | for Use (Indicati | #2 [| Yes No Doesn't Apply |
| Outcomes Attributed to Adverse Event (Check all that apply) | | | #1 teething pain | | 8. Eve | nt Reappeared After |
| ☐ Death: | Disability or Permanent | Damage | | | | ntroduction? Yes No Doesn't |
| (mm/dd/yyyy) Life-threatening | Congenital Anomaly/Bir | th Defect | #2 | | "' _ | Apply |
| ☐ Hospitalization - initial or prolonged ☑ | | | 6. Lot# | 7. Expiration | n Date #2 | Yes No Doesn't Apply |
| Required Intervention to Prevent Perm | | | #1 | #1 | 9. ND | C # or Unique ID |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (| | #2 | #2 | | 3-3127-1 |
| 09/26/2014 | 11/15/2014 | | E. SUSPECT ME | DICAL DEVIC | E | |
| 5. Describe Event, Problem or Product Us | | · · · · · · · · · · · · · · · · · · · | 1. Brand Name | | | |
| See page 2 for complete tex | | | | | | |
| | | | 2. Common Device Na | ma | | |
| | | | 2. Common Device Na | ····· | | |
| | | | | | | |
| | | | 3. Manufacturer Name | City and State | | |
| | | | | | | |
| | | | | | | |
| | | | 4. Model# | Lot# | | 5. Operator of Device |
| | | | | | | Health Professional |
| | | | Catalog # | Expiratio | n Date (mm/dd/yyy | y) Lay User/Patient |
| | | | | | | Other: |
| 6. Relevant Tests/Laboratory Data, Include | ting Dates | | Serial # | Other# | | |
| See page 3 for complete tex | kt. | | Ourial II | Calci II | | |
| | | | | | | |
| | | | 6. If Implanted, Give D | ate (mm/dd/yyyy) | 7. If Explanted, | Give Date (mm/dd/yyyy) |
| | | | 8. Is this a Single-use | Device that was F | Reprocessed and I | Reused on a Patient? |
| | | | Yes No | | | |
| | | | 9. If Yes to Item No. 8, E | nter Name and Ad | dress of Reprocess | Dr |
| 7. Other Relevant History, Including Pree | xisting Medical Conditio | ons (e.g., | | | | |
| allergies, race, pregnancy, smoking and a | alcohol use, liver/kidney pi | roblems, etc.) | | | | |
| See page 4 for complete ter | A | | F. OTHER (CONC | | | |
| | ^T 1 8 | | Product names and th | erapy dates (excl | ude treatment of ev | ent) |
| | CTU | | | | | |
| | NOV 1 7 2014 | L | | | | ř. |
| | 1101 2 2 2017 | | G. REPORTER (S | ee confidentia | lity section on | hack) |
| | | | 1. Name and Address | oo oomidentid | my deduction on | odony |
| C. PRODUCT AVAILABILITY | | | (b) (6) | | | Do |
| Product Available for Evaluation? (Do not | t send product to FDA) | | | | | DS (NOV 17) |
| Yes No Returned to Manu | ufacturer on: | v/dd/yyyy) | | | | NOV 1 - |
| D. SUSPECT PRODUCT(S) | (17117) | | | | | 17 |
| 1. Name, Strength, Manufacturer (from pro | oduct label) | | Phone # | | E-mail | |
| #1 Name: Hylands teething tabl | ets | | | | (b) (6) | |
| Strength: Manufacturer: | | | 2. Health Professional | 3. Occupation | | 4. Also Reported to: |
| | | | Yes No | | | Manufacturer |
| *2 Name: Strength: | | | 5. If you do NOT want y | our identity disclos | sed | User Facility |
| Manufacturer: | | | to the manufacturer, | | | Distributor/Importer |

B.5. Describe Event or Problem (continued)

My son began using Hylands Teething tablets in Sept 2014. He began to develop extremely high fevers, dry skin, seizures, anemia, vomiting and urinary retention. It took 2 months of many tests and hospital visits to realize it was the belladonna causing all the problems. He has not taken any tablets in 2 weeks and is a new child. He is only 7 months old and NEVER had more than 3 tablets a day. We are still doing testing to see if any permanent damage has been done.

Individual Case Safety Report

10589980-01-00-02

DSS NOV 1 7 2014 B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

chest xrays, blood cultures, CBC, CMP, UA

Individual Case Safety Report

10589980-01-00-03

DSS NOV 1 7 2014 B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:Hispanic/Latino Medical Conditions: none

Allergies: none

Important Information:

RX Meds:

OTC Meds: iron

Individual Case Safety Report



10589980-01-00-04

DSS NOV 1 7 2014 or use by user-facilities, distributors and manufacturers MANDATORY reporting

| CaseID: 10601392 Eefm approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
|--|
|--|

| | See OMB statement on reverse |
|----------------------|------------------------------|
| Mfr Report # 54973 | |
| JF/Importer Report # | |
| | |

PLEASE TYPE OR USE BLACK INK

1 of

| _ | | | | | |
|--|-----------------|-------------------|---|-------------------------------|---------------|
| f <u>5</u> | į | | | | FDA Use Only |
| C. SUSPECT PROD | UCT(S) | | | | |
| 1. Name (Give labeled stre | ngth & mfr/lab | eler) | | | |
| #1 HYLAND'S BABY | TEETHING | TABLETS | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Ro | ute Used | | | f unknown, g | ive duration) |
| #1 2TABS BID-QID | AS NEEDE | | (or best e | stimate) | |
| | | _ | | | |
| #2 | | #2 | f f | 11-1-1-1-1 | |
| 4. Diagnosis for Use (India | | a TN | | Abated After ed or Dose R | |
| #1 TEMP RELIEF TE | EEIHING P | AIN . | #1 📝 Y | es No | Doesn't Apply |
| #2 | | | #2 🗍 Y | es No | Doesn't |
| 6. Lot # | 7. Exp. Date | • | | | ☐ Apply |
| #1A52014 | #1 | | | Reappeared oduction? | After |
| #2 | #2 | | #1 🕢 Y | es No | Doesn't Apply |
| 9. NDC# or Unique ID | | | | | Doesn't |
| 54973-3127-3 | | | #2 Y | | LJ Apply |
| 10. Concomitant Medical RANITIDINE SINCE | | | | reatment of e | event) |
| RANTITOTNE SINCE | CUITD MY | S I WEEK C | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | |
| | | | | | |
| | | | (0 | ontinue on | nage 21 |
| D. SUSPECT MEDIC | CAL DEVIC | :E | ب) | Orkinae ori | page 3) |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 12h B | rocode | |
| 2. Common Device Name | | | 20. F | TOCOGE | |
| 3. Manufacturer Name, Ci | ity and State | | | | |
| | | | | | |
| 4. Model# | Lot # | | | 5. Operator | of Device |
| | | | | Health | Professional |
| Catalog # | Expira | tion Date (mm/c | dd/yyyy) | Lay Us | er/Patient |
| Serial# | Uniqu | e Identifier (UDI |)# | Other: | |
| | | | | | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Expla | anted, Giv | e Date (mm/ | dd/yyyy) |
| 8. Is this a Single-use Dev | vice that was | Paprocessed as | nd Pausa | d on a Patier | 112 |
| Yes No | VICE (IIIAL WAS | Neprocessed at | na neuse | | |
| 9. If Yes to Item No. 8, En | ter Name and | Address of Rep | processor | | |
| | | | | ח | SS |
| | | | | 2 | 5 0 |
| 10. Device Available for E | valuation? (D | o not send to FD |)A) | NOV 2 | 0 2014 |
| ☐ Yes ☐ No | | to Manufacturer | • | | U LUIT |
| | | | | (mm/dd/yy | |
| 11. Concomitant Medical | Products and | Therapy Dates | (Exclude | treatment of | event) |
| | | | | | |
| | | | (C | ontinue on | pagé 3) |
| E. INITIAL REPORT | ER | | | | |
| Name and Address | | | | | |
| (b) (6) | | NOV | 19 | 2014 | |
| (b) (6) | | 1101 | | | |
| (b) (6) USA | | | | | |
| Phone # | 1 | Email Address | | | |
| (b) (6) | | | | | |
| 2. Health Professional? | 3. Occupation |) | | nitial Report Report to FD | |

NA

Yes No V Unk.

Yes V No

| | 0A (2/13) | | | Page 1 |
|--------------------------------|---|--|-------------------------------------|-----------------|
| A. PATIENT INF | ORMATION | | 1. (1.6) | |
| 1. Patient Identifier | 2. Age at Time | | 3. Sex | 4. Weight |
| (b) (6) | of Event: 12 | Months | | |
| | or | | ✓ Female | or lbs |
| In confidence | Date of Birth: | | Male Male | kgs |
| B. ADVERSE EV | VENT OR PRODU | ICT PROBLE | M | |
| 1. Adverse Even | | oduct Problem (e | | unctions) |
| 2. Outcomes Attribut | | Oduct Froblem (e | g., deroctarman | onenons) |
| (Check all that appl | | | | |
| Death: | (mm/dd/yyyy) | Disability of | or Permanent Da | mage |
| Life-threatenin | | Congenita | Anomaly/Birth D | Defect |
| √ Hospitalization | - initial or prolonged | Other Seri | ous (Important M | ledical Events) |
| Required Inter | vention to Prevent Perr | nanent Impairmen | t/Damage (Devic | es) |
| 3. Date of Event (mn | n/dd/yyyy) | 4. Date of This | Report (mm/do | Vyyyy) |
| 11/0 | 1/2014 | | 11/05/2014 | . |
| 5. Describe Event or | Problem | 1 | | |
| THE DEPOSTER | OM AMERICA | 0 1 VETE | D DALLOUMES | |
| 1 | STATED THAT HI CING SEIZURES | | | |
| TEETHING TABLE | | SHE BEGAN | | |
| "TEETHING TAB | LETS" WHEN SHE | WAS 6 MONT | HS OLD. W | HEN SHE |
| | OLD, SHE HAD 3 | | | |
| HOSPITALIZED WAS: "FEBRIL | | THE DIAGNO THE USE OF | | |
| | DISCONTINUED F | | | AN AGAIN |
| ABOUT 3 WEEKS | AGO. ON (b) (6) | THE C | HILD HAD A | NOTHER |
| | AS HOSPITALIZE | | | - 1 |
| | DOCTORS COULD AT THAT TIME A | | | |
| i e | A COUPLE OF WE | | AN DEG TO | 55 |
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| | | Here | ACTO | |
| | | | . | |
| | | NOV 1 | 9 2014 | |
| | | 110 1 3 | (Continue o | n page 3) |
| 6. Relevant Tests/Lat | boratory Data, Includi | ng Dates | | |
| CT SCAN NO | RMAL RESULTS | C | DR | |
| EEG ORDERED AI | ND WILL BE DON | E IN 2 WEEK | S. | |
| | | | | |
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| | | | | |
| 7 Other Belevent III | toni lagludia a Da | inting Madinal C | (Continue or | |
| race, pregnancy, sn | story, Including Preex noking and alcohol use, | nsting Medical Co hepatic/renal dys | nations (e.g., a function, etc.) | nergies, |
| | | ES NO KNO | WN ALLERGI | re 1 |
| NO FAMILY HIST | | . 10 1110 | | ES. |
| | | BS. NO KNO | | Lo. |
| NO FAMILY HIST | | ES. NO KNO | | LS. |
| NO FAMILY HIST | | es. No kno | | LJ. |
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| NO FAMILY HIST | | or no mo | | ES. |
| NO FAMILY HIST | | or no mo | (Continue or | |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

CaseID: 10601392 Individual Case Safety Report FDA USE ONLY Page 2 of 5 10601392-01-00-02 H. DEVICE MANUFACTURERS ONLY Type of Reportable Event 2. If Follow-up, What Ty pe? User Facility Importer Death Correction 3. User Facility or Importer Name/Address Serious Injury Additional Information Malfunction Response to FDA Request Device Evaluation 3. Device Evaluated by Manufacturer? Device Manufacture □ate (mm/yyyy) Not Returned to Manufacturer 4. Contact Person 5. Phone Number Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: 5. Labeled for Single Use? 6. Date User Facility or Type of Report 8. Date of This Report Importer Becam (mm/dd/yyyy) Yes No Aware of Event (mm/dd/yyyy) Initial 6. Event Problem and Evaluation Codes (Refer to coding manual) Follow-up# Patient 9. Approximate 10. Event Problem Codes (Refer to coding manual) Patient Device Code Code Device Code Method 11. Report Sent to FDA? 12. Location Where Event Occurred Results Hospital Outpatient
Diagnostic Facility Yes (mm/dd/yyyy) Home No Conclusions Ambulatory Surgical Facility Nursing Home 13. Report Sent to Manufacturer? 7. If Remedial Action Initiated, Check Type Outpatient Treatment Facility 8. Usage of Device Yes Recall Initial Use of Device (mm/dd/yyyy) Notification ☐ No Other: Repair Reuse Inspection (Specify) 14. Manufacturer Name/Address Replace Unknown Patient Monitoring Modification/ If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: Relabeling Adjustment Other: 10. Additional Manufacturer Narrative and / or 11. Corrected Data G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number Name 310-768-0700 EDYTA FRACKIEWICZ 3. Report Source (Check all that apply) Address Foreign HYLAND'S, INC. 154 W. 131ST STREET Study LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM Date Received by Manufacturer (mm/dd/yyyy) User Facility Company (A)NDA# 11/04/2014 Representative IND# Distributor 6. If IND, Give Protocol# NOV 2 0 2014 Other: BLA# PMA/ 7. Type of Report 510(k) # (Check all that apply) Combination Product 30-day 5-day Yes Periodic 7-day Pre-1938 Yes ☐ 10-day 🗸 Initial OTC Product Yes والمراج والمعاطون √ 15-day Follow-up # 9. Manufacturer Report Number 8. Adverse Event Term(s) SEIZURES

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

54973 AE # 1577

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

NOV 19 2014

Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety Report





| COMPLAINT #: | 2587 |
|--|---|
| DATE OF COMPLAINT: | 11/04/14 |
| ITEM CODE: | BTETT40 |
| LOT NO.: | A52014 |
| | |
| | |
| STATE: (b) (6) | |
| ZIP CODE: | |
| | |
| | |
| AT A TIME 2 – 4 TIMES PER D SLETS" DAILY, BUT WAS TAKIN SIN THE SAME DAY, THE REP RTER DESCRIBED HER AS BE THAT CPR WAS ADMINISTER THE REPORTER, THE DIAGNO DT HAVE ANOTHER SEIZURE , BHTER BEGAN TAKING THE "B SPITALIZED OVERNIGHT, PER TI ILL HAVE IN A COUPLE OF WEE AND APPROXIMATELY 5 – 7 MI F 100.1 "F ON (0) (6) PER THE T, BUT WILL HAVE ONE IN A COU DTHER THAN ACID REFLUX. PE TER STATED THAT SHE HAS NEY LO'S FAMILY. THE REPORT STA K TO CONTACT HIM FOR FURTH R ATTACH A SEPARATE SHEER RATTACH A SEPARATE SHEER RATTACH A SEPARATE SHEER CONTACT HIM FOR FURTH RATTACH A SEPARATE SHEER CONTACT HIM FOR FURTH CONTACT HIM F | IAY, WHEN SYMPTOMS WERE NG THEM EVERY OTHER DAY AT ORTER STATED THAT SHE HAD EING "LIMP" AND NOT BREATHING, ED TO HIS DAUGHTER. AT THAT ISIS AT THAT TIME WAS "FEBRILE AND THE USE OF THE "BABY ABY TEETHING TABLETS" AGAIN THE REPORTER, THE DOCTORS DID KS. PER THE REPORTER, THE CHILD NUTES AFTER SHE AWOKE, SHE E REPORTER, THE CHILD HAD A CT JPLE OF WEEKS. PER THE R THE REPORTER, THE CHILD HAS VER HAD A PROBLEM WITH IT. PER TED THAT THE CHILD HAS A ER INFORMATION. |
| | (CIRCLE ONE) |
| UPS CALL T | AG ISSUED: Y (NE) |
| DATE PRODUCT | RECEIVED: |
| | |
| nvestigation | n report. |
| 11/04/14 (b) (6) | |
| | DSS |
| DATE: | NOV 2 0 20 |
| AE #: | 1577 |
| | |
| (b) (6) | |
| RV. (b) (b) | |
| вт: _ | NOV 19 2014 |
| вт: _ | NOV 19 2014 [[-[0-14] |
| | DATE OF COMPLAINT: ITEM CODE: LOT NO.: STATE: (b) (6) ZIP CODE: DAUGHTER HAD BEEN EXPERSTATED THAT SHE BEGAN TA AT A TIME 2 – 4 TIMES PER D SILETS" DAILY, BUT WAS TAKING THE REPORTER, THE DIAGNOOTH HAVE ANOTHER SEIZURE AND APPROXIMATELY 5 – 7 MIN F 100.1 °F ON (b) (6) PER THE THAN ACID REFLUX. PER SITE THAN ACID REFLUX. PER SITE THAN ACID REFLUX. PER STATED THAT SHE HAS NEVED STATED THAN ACID REFLUX. PER STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STATED THAT SHE HAS NEVED STAMILY. THE REPORT STATE SHE HAS NEVED STATED THAT SHE HAS NEVED STATED |

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

CaseID: 10601392



10601392-01-00-04



erious Adverse Event SAE-0054-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A52014, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A52014 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A52014. The Baby Teething bulk lot # 121976 was tested for total Atropine and Scopolamine and the results were with in specification of (4) ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints has been received for Hyland's Baby Teething Tablets lot # A44514.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A52014.

Manufacture and processing occurred within established procedures to ensure product quality.

Date

11-7-14

DSS NOV 2 0 2014

NOV 19 2014

CaseID: 10601392

VERSE EVENT DATA FORM

| 10601 | 392-01-00-05 | |
|---------------------|--|--|
| AE #: | 1577 | COMPLAINT #: 2587 |
| SECTION I | PATIENT INFORMAT | ION (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) - | |
| ADDRESS: | - | |
| CITY: | | STATE: (b) (6) |
| COUNTRY | USA (b) (6) | ZIP CODE: |
| PHONE #: E-MAIL: | (5) (6) | |
| SECTION II | PACKAGING INFORM AFFIX PACKAGING LABEL HE | |
| | Tecting Tolers Annual General Section Control of Contr | Teething Tablets |
| | | The state of the s |
| SECTION III | CORRECTIVE ACTIO | <u>N:</u> |
| | | |
| | | DS |
| CORRECTIV | E ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: | | NOV 19 2014 |
| REVIEWED E | BY MANAGEMENT BY: | DATE: 11-10-14 |

BY:

DATE: 11-07-14



Adverse Event Reporting Program

| Adverse Event Reporting Program | rrors | | | 7 1 7 0 |
|---|---|----------------------------|--------------------------|---|
| A. PATIENT INFORMATION | 2. Dose or Amount | | | |
| 1. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight | #1 2 | Freque | | by mouth |
| Date of Birth: 14 Months Female 22 lb | | daily | | by moden |
| (b) (6) | #2 | | | |
| in confidence | | | | |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply: | Dates of Use (If unkno (or best estimate) | wn, give duration) | | ent Abated After Use ped or Dose Reduced? |
| 1. Adverse Event Product Problem (e.g., defects/malfunctions) | #1 11/12/2014 - 13 | 1/12/2014 | 1 1 | Yes No Does |
| Product Use Error Problem with Different Manufacturer of Same Medicine | #2 | | | Apply |
| Outcomes Attributed to Adverse Event (Check all that apply) | 4. Diagnosis or Reason | | n) | Yes No Doesi |
| Death: Disability or Permanent Damage | #1 My son had a to | oth coming in | . 8. Ev | ent Reappeared After introduction? |
| (mm/dd/yyyy) | #2 | | _ | Yes No ✓ Doesr |
| Life-threatening Congenital Anomaly/Birth Defect | | T | | Apply |
| ✓ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events) ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices) | 6. Lot # #1 | 7. Expiration #1 08/06/ | 2014 | Yes No Doesi |
| | #2 | - #2 | | C # or Unique ID |
| 3. Date of Event (mm/dd/yyyy) 11/14/2014 4. Date of this Report (mm/dd/yyyy) 11/26/2014 | E. SUSPECT MED | 1 | | 73-3127-3 |
| 5. Describe Event, Problem or Product Use Error | 1. Brand Name | ICAL DEVICE | | |
| See page 2 for complete text. | | | | |
| | 2. Common Device Name | | | |
| | 2. Common Device Name | , | C | 10 |
| | | | DEC - | 7.00** |
| | 3. Manufacturer Name, C | ity and State | חדר ב | 1 2014 |
| | | | | |
| | 4. Model # | Lot# | | Is a |
| | 4. Model # | LOI # | | 5. Operator of Device |
| | | | | Health Professiona |
| | Catalog # | Expiration | Date (mm/dd/yyy | y) Lay User/Patient |
| . Relevant Tests/Laboratory Data, Including Dates | | | | Other: |
| See page 3 for complete text. | Serial # | Other# | | |
| | | | | |
| | 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explanted, | Give Date (mm/dd/yyyy) |
| • | 8. Is this a Single-use Dev | vice that was Per | processed and E | Davis and an a David and |
| | Yes No | rice that was re | processed and r | reused on a Patient? |
| | 9. If Yes to Item No. 8, Ente | r Name and Addre | ss of Reprocess | or |
| Other Relevant History, Including Preexisting Medical Conditions (e.g., | | | | |
| allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) See page 4 for complete text. | F | | | |
| | F. OTHER (CONCO | | | |
| | Product names and thera | py dates (exclude | e treatment of eve | ent) |
| | | | | |
| | | | | |
| | | | | |
| | G. REPORTER (See | confidentialit | y section on l | back) |
| | 1. Name and Address | confidentialit | y section on l | back) |
| | | confidentialit | y section on l | back) |
| PRODUCT AVAILABILITY roduct Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: | 1. Name and Address | confidentialit | y section on l | back) |
| Yes No Returned to Manufacturer on: (mm/dd/yyyy) | 1. Name and Address | confidentialit | y section on I | back) |
| Yes No Returned to Manufacturer on: (mm/dd/yyyy) SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) | 1. Name and Address (b) (6) Phone # | | y section on I | back) |
| Yes No Returned to Manufacturer on: (mm/dd/yyyy) SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hyland's Baby Teething Tablets | 1. Name and Address (b) (6) | | | back) |
| Yes No Returned to Manufacturer on: (mm/dd/yyyy) SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hyland's Baby Teething Tablets | 1. Name and Address (b) (6) Phone # (b) (6) | | E-mail (b) (6) | |
| Yes No Returned to Manufacturer on: (mm/dd/yyyy) SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hyland's Baby Teething Tablets | 1. Name and Address (b) (6) Phone # (b) (6) 2. Health Professional? 3 | | E-mail (b) (6) | 4. Also Reported to: |
| Yes No Returned to Manufacturer on: (mmVdd/yyyy) SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) Name: Hyland's Baby Teething Tablets Strength: n/a | 1. Name and Address (b) (6) Phone # (b) (6) | . Occupation | E-mail (b) (6) | |

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reporting of problems and

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FDA USE ONLY

Triage unit sequence #

B.5. Describe Event or Problem (continued)

My son who is 14 months old, was taking Hyland's Baby Teething tablets on (b) (6) My son had 3 seizures within that 24 hour period. He was admitted and was kept for 4 days. I at first did not think anything about the teething tablets causing the seizures. It was then when I researched and realized I was not the only parent that has had the same/similar issue. We have since stopped administering the teething tablets.

Individual Case Safety Report

10619563-01-00-02

DSS DEC 01 2014

The company of the straight for the first of the straight of t

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

EEG- Normal (b)(6) MRI- Normal (b)(6) had caused my son to have the 3 seizures.

The Doctor at (b) (6)

Children's Hospital could not figure out what

Individual Case Safety Report

10619563-01-00-03

DSS DEC 0 1 2014 B.7. Other Relevant History, Inc

That violat Case Safety Report

10619563-01-00-04

e, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions: N/A

Allergies: n/A

Important Information: N/A

RX Meds: None

OTC Meds: Children's Acetaminophen for fever.

DSS DEC 0 1 2014

| Individual Case | Safety Report |
|-----------------|---------------|
| | |
| | |
| | |
| | |

EASE,

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ct problems and Triage unit errors A. PATIENT INFORMATION Dose or Amount Frequency Route 1. Patient Identifier | 2. Age at Time of Event or 4. Weight Date of Birth: √ Female 5 Months lb Male kg In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Dates of Use (If unknown, give duration) from/to (or best estimate) 5. Event Abated After Use Check all that apply: Stopped or Dose Reduced? #1 Yes No Doesn't 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine #2 #2 Yes No Doesn't 2. Outcomes Attributed to Adverse Event (Check all that apply) 4. Diagnosis or Reason for Use (Indication) 8. Event Reappeared After Death: Disability or Permanent Damage Reintroduction? (mm/dd/yyyy) #1 Yes No Doesn't Apply #2 Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Doesn't 6. Lot# #2 Yes No 7. Expiration Date Required Intervention to Prevent Permanent Impairment/Damage (Devices) #1 #1 9. NDC # or Unique ID #2 3. Date of Event (mm/dd/yyyy) #2 4. Date of this Report (mm/dd/yyyy) 11/24/2014 E. SUSPECT MEDICAL DEVICE 5. Describe Event, Problem or Product Use Error See page 2 for complete text. 2. Common Device Name TYPE OR USE BLACK INK 3. Manufacturer Name, City and State 4. Model # Lot# 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: 6. Relevant Tests/Laboratory Data, Including Dates Serial # Other# See page 3 for complete text. 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) See page 4 for complete text. F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) G. REPORTER (See confidentiality section on back) 1. Name and Address C. PRODUCT AVAILABILIT (b) (6) Product Available for Evaluation? (Do not send product to FDA) ✓ Yes 🔲 No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label) Phone # E-mail #1 Name: Teething tablet (b) (6) Strength: Julian teething tablets Manufacturer: 2. Health Professional? 3. Occupation 4. Also Reported to: #2 Name: Yes No Manufacturer Strength: DEC 0 1 2014 5. If you do NOT want your identity disclosed User Facility Manufacturer: to the manufacturer, place an "X" in this box: ☐ Distributor/Importer FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event,

ner Report CTES

reporting of

*⊋*așelD: 10619580

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

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B.5. Describe Event or Problem (continued)

My infant had seizure believed to be a direct result of the teething tablets

Individual Case Safety Report

Case Salety Report

10619580-01-00-02

DSS DEC 0 1 2014 B.6. Relevant Tests/L EEG Individual Case Safety Report

CaseID; 19619580/

DSS DEC 01 2014 B.7. Other Relevant History, Inc

Race:White Medical Conditions: None

Allergies:

Important Information:

RX Meds:

OTC Meds:

10619580-01-00-04

e, hepatic/renal dysfunction, etc.) (continued)

DSS DEC 01 2014



The FDA Safety Information and Adverse Event Reporting Program

| umer | Reposito |
|------|----------|
| | ~ 1 |

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

RY reporting of luct problems and product use errors

| | FDA USE ONLY | |
|---------------------------|--------------|--|
| Triage unit sequence # | 574456 | |
| | | |

| i. Patient identifier ; | | | | - 44 - | | | | Route |
|--|---|--|--------------------------------------|---|--|--|--------------------------------------|--|
| (b) (6) | 2. Age at Time of Ev Date of Birth: | ent or 3. Sex | 4. Weight | #1 2 | | Four daily | times | Taken by mouth |
| | 2 Years | ☐ Fema | 30 lb | | | | | |
| | (b) (6) | ✓ Male | or kg | #2 | | | | |
| In confidence | EVENT PROPU | - | —— "s | | | | | |
| heck all that apply: | EVENT, PRODUC | CT PROBLEM O | RERROR | 3. Dates (or be | of Use (If unknownst est estimate) | vn, give duration | n) from/to | 5. Event Abated After Use Stopped or Dose Reduced? |
| . ✓ Adverse Event | f Product Pro | blem (e.g., defects/ma | Munctions) | 1 ' | 24/2014 - 04 | /28/2014 | | #1 Ves No Doesn't |
| | | | urer of Same Medicine | #2 | | - | | Apply |
| | uted to Adverse Ever | | | | osis or Reason fo | or Use (Indicati | onl | #2 Yes No Doesn't |
| (Check all that app | oly) | | | - | ething | or odd (marcan | <i>311)</i> | 8. Event Reappeared After |
| Death: | | Disability or Perma | anent Damage | | | | | Reintroduction? |
| Life-threatening | mm/dd/yyyy) | Congenital Anoma | ly/Birth Defect | #2 | | | | #1 Yes No Doesn't Apply |
| Hospitalization | - initial or prolonged | ✓ Other Serious (Imp | ortant Medical Events) | 6. Lot# | | 7. Expiration | Date | #2 Yes No Doesn't |
| Required Interv | ention to Prevent Per | manent Impairment/Da | amage (Devices) | #1 | | #1 | | 9. NDC # or Unique ID |
| 3. Date of Event (mn | | 4. Date of this Rep | | #2 | | #2 | | 54973-3127-1 |
| 05/01/2014 | ,,,,,,, | 12/02/2014 | | E. SU | SPECT MEDI | | F | 34973-3127-1 |
| . Describe Event, F | Problem or Product L | | | 1. Brand | | OAL DEVIO | - | |
| See page 2 f | or complete te | xt. | | | | | | |
| | | | | | an Davier | | | |
| | | | | 2. Comn | non Device Name |) | | |
| | | | | | | | | |
| | | | | 3. Manu | acturer Name, Ci | ity and State | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | 4. Model | # | Lot# | | 5. Operator of Device |
| | | | | | | | | Health Professional |
| | | | | Catalo | g# | Expiration | Date (mm | /dd/yyyy) Lay User/Patient |
| | | | | | - | 2000 | | |
| . Relevant Tests/La | boratory Data, Inclu | ding Dates | | | | | | Other: |
| | | | | Serial | # | Other# | | |
| | | | | | | - 1 | | |
| | | | | | | | | |
| | | | | 6. If Impl | anted, Give Date | (mm/dd/yyyy) | 7. If Expl | anted, Give Date (mm/dd/yyyy) |
| | | | | | | | | , |
| | | | | 8. Is this | | | | anted, Give Date (mm/dd/yyyy) d and Reused on a Patient? |
| | | | | 8. Is this | a Single-use Dev | ice that was R | eprocessed | d and Reused on a Patient? |
| Other Releyant His | story, including Pree | xisting Medical Cond | litions (e.g. | 8. Is this | a Single-use Dev | ice that was R | eprocessed | d and Reused on a Patient? |
| allergies, race, preg | gnancy, smoking and a | xisting Medical Conc alcohol use, liver/kidne | litions (e.g., y problems, etc.) | 8. Is this | a Single-use Deves No o Item No. 8, Enter | rice that was Ro | eprocessed | d and Reused on a Patient? |
| allergies, race, preg | story, including Pree gnancy, smoking and a or complete te: | alcohol use, liver/kidne | litions (e.g., ny problems, etc.) | 8. Is this Yes to 9. If Yes to F. OTH | a Single-use Devels No o Item No. 8, Enter | rice that was Ro | eprocessed | d and Reused on a Patient? rocessor PRODUCTS |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidne | litions (e.g., ly problems, etc.) | 8. Is this Yes to 9. If Yes to F. OTH | a Single-use Deves No o Item No. 8, Enter | rice that was Ro | eprocessed | d and Reused on a Patient? rocessor PRODUCTS |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidne xt. | ny problems, etc.) | 8. Is this Yes to 9. If Yes to F. OTH | a Single-use Devels No o Item No. 8, Enter | rice that was Ro | eprocessed | d and Reused on a Patient? rocessor PRODUCTS |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidne | ny problems, etc.) | 8. Is this Yes to 9. If Yes to F. OTH | a Single-use Devels No o Item No. 8, Enter | rice that was Ro | eprocessed | d and Reused on a Patient? rocessor PRODUCTS |
| allergies, race, preg | gnancy, smoking and a | alcohol use, liver/kidne xt . | ny problems, etc.) | 8. Is this Yes 9. If Yes t | a Single-use Devise No Is No I | VICE that was Ro | eprocessed ress of Rep DICAL F | d and Reused on a Patient? rocessor PRODUCTS It of event) |
| See page (fo | gnancy, smoking and i | alcohol use, liver/kidne xt. | ny problems, etc.) | 8. Is this Yes 9. If Yes t F. OTH Product to | a Single-use Devels No o Item No. 8, Enter | VICE that was Ro | eprocessed ress of Rep DICAL F | d and Reused on a Patient? rocessor PRODUCTS it of event) |
| See page of formal see page of f | gnancy, smoking and a correction or complete te: | CTU DEC 03 | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product to | a Single-use Devise No s No o Item No. 8, Enter IER (CONCON names and therap | VICE that was Ro | eprocessed ress of Rep DICAL F | d and Reused on a Patient? rocessor PRODUCTS it of event) |
| See page for | vallability revaluation? (Do not | CTU DEC 0 3 | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product I | a Single-use Devise No s No o Item No. 8, Enter IER (CONCON names and therap | VICE that was Ro | eprocessed ress of Rep DICAL F | d and Reused on a Patient? rocessor PRODUCTS it of event) |
| See page for | gnancy, smoking and a correction or complete te: | CTU DEC 0 3 t send product to FDA) | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product I | a Single-use Devise No s No o Item No. 8, Enter IER (CONCON names and therap | VICE that was Ro | eprocessed ress of Rep DICAL F | d and Reused on a Patient? rocessor PRODUCTS It of event) |
| See page for | VAILABILITY revaluation? (Do not) | CTU DEC 0 3 t send product to FDA) | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product I | a Single-use Devise No s No o Item No. 8, Enter IER (CONCON names and therap | VICE that was Ro | eprocessed ress of Rep DICAL F | d and Reused on a Patient? rocessor PRODUCTS it of event) |
| PRODUCT AV roduct Available for SUSPECT PR | VAILABILITY revaluation? (Do not Returned to Manua SODUCT(S) anufacturer (from pro | DEC 0 3 t send product to FDA) ufacturer on: | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product t G. REP 1. Name (b) (6) | a Single-use Devise No s No o Item No. 8, Enter IER (CONCON names and therap | VICE that was Ro | E-mail | d and Reused on a Patient? rocessor PRODUCTS it of event) |
| See page for | VAILABILITY revaluation? (Do not) Returned to Manuary | DEC 0 3 t send product to FDA) ufacturer on: | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product (G. REP 1. Name ((b) (6) | a Single-use Devise No s No o Item No. 8, Enter IER (CONCON names and therap | VICE that was Ro | EDICAL For the treatment | d and Reused on a Patient? rocessor PRODUCTS it of event) |
| See page for product Available for Yes No SUSPECT PR Name: Strength, Mane: hyland is strength: | VAILABILITY revaluation? (Do not Returned to Manua CODUCT(S) anufacturer (from pro- | DEC 0 3 t send product to FDA) ufacturer on: | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product t G. REP 1. Name a (b) (6) | a Single-use Development of the No. 8, Enter o | Name and Add | E-mail | d and Reused on a Patient? PRODUCTS It of event) DEC 0 |
| See page for | VAILABILITY revaluation? (Do not Returned to Manua CODUCT(S) anufacturer (from pro- | DEC 0 3 t send product to FDA) ufacturer on: | 2014 | 8. Is this Yes 9. If Yes t F. OTH Product (G. REP 1. Name (b) (6) Phone # (b) (6) | a Single-use Development of the No. 8, Enter o | Name and Add | E-mail | d and Reused on a Patient? PRODUCTS It of event) DEC 0 |
| See page for product Available for Yes No SUSPECT PR Name: Strength, Mane: hyland is strength: | VAILABILITY revaluation? (Do not Returned to Manua CODUCT(S) anufacturer (from pro- | DEC 0 3 t send product to FDA) ufacturer on: | 2014 | 8. Is this Ye 9. If Yes t F. OTI- Product t G. REP 1. Name t (b) (6) Phone # (b) (6) | a Single-use Development of the No. 8, Enter o | VICE that was Revenue and Addition of MITANT) ME by dates (exclude confidential) | E-mail (b) (6) | d and Reused on a Patient? PRODUCTS It of event) DEC 0 |

B.5. Describe Event or Problem (continued)

Gave my son the right dose and a couple of days after he had a seizure

Individual Case Safety Report

dase Safety Report

10627664-01-00-02

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Important Information:

RX Meds:

Individual Case Safety Report

10627664-01-00-03



(Y reporting of luct problems and

umer Report

 $C_{\mathcal{D}_{\mathcal{I}_{\mathcal{X}}}}$

Triage unit

| CaseID: 10631888 | , |
|---|---|
| orm Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse | |

| | | 100010000 | | | | | roblems and | Triag | ge unit uence# | 574 | 1457 | 7 | | | |
|-----------------------|--|--|-----------------------|------------|------------|-----------------|---|------------|-------------------|------------|-------------|--|---------------|--|--|
| | • | nnormation and Reporting Progra | | | produc | use erro | ors) (| | | <u> </u> | | | | | |
| í | | | | | | 2. | Dose or Amount | <u> </u> | Frequen | | Route | | | | |
| | A. PATIENT IN | 2. Age at Time of Ev | rent or 3. Sex | | 4. Weight | | DOSE OF ARROUNCE | | | 109 | | | | | |
| | b) (6) | Date of Birth: | | | 4. Weight | | 1 | | 1 | l l | | | | | |
| Ì | ,, (, | 18 Months | L | Female | | . lb #2 | | | \ <u></u> | | | | | | |
| | In confidence | | 🗆 ! | Male | or | kg | | | | | | | ŀ | | |
| | | EVENT, PRODUC | CT PROBLEM | I OR ER | ROR | 3. D | ates of Use (If unkn | own, give | duration) | from/to | | Abated A | | | |
| - 1 | Check all that apply: | heck all that apply: | | | | | (or best estimate) #1 | | | | | Stopped or Dose Reduced? #1 ✓ Yes ☐ No ☐ Doesn't | | | |
| | 1. Adverse Event | | | | | | 40 | | | | | 62 140 | Apply | | |
| l | Product Use E | Product Use Error Problem with Different Manufacturer of Same Medicine | | | | | | | | | | | Doesn't | | |
| | 2. Outcomes Attribu | uted to Adverse Ever oly) | nt | | | | 4. Diagnosis or Reason for Use (Indication) #1 Teething pain for babies | | | | | 8. Event Reappeared After Reintroduction? #1 Yes No Doesn't | | | |
| | Death: | | Disability or P | ermanent E | Damage | _ | | | | | | | | | |
| | (mm/dd/yyyy) ✓ Life-threatening | | | | | #2 | ! | | | | Apply Apply | | | | |
| . | | - initial or prolonged [| - | - | | 6. L | ot# | 7. E | xpiration | Date | #2 🔲 Y | es No | Doesn't | | |
| | | vention to Prevent Per | _ | | | #1 | | #1 | • | | 9. NDC # | or Uniqu | | | |
| | | | 4. Date of this | | | — #2 | | #2 | | | | • | | | |
| | 3. Date of Event (mi | nvadvyyyy) | 12/02/20 | | iibuwyyyy) | | SUSPECT MEI | DICAL | DEVICE | | | | | | |
| ŀ | 5 Describe Event I | Problem or Product l | | 014 | | 1 | rand Name | | | | | | | | |
| | | or complete te | | | | | | | | | | | | | |
| | | _ | | | | - | | | | | | | | | |
| | | | | | | 2. 0 | ommon Device Nar | me | | | | | | | |
| Ż | | | | | | | | | | | | | | | |
| × | | | | | | 3. M | lanufacturer Name, | City and | State | | | | | | |
| ¥ | | | | | | | | | | | | | | | |
| B | | | | | | | | | | | | | | | |
| SE | | | | | | 4. N | lodel # | L | ot # | | | 5. Operat | or of Device | | |
| | | | | | | | | . 1 | | | | Health | Professional | | |
| TYPE OR USE BLACK INK | | | | | | | atalog # | | xpiration | Date (mn | n/dd/www) | ∏ Lav U | ser/Patient | | |
| 田 | | | | | | - | | | | | | | | | |
| | 0.0.1 | | -di Data | | | | | | | | | Other | | | |
| | | aboratory Data, incl u for complete te | - | | | s | erial # | ۱۹ | Other # | | | | | | |
| Ϋ́ | occ page o i | or compress so | | | | | | | | | | | | | |
| PL | See page 3 for complete text. | | | | | 6. lf | Implanted, Give Da | ate (mm/c | (d/yyyy) | 7. If Exp | planted, G | ive Date (| nm/dd/yyyy) | | |
| | | | | | | | Able a Clumb | Davilsa Ab | -t D | | -dd D- | | Detient? | | |
| | | | | | | | this a Single-use I | pevice (II | al was K | pprocesse | eu anu Ke | useu on a | rauentr | | |
| | | | Yes to Item No. 8, Er | nter Name | and Add | ress of Re | processor | | | | | | | | |
| | 2 Other Delevent History Including Presulation Medical Conditions /- | | | | | | | | | | | | | | |
| | 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) | | | | | | | | | | 4 - 1 - 1 | | * | | |
| | See page 4 | for complete to | ext. | | | F. | OTHER (CONC | OMITA | NT) ME | DICAL | PRODU | ICTS | | | |
| ı | per exist of | | | | | Pro | duct names and the | erapy da | tes (exclu | de treatme | nt of even | Ų . | | | |
| | | | CTU | | | | | | - | | 79 | | | | |
| | | | | | | | , A | Ĩ,Ψ, | | | | | | | |
| | | U | EC 0 3 20 | 14 | | | | | | | | | | | |
| | | | | v. Vita | | 1 | REPORTER (S) | ee conf | idential | ity secti | on on b | ack) | 7 7 7 7 7 7 7 | | |
| | C. PRODUCT A | VAILABILITY | | | | | (6) | | | | | A STATE | | | |
| | | or Evaluation? (Do n | ot send product to | o FDA) | | | | | | | | | 1. 7+ | | |
| | ☑ Yes ☐ No | Returned to Mar | nufacturer on: | | | _ | | | | | | | | | |
| | D. SUSPECT P | PODLICT(S) | | (mm/ | dd/yyyy) | | | | | | | | | | |
| | | Manufacturer (from p | product lahel) | | | | ne # | | - | E-mail | | | | | |
| 1 | | teething tabl | | | | (b) (d | 5) | | | (b) (6) | | | | | |
| | Strength: | _ | | | | - | la a Mila Barata a di di | 10.0 | | | 1. | Ales D | nutari ta: | | |
| V | Manufacturer: H | yland | | | | 2. H | iealth Professional1 | 7 3. Occ | upation | | 4 | . Also Rep | | | |

Strength:

Manufacturer:

5. If you do NOT want your identity disclosed

B.5. Describe Event or Problem (continued)

Hyland teething tablets cause severe tooth decay and seizures.

Individual Case Safety Report

10631888-01-00-02

My son had seizures from these tablets and severe tooth decay on his 4 top teeth



10631888-01-00-03

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:--Medical Conditions: none

Allergies: none

Important Information:

RX Meds:

OTC Meds: Probiotic and children vitamin

Individual Case Safety Report



10631888-01-00-04



ser-facilities, rs and manufacturers ORY reporting

| Fo | rm Approv | 9 BE | | | atement on | |
|-------|-----------|------|---|------|------------|--|
| port# | 54973 | AE | # | 1579 | | |

| | | | See OMB states | nent on reverse |
|---------------|----------|------|----------------|-----------------|
| Mfr Report# | 54973 | AE H | F 1579 | |
| UF/Importer I | Report # | | | |
| | | | | |

| FORM | FUA | 350UA | (2/13) |
|------|------------|-------|--------|

PLEASE TYPE OR USE BLACK INK

| -OKM FDA 350 | UA (2/13) | | | ı uyu |
|--|---|---------------------------------------|---------------------------------------|--------------------|
| A. PATIENT INF | ORMATION | | | |
| . Patient Identifier b) (6) | Age at Time of Event: | | 3. Sex | 4. Weight |
| | or | | Female | lbs |
| In confidence | Date of Birth: | | Male | or kgs |
| | VENT OR PRODUC | CT PROBLE | VI | Kgo |
| | | | | inactions) |
| Adverse Even | t and/or Pro | duct Problem (6 | .g., derects/man | unctions) |
| (Check all that appl | | | | |
| Death: | (mm/dd/yyyy) | Disability o | r Permanent Da | mage |
| Life-threatenin | | Congenital | Anomaly/Birth D | Defect |
| Hospitalization | - initial or prolonged | Other Seri | ous (Important M | ledical Events) |
| · | vention to Prevent Perma | | | |
| 3. Date of Event (mn | | 4. Date of This | Report (mm/dd | |
| 5. Describe Event or | 00/2012 Problem | <u> </u> | 11/18/2014 | |
| | | | | |
| SEIZURES REPO | RTED IN A CHILD | | | |
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| | | DEA | CIVE | n |
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| | | DEC (| 3 2014 | |
| | | <i>a</i> | CO (1780) | |
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| | | | | |
| | | | | |
| | | | (Continue or | n page 3) |
| . Relevant Tests/Lat | ooratory Data, Including | g Dates | , | , p = g = 7 |
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| | | | | |
| | | | | |
| | | | (Continue or | |
| Other Relevant His race, pregnancy, sn | story, Including Preexis noking and alcohol use, I | ting Medical Co hepatic/renal dysi | nditions (e.g., al function, etc.) | liergies, |
| | | | | |
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| | | | | |
| | | | (Continue or | n page 3) |

| Submission of a report does not constitute an admission that med | lical |
|--|-------|
| personnel, user facility, importer, distributor, manufacturer or pro | duct |
| caused or contributed to the event. | |

| - 6 | | | | |
|--|--------------------|---------------|------------|------------------------------------|
| f <u>5</u> | | | | FDA Use Only |
| C. SUSPECT PRODU | JCT(S) | | | |
| 1. Name (Give labeled stren #1 HYLAND'S TEETH | | | | |
| #2 | | | | |
| 2. Dose, Frequency & Rout | te Used | | | f unknown, give duration) |
| ·#1 | | | (or best e | |
| #2 | | #2 | · · · · | |
| 4. Diagnosis for Use (Indica | ation) | L | | Abated After Use |
| #1 TEMP RELIEF TE | ETHING PAIN | | #1 Y | ed or Dose Reduced? es No Apply |
| #2 | 7 Euro Data | | #2 Y | es No Doesn't |
| 6. Lot# #1 | 7. Exp. Date #1 | - | | Reappeared After |
| | #2 | | Reintro | oduction? |
| #2 9. NDC# or Unique ID | L#4 | | #1 Y | es No [V] Apply |
| 54973-7504-1 | | | #2 Y | es No Doesn't Apply |
| 10. Concomitant Medical P | roducts and Ther | apy Dates | (Exclude t | reatment of event) |
| | | | | |
| | | | | |
| | | | C | ontinue on page 3) |
| D. SUSPECT MEDIC | AL DEVICE | | | |
| 1. Brand Name | | | | |
| 2. Common Device Name | | | 2b. P | rocode |
| 3. Manufacturer Name, City | y and State | | | |
| | | | | |
| 4. Model# | Lot# | | | 5. Operator of Device |
| | | | | Health Professional |
| Catalog # | Expiration (| Date (mm/c | id/yyyy) | Lay User/Patient |
| Serial # | Unique Ider | ntifier (UDI |)# | Other: |
| 6. If Implanted, Give Date (| /mm/dd/vvvv) | 7. If Expl | inted. Giv | e Date (mm/dd/yyyy) |
| | | | | |
| 8. Is this a Single-use Devi | ce that was Repro | ocessed ar | d Reuseo | I on a Patient? |
| 9. If Yes to Item No. 8, Ente | er Name and Addr | ess of Rep | rocessor | |
| - | | | | |
| | | | | |
| 10. Device Available for Ev | aluation? (Do not | send to FD | A) | |
| Yes No [| Returned to Ma | anufacturer | on: | (mm/dd/yyyy) |
| 11. Concomitant Medical P | roducts and There | apy Dates | (Exclude | |
| | | | | , |
| | | | (C | ontinue on page 3) |
| E. INITIAL REPORTE | ER | | ,,, | on page of |
| 1. Name and Address (b) (6) | | | | |
| (0) (0) | | | | |
| | | | | |
| | | | | |
| Phone # (b) (6) | Email (b) (6) | Address | | |
| | Occupation | | [4. Ir | nitial Reporter Also Sent |
| Ves □ No C | Other Healthc | are Prof | l R | eport to FDA Yes No V Unk. |
| DEC 03 2014 | | $-\mathbf{p}$ | SS | |
| DEC AS TALL | | - | | 014 |

DEC 0 4 2014

| User Facility | ∐ lmp | porter | |
|---|--|---|--|
| 3. User Facility or Imp | orter Name | e/Address | |
| | | | |
| | | | |
| | | | |
| | | | |
| 4. Contact Person | | 5. Phone N | lumber |
| 6. Date User Facility of | vr | 7. Type of Report | 8. Date of This Report |
| Importer Became Aware of Event (min | | 1_" | (mm/dd/yyyy) |
| | ,,,,, | Initial | |
| 9. Approximate | In Event | Problem Codes (Refer to cod. | ing manual) |
| Age of Device | ١ ـ | Troblem codes (Neter 10 cod. | Ing manual) |
| | Patient Code | | |
| ļ | Device | _ | - |
| 11. Report Sent to FD | Code [| 12. Location Where Event | Occurred |
| Yes | ••• | Hospital | Outpatient |
| □ No (mm/da | √уууу) | Home | Diagnostic Facility |
| 13. Report Sent to Ma | nufacturer | Nursing Home | Ambulatory Surgical Facility |
| Yes | | Outpatient Treatment Facility | nt |
| No (mm/dd | (уууу) | Other: | |
| | | | (Specify) |
| 14 Manufacturer Nam | | | |
| 14. Manufacturer Nam | e/Address | | |
| 14. Manufacturer Nam | e/Address | | |
| 14. Manufacturer Nam | e/Address | | |
| 14. Manufacturer Nam | e/Address | | |
| | | 35 | |
| 14. Manufacturer Nam G. ALL MANUFA 1. Contact Office (and | CTURE | | 2. Phone Number |
| G. ALL MANUFA 1. Contact Office (and Name | CTUREF Manufactu | | 2. Phone Number 310-768-0700 |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) | CTUREF Manufactu | | 310-768-0700 3. Report Source |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address | CTUREF Manufactu | | 310-768-0700 3. Report Source (Check all that apply) |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. | CTUREF Manufactu | | 310-768-0700 3. Report Source |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address | CTUREF Manufactu ICZ IREET | uring Site for Devices) | 310-768-0700 3. Report Source (Check all that apply) Foreign |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW: Address HYLAND'S, INC. 154 W. 131ST S: LOS ANGELES, CA | CTUREF Manufactu ICZ IREET | uring Site for Devices) | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S | CTURES Manufactu ICZ IREET A 9006 | uring Site for Devices) | 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW: Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, C. Email Address STANDARD@HYLANI 4. Date Received by | CTUREF Manufactu ICZ IREET A 9006 | uring Site for Devices) | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW: Address HYLAND'S, INC. 154 W. 131ST S: LOS ANGELES, C: Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d) | CTURER Manufactu ICZ IREET A 9006 DS.COM | aring Site for Devices) | 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d) 11/14/20 | CTURES Manufactu ICZ TREET A 9006 DS.COM Id/yyyy) 014 | 1 5. | 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW: Address HYLAND'S, INC. 154 W. 131ST S: LOS ANGELES, C: Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d) | CTURES Manufactu ICZ TREET A 9006 DS.COM Id/yyyy) 014 | 1 5. (A)NDA# | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, CA Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d 11/14/20 6. If IND, Give Protoco | CTURES Manufactu ICZ TREET A 9006 DS.COM Id/yyyy) 014 | 5. (A)NDA# IND# BLA# PMA/ | 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d) 11/14/20 | CTURES Manufactu ICZ IREET A 9006 DS.COM Id/yyyy) 014 | 5. (A)NDA # IND # BLA # PMAV 510(k) # | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, Co. Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 11/14/20 6. If IND, Give Protoco | CTURES Manufactu ICZ IREET A 9006 DS.COM Id/yyyy) 014 | 5. (A)NDA# IND# BLA# PMA/ | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: PHARMACY |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 11/14/20) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day 30-da 7-day Perio | CTURES Manufactu ICZ IREET A 9006 DS.COM Id/yyyy) 014 II# | 1 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: PHARMACY |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST S' LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 11/14/20) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day 30-da 7-day Perio 10-day Initial | CTURES Manufactu ICZ IREET A 9006 DS.COM Id/yyyy) 014 I# | 5. (A)NDA# IND# BLA# PMAV 510(k)# Combination Product Yes | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: PHARMACY |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, Co. Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d 11/14/20) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) | CTURES Manufactu ICZ IREET A 9006 DS.COM Id/yyyy) D14 I# | 5. (A)NDA# IND# BLA# PMAV 510(k)# Combination Product Yes Pre-1938 Yes OTC Product Yes | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: PHARMACY ASSISTANT |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, Co. Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 11/14/20) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day | CTURES Manufactu ICZ TREET A 9006 DS.COM Id/yyyy) D14 I# ay dic w-up# t Number | 5. (A)NDA # | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: PHARMACY ASSISTANT |
| G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, Co. Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d 11/14/20) 6. If IND, Give Protoco 7. Type of Report (Check all that apply) | CTURES Manufactu ICZ TREET A 9006 DS.COM Id/yyyy) D14 I# ay dic w-up# t Number | 5. (A)NDA# IND# BLA# PMAV 510(k)# Combination Product Yes Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(s) | 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other: PHARMACY ASSISTANT |

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | | FDA USE ONLY |
|--------------------------------|-----------------------|---|
| | | |
| of <u>5</u> | | |
| H. DEVICE MANUFAC | TURERS ONLY | |
| Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death | | Correction |
| = | | Additional Information |
| Serious Injury | | |
| Malfunction | | Response to FDA Request |
| | | Device Evaluation |
| 3. Device Evaluated by Manu | ıfacturer? | 4. Device Manufacture Date |
| Not Returned to Manu | ıfacturer | (mm/yyyy) |
| Yes Evaluation | Summary Attached | |
| ☐ No (Attach page to ex | colain why not) or | 5. Labeled for Single Use? |
| provide code: | ,,, | |
| İ | | Yes No |
| 6. Event Problem and Evalua | ation Codes (Refer to | coding manual) |
| Patient | | |
| Code | | |
| Device |]_[| _ |
| Code | | |
| Method | - | - - |
| ⊨ | = | |
| Results | |]-[] |
| I = | | |
| Conclusions | | |
| 7. If Remedial Action Initiate | d, Check Type | . Usage of Device |
| Recall N | otification | Initial Use of Device |
| | spection | Reuse |
| | atient Monitoring | Unknown |
| | | If action reported to FDA under |
| | djustment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | • |
| - | : | |
| 10. Additional Manufactu | was Massative a | nd / or 11. Corrected Data |
| Additional mandiacto | net Harrative a | 11. Confected Data |
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CaseID: 10638399

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Address.

DEC 03 2014



ODOTOMIER COM EANT RECORD



| 10638399-01-00-0 | 03 | COMPLAINT#: _2009 | |
|----------------------------------|---------------------------------------|--|-------------------|
| TAKEN BY: | EDITATIONONEVIOZ | DATE OF COMPLAINT: 11/14/14 | |
| PRODUCT: | HYLAND'S TEETHING TABLETS | ITEM CODE: TEET | |
| SIZE: | UNKNOWN | LOT NO.: NOT PRO | VIDED |
| REPORTER: (b) (6) |) | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | (b) (6) STATE: | |
| COUNTRY: USA | | | |
| (b) (6) | | ZIP CODE: | |
| PHONE #: | | | |
| E-MAIL: | | ATTORNEY REPORTS SEIZURES FOLLOWING USE OF | TEETHING TABLETS. |
| NATURE OF COMPLAINT: | SPOKE WITH PHARMACY ON 11/14 | /14. | |
| | | | |
| | FOR ADDITIONAL SPACE PLEASE US | E REVERSE OR ATTACH A SEPARATE SHEET | |
| | | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR INSPECTION | Y (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT BE RETURNED | D: |
| | | | |
| | | UPS CALL TAG ISSUED | D: (CIRCLE ONE) |
| | | | , |
| | | DATE PRODUCT RECEIVED | D: |
| SECTION II: IN | IVESTIGATION | | |
| INVESTIGATION; | PLEASE SEE ATTACHED INVESTIGATION RE | EPORT. | |
| | | | |
| | | | |
| | | | |
| | | | |
| | RDED TO PHARMACIST / NURSE FOR EVALUA | | |
| ADVERSE EVENT FORWAR | RDED TO PHARMACIST / NURSE FOR EVALUA | TION BY: EDYTA FRACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| | | | |
| | | - 1,1,2,1,1,1 | |
| 10-14-4 | | | |
| CORRECTIVE ACTION(S) C | OMPLETED BY: | DATE: | |
| | | | |
| SECTION IV: AD | VERSE EVENT REPORTS | AE #:1579 | |
| ADVERSE EVENT SERIOUS | s: (_Y), N | | |
| ADVERSE EVENT REPORTI | ED ON: 11/14/14 | BY: EDYTA FRACKIEWICZ | |
| SECTION V: | | EDITATING NEW CZ | |
| SCOTION V. | | 0 | |
| REVIEWED BY MANAGEME | NT BY: Lyman | DATE: 11-25 | 5-14 |
| 514 | Thin Bour | DATE: 11-25 | 1.111 |
| BY: | QA / QC DIRECTOR | DATE: 11-2- | 177 |
| | | | DSS |
| cc: QA/QC | Production | | |

cc: QA / QC Packaging Production Shipping / Receiving

DEC 0

Form # VD1





CaseID: 10638399

SAE-0056-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and twenty-seven (127) Adverse Events (AE) which also included thirty-three (33) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

11/21/14 Date

DEC 03 2014

DSS nec 0 4 21114



RSE EVENT DATA FORM



| SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) NAME: UNKNOWN CHILD | |
|---|-----|
| NAME: UNKNOWN CHILD | |
| | |
| ADDRESS: | |
| | |
| CITY: STATE: | |
| COUNTRY: USA ZIP CODE: | |
| PHONE #: | |
| E-MAIL; | |
| SECTION II: PACKAGING INFORMATION: | |
| AFFIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPIPANELS) | LAY |
| White the control of | |
| SECTION III: CORRECTIVE ACTION: | |
| | |
| | |
| CORRECTIVE ACTION(S) COMPLETED BY: DATE: | |
| SECTION IV: | |
| REVIEWED BY MANAGEMENT BY: Dayman Dalu Date: 11-25- | 14 |
| BY: | |
| QA / QC DIRECTOR | |

DEC 03 2014 DEC 0 4 2014

FORM SAE01



| 10642973 | | eporting of problems and () | Triage unit | FDA USE O | NLY |
|---|--|------------------------------|----------------------|--------------------|-------------------------------|
| | | rors. | sequence # | 215 | /// |
| Adverse Event Reporting Progra | ım | _ | / L | | |
| A. PATIENT INFORMATION 1. Patient Identifier 2. Age at Time of Even Date of Birth: 4 Months (b) (6) | Female 70 lb | #2 | Frequenc | ey Route | |
| In confidence B. ADVERSE EVENT, PRODUC | | 3. Dates of Use (If unknown | un dive duration) t | mmto 5 Even | t Abated After Use |
| Check all that apply: | T PROBLEM OR ERROR | (or best estimate) | | Stopped | or Dose Reduced? |
| | lem (e.g., defects/malfunctions) | #1 07/01/2007 - 08 #2 | 3/31/2009 | #1 LIY | es ☑ No ☐ Doesn't Apply |
| 2. Outcomes Attributed to Adverse Event | Different Manufacturer of Same Medicin | 4. Diagnosis or Reason | for Use (Indication) |) #2 🗆 Y | res No Doesn't |
| (Check all that apply) | <u> </u> | #1 Teething | | | t Reappeared After roduction? |
| (mm/dd/vvvv) | Disability or Permanent Damage | #2 | | #1 🔲 | es No Doesn't Apply |
| | ☐ Congenital Anomaly/Birth Defect ☐ Other Serious (Important Medical Events | 6. Lot# | 7. Expiration D | Date #2 | res No Doesn't |
| Required Intervention to Prevent Perm | | #1 | #1 | | # or Unique ID |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of this Report (mm/dd/yyyy) | #2 | #2 | | |
| 08/07/2009 | 12/08/2014 | E. SUSPECT MED | ICAL DEVICE | | |
| Describe Event, Problem or Product Uses page 2 for complete tex | | 1. Brand Name | | | |
| • | | 2. Common Device Nam | | | |
| | | 2. Common Bovice Num | • | | <i>P</i> 371 s |
| | | 3. Manufacturer Name, C | ity and State | | CTU |
| | | | , | D) | EC - 9 2014 |
| | | 4. Model # | Lot# | | 5. Operator of Device |
| | | | | | Health Professional |
| | | Catalog # | Expiration (| Date (mm/dd/yyyy) | Lay User/Patient |
| | | | | | Other: |
| 6. Relevant Tests/Laboratory Data, Include See page 3 for complete test | • • | Serial# | Other# | | |
| | | 6. If Implanted, Give Date | e (mm/dd/yyyy) | 7. If Explanted, G | ive Date (mm/dd/yyyy) |
| | | 8. Is this a Single-use De | evice that was Rep | processed and Re | used on a Patient? |
| | | 9. If Yes to Item No. 8, Ent | er Name and Addre | ess of Reprocessor | |
| 7. Other Relevant History, Including Pree allergies, race, pregnancy, smoking and a | xisting Medical Conditions (e.g., | 1 | | | |
| See page 4 for complete te | | F. OTHER (CONCO | OMITANT) MEI | DICAL PRODU | JCTS |
| | | Product names and then | | | |
| | | | | | |
| | | 6 0500000 | | | |
| | | G. REPORTER (Sec | e confidentialit | y section on b | ack) |
| B. PRODUCT AVAILABILITY Product Available for Evaluation? (Do no. | t send product to EDA) | (b) (6) | | | DSS |
| Yes ✓ No ☐ Returned to Manu | ufacturer on: | | | | DS: DEC 0 9 |
| D. SUSPECT PRODUCT(S) | (mm/dd/yyyy) | | | | JEC (0 9 |
| . Name, Strength, Manufacturer (from pro | • | Phone # (b) (6) | | E-mail (b) (6) | |
| *1 Name: Hyland Teething Table Strength: | ets | (5) (6) | | (~) (0) | |
| Manufacturer: | | 2. Health Professional? | 3. Occupation | 4 | . Also Reported to: |
| 2 Name: | | Yes No | | | Manufacturer |
| Strength: | | 5. If you do NOT want you | | | User Facility |

 $CD_{\mathcal{Z}_{\mathcal{R}}^{\prime}}$

: Report

Case D. 10642973
Form Approved: OMB No. 0910 0291, Expires: 12/31/2011
See OMB statement on reverse.

B.5. Describe Event or Problem (continued)

My child took the Hyland Teething Tablets while teething. He was diagnosed with Petit Mal Seizures after taking the tablets.

Individual Case Safety Report

10642973-01-00-02

DSS DEC .0 9 2014

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

Beginning in August of 2009 we noticed our son blanking out we took him to the doctor and after many test through three different physicians we found he had Petit Mal Seizures.

Individual Case Safety Report

10642973-01-00-03

DSS DEC 0 9 2014 B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Important Information:

RX Meds:

OTC Meds:

Individual Case Safety Report



10642973-01-00-04

DSS DEC .0 9 2014



| | U(| | | | orting of FDA USE ONLY oblems and Triage unit 5.15.1.2 | | | | | NLY | | • | | |
|-----------------------|--------------------------------------|--|-----------|-------------------------------------|--|-----------------|---------------------------------------|----------|--------------|--------------|--------|-------------|--------------------------|------------------------|
| | | 7.05430 | 183-D. | 1-00-01 | | | s / (/ | sequ | ience# | 51 | 91 | 21 | | 4 |
| | Auverse Event i | vehorming i rogi | | | | _ | 1/9 | | | | | | | _ |
| | A. PATIENT IN 1. Patient Identifier | | vent or | 3. Sex | 4. Weight | 2. l #1 | Dose or Amount | | Four ti | | | | | l |
| | b) (6) | Date of Birth: | vent or | _ | 20 _{lb} | | 2-3 tablets 4 times daily | | daily | ll'ak | en by | / mouth | | |
| | | 7 Months (b) (6) | | Female | | #2 | | \equiv | | Ti- | | | | |
| | In confidence | | | ✓ Male | kgkg | | | | | | | | | _ |
| | | EVENT, PRODU | CT PR | OBLEM OR E | RROR | | tes of Use (If unknown best estimate) | n, give | duration) f | | | Abated Af | | |
| | Check all that apply: | t Product Pro | hlem (e | g., defects/malfui | actions) | | 0/13/2014 - 12/ | 01/2 | 014 | | | es No | Doesn | t |
| | Product Use E | _ | , , | • | r of Same Medicine | #2 | | | | | | es No | Apply Doesn | - 't |
| | 2. Outcomes Attribu | uted to Adverse Eve | nt | | | | agnosis or Reason for | r Use | (Indication) |) | | Reappeare | Apply | _ |
| | (Check all that app Death: | PIY) | ☐ Disal | bility or Permane | nt Damace | "' | Teething Baby | | | | | oduction? | | |
| | | mm/dd/yyyy) | _ | • | - | #2 | | | | #1 | □ Y | es No | ✓ Doesn Apply | t |
| | Life-threatening | g - initial or prolonged | | genital Anomaly/E | | 6. Lo | t# | 7. E | xpiration D | Date #2 | Y | es No | Doesn | t |
| | | vention to Prevent Per | | | | #1 | | #1 | | _ | NDC # | f or Unique | Apply | - |
| | 3. Date of Event (mi | m/dd/vvvv) | 4. Dat | e of this Report | (mm/dd/vyvy) | #2 | | #2 | | | | - | | |
| | 10/13/2014 | | 12/ | 08/2014 | | | SUSPECT MEDIC | CAL | DEVICE | | | | | |
| | · · | Problem or Product | | or | | 1. Bra | and Name | | | | | | | |
| | See page 2 1 | for complete te | ext. | | | | | | | | | | | |
| u | _ | | | | | 2. Co | mmon Device Name | | | | | | | _ |
| Ň | | | | | | | | | | | | | | |
| CK | | | | | | 3, Ma | nufacturer Name, Cit | y and | State | | C | TU | | - |
| LA | | | | | | | | | | | | - () | | |
| TYPE OR USE BLACK INK | | | | | | 4. Mo | vdel # | 117 | ot# | DE | C- | 9-2014 | r of Device | - |
| US | | | | | | 4. 1010 | , | [- | | | | _ | Professiona | |
| OR | | | | | | | 4-1# | 1 | | 2-1- ((-1-1 | 44 | _ | | |
| PE | | | | | | La | talog# | = | xpiration t | Date (mm/dd | ומממי | Lay Us | enPatient | |
| | 6 Relevant Tests/L | aboratory Data, Incl | uding Da | ites | | | | | | | | Other: | | |
| SE | | for complete te | - | | | 36 | rial # | ١ | ther# | | | | | |
| PLEASE | | | | | | C 161 | malastad Chia Data | (70,00/4 | /d6 1 | 7 If Evalua | 100 | - Data (m | | _ |
| P | | | | | | 0. 11 1 | mplanted, Give Date (| (mmva | (a/yyyy) | 7. If Explan | tea, G | ive Date (m | im/aa/yyyy) | |
| | | | | | | | this a Single-use Devi | ice tha | at was Rep | processed a | nd Re | used on a l | Patient? | _ |
| | | | | | | | Yes No Yes to Item No. 8, Enter | Name | and Addre | ss of Reproc | essor | | | _ |
| | | | | | | | to to nom no. e, zmo | ,,,,,,,, | and Addition | or noprov | , | | | |
| | allergies, race, pre | listory, Including Pre egnancy, smoking and | alcohol | Medical Condit use, liver/kidney | ions (e.g., problems, etc.) | | | | | | | | | |
| | See page 4 i | for complete t | ext. | | | F. C | THER (CONCO | ATIN | NT) ME | DICAL PR | ODU | CTS | | |
| | | | | | | Prod | uct names and therap | y date | es (exclude | treatment o | f even | t) | | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| | | | | | | G. F | REPORTER (See | confi | identialit | y section | on ba | ack) | | |
| | C. PRODUCT A | VAILABILITY | | | | 1. Na (b) (| me and Address | | | | | | ı | _ |
| | | or Evaluation? (Do n | ot send p | product to FDA) | | | | | | | | | | 22(|
| | ☑ Yes ☐ No | Returned to Ma | nufacture | | um/ddha | | | | | | | | | JO |
| | D. SUSPECT P | RODUCT(S) | | (m | m/dd/yyyy) | | | | | | | | UEC |)SS <u>0</u> 9 2014 |
| | Name, Strength, I | Manufacturer (from p | | bel) | | Phon (b) (6) | | | | E-mail | | | | 017 |
| | | s Teething tab | | ., | | (3) (3) | | | | (b) (6) | | | | |
| | Manufacturer: A3 | tablets 4 time: 39914 | s dall | У | | 2. He | alth Professional? 3. | . Occı | upation | | 4. | Also Repo | rted to: | _ |
| | #2 Name: | | | | | | Yes No | | | | | Manufa | | |
| | Strength: | | | | | | ou do NOT want your i | | | | | ☐ User F | acility utor/Importer | |
| | Manufacturer: | | | | |] [6] | uio manulacturer, piaci | ₩ 411 "/ | A HI WIIS D | ох. <u> </u> | | | nonimportei | |

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

B.5. Describe Event or Problem (continued)

My son began teething at about 7 months and I began to use the product Hylands teething tablets. Soon after me using this product with my son, he had 4 episodes where he would stock breathing and causing im to be very lethargic. He was tehn hospitalized and after 5 days of intensive testing the Dr diagnoised him with seizures because they said that his episodes has characteristics of seizures. He was then given a seizure medication. I truly believe that he began getting these episodes due to the Hylands teething tablets, because before he used this product he was a perfect healthy baby that was never sick.

Individual Case Safety Report

10643083-01-00-02

DSS DEC 0 9 2014 B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

CaseID: 10643083 /

These lab were done between (b)(6) He had an EEG, MRI, EKG, blood work, Gastro testing. None of these labs showed anything that could have caused these events.

Individual Case Safety Report

10643083-01-00-03

DSS DEC 0 9 2014

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions: He was diagnoised with seizures after using this product

Allergies:

Important Information:

RX Meds: He is now taking Keppra medication to prevent any other episodes

Individual Case Safety Report



10643083-01-00-04



by user-facilities, butors and manufa ATORY reporting 10648706-01-00-01

| CaseID: 10648706 | |
|--|----|
| rm Approved: OMB No. 0910-0291, Expires: 6/30/20 | 15 |

Mfr Report # 54973

| FORM | FDA | 3500A | (2/13) |
|------|-----|-------|--------|
|------|-----|-------|--------|

| FORM FDA 3500A (2/13) | | | Page 1 |
|--|------------------------------------|-------------------------------------|---------------|
| A. PATIENT INFORMATION | | | |
| 1. Patient Identifier 2. Age at Time (b) (6) | | 3. Sex | 4. Weight |
| of Event: 11 | Months | Female | lbs |
| Date In confidence of Birth: | | ✓ Male | or |
| In confidence of Birth: B. ADVERSE EVENT OR PRODUC | T PROBLEM | | kgs |
| | | | |
| Adverse Event and/or Pro Outcomes Attributed to Adverse Event | duct Problem (e. | g., delects/manu | inctions) |
| (Check all that apply) | | | |
| Death: (mm/dd/yyyy) | _ Disability or | Permanent Dan | nage |
| Life-threatening | | Anomaly/Birth D | |
| Hospitalization - initial or prolonged | ш | us (Important Me | Ί |
| Required Intervention to Prevent Perma | | | - |
| 3. Date of Event (mm/dd/yyyy) 11/17/2014 | 4. Date of This F | Report (<i>mm/dd/</i> 1/25/2014 | <i>(YYYY)</i> |
| 5. Describe Event or Problem | - | 1/20/2017 | |
| | | | |
| FATHER REPORTED THAT THE CHI | | | |
| OF A DRY CONSTANT COUGH AND I TEETHING TABLETS BECAUSE HE | | | |
| COUGH BECAUSE CHILD SOMETIME | | | |
| | THER GAVE 3 | | |
| ABOUT 1.5 HOURS LATER THE CHI | | | |
| AND LABORED, HE WAS LETHARGIC 102 DEGREES. THE WIFE GAVE | | | |
| A COUPLE OF DAYS LATER THE FI | | | |
| AFTER GIVING THE HYLAND'S BAN | BY TEETHING | TABLETS, | AFTER |
| THE INITIAL EPISODE, THE CHIL | | | |
| AND WAS DIAGNOSED WITH RSV (F VIRUS), A DOUBLE EAR INFECTION | | | i |
| PRESCRIBED AN UNKNOWN ANTIBIO | | | |
| STEROIDS. SYMPTOMS ARE IN TH | * | | |
| | | | Ī |
| | | | l |
| | | |] |
| | | | 1 |
| | | | - 1 |
| · | (| Continue on | page 3) |
| 6. Relevant Tests/Laboratory Data, Including | Dates | | |
| 11/21/14: CHILD TAKEN TO THE | | | |
| WITH RSV (RESPIRATORY SYNCYTI INFECTION AND THRUSH. | AL VIRUS), | A DOUBLE | EAR |
| THE BOTTON AND THROUGH. | | | - 1 |
| | | | - 1 |
| | | | - 1 |
| | • | | |
| Re | ceive | 90 | j |
| | Mari At also at a balada da also a | Continue on p | page 3) |
| Other Relevant History, Including Preexistic race, pregnancy, smoking and alcohol use, including the pregnancy of the present | | | |
| DRY CONSTANT COUGH. | paric/renangyenin | etton, etc.) | |
| | | | |
| | CDR | | |
| | CDV | | |
| | | | |
| | | | |
| | | | 1 |
| | | | - 1 |
| | | Continue on p | |
| Submission of a report does not const | itute an admis | ssion that m | edical |
| ersonnel, user facility, importer, distr aused or contributed to the event. | ibutor, manut | acturer or pi | roduct |

| ORY reporting | UF/Importer R | eport # | |
|---|----------------------------------|---------------------|-----------------------------|
| of <u>5</u> | | | EDA Hea On |
| C. SUSPECT PROD | UCT(S) | | FDA Use On |
| 1. Name (Give labeled stre | ngth & mfr/labeler) | | |
| #1 HYLAND'S BABY | TEETHING TA | ABLETS | |
| #2 | | | |
| 2. Dose, Frequency & Ro | ute Used | | (If unknown, give duration) |
| #1 3 TABS CRUSHE | BY MOUTH | from/to (or best | estimate) |
| #2 | | #2 | |
| 4. Diagnosis for Use (India | cation) | | t Abated After Use |
| #1 TEMP RELIEF TH | • | Stop | ped or Dose Reduced? |
| #2 | | | Yes ☐ No ☑ Doesn' Apply |
| 6. Lot # | 7. Exp. Date | #2 | Yes No Doesn' |
| #1 | #1 | 8. Even | t Reappeared After |
| | | Reint | roduction? |
| #2 9. NDC# or Unique ID | #2 | #1 [] | Yes No Doesn' Apply |
| 54973-3127-1 | | #2 🔲 | Yes No Doesn' |
| 10. Concomitant Medical F | roducts and The | rapy Dates (Exclude | |
| IBUPROFEN | | | |
| | | | |
| | | | |
| | | (0 | Continue on page 3) |
| D. SUSPECT MEDIC | AL DEVICE | | |
| 1. Brand Name | | | |
| 2. Common Device Name | | 2b. F | rocode |
| 3. Manufacturer Name, Cit | v and State | | |
| ,, | , | | |
| 4. Model# | 11-48 | | T |
| 4. model# | Lot # 5. Operator of Device | | |
| Catalog # | Expiration Date (mm/dd/yyyy) | | |
| | Lay User/Patient | | |
| Serial # | Unique identifier (UDI) # Other: | | |
| 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) | | | |
| | | | |
| 8. Is this a Single-use Devi | ce that was Repro | cessed and Reuse | d on a Patient? |
| 9. If Yes to Item No. 8, Ente | r Name and Addre | ess of Reprocessor | |
| | | | |
| | | | |
| to Danie Augustiatis to E | | | Dea |
| 10. Device Available for Ev | _ | , | 033 |
| | Returned to Ma | | (mr) 7777 1 20 |
| 11. Concomitant Medical Pr | oducts and Thera | py Dates (Exclude | treatment of event) 40 |
| | | | |
| | | (C | ontinue on page 3) |
| E. INITIAL REPORTE | R | , - | , , |
| 1. Name and Address b) (6) | | | |
| <i>5</i> / (5/ | | | |
| b) (6) USA | | | |
| | | | |
| Phone # | T Email A | Address | |
| (b) (6) | (b) (6) | Address | |
| 2. Health Professional? 3. | Occupation | [4. In | itial Reporter Also Sent |
| ☐ Yes 📝 No N | Α | חבל ב | eport to FDA |

Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up#

Importer

3. User Facility or Importer Name/Address

2. UF/Importer Report Number

5. Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

(Specify)

2. Phone Number 310-768-0700

Foreign

Literature ✓ Consumer

User Facility Company

Distributor

Other:

Study

3. Report Source (Check all that apply)

Health Professional

Representative

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

☐ No

Yes

☐ No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM 4. Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

7-day Periodic

√ 15-day Follow-up # 9. Manufacturer Report Number

54973 AE # 1582

☐ 10-day 🗸 Initial

7. Type of Report

5-day

11/17/2014

30-day

HYLAND'S, INC.

Email Address

Address

1. Contact Office (and Manufacturing Site for Devices)

ıge 2

| of ⁵ | |
|---|--|
| H. DEVICE MANUFACTURERS ONLY | |
| 1. Type of Reportable Event Death Serious Injury Malfunction | 2. If Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation |
| Device Evaluated by Manufacturer? Not Returned to Manufacturer Yes Evaluation Summary Attached | 4. Device Manufacture Date (mm/yyyy) |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| Recall Notification Repair Inspection Replace Patient Monitoring Relabeling Modification/ Adjustment Other: | 8. Usage of Device Initial Use of Device Reuse Unknown 9. If action reported to FDA under 21 USC 360I(f), list correction/ removal reporting number: |
| | |
| | |
| | DSS DEC 1 1 2014 |

CaseID: 10648706

FDA USE ONLY

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

510(k)#

Product

Pre-1938

Combination

OTC Product Y Yes

8. Adverse Event Term(s)

LETHARGY, FEVER

Yes

Yes

RAPID & LABORED BREATHING,

IND#

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

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COMPLAINT RECORD



| 106487 | 06-01-00-03 | c | COMPLAINT #: | 2592 | | |
|---|---|--|--|--|--|-------------------------------------|
| | - AMIL | | COMPLAINT: | | | _ |
| PRODUCT: SIZE: | HYLAND'S BABY TEETHING | TABLETS | ITEM CODE: | | | _ |
| SIZE: REPORTER: | 135 TABLETS (b) (6) | | LOT NO.: | THREW AWAY | Y BOTTLE | _ |
| ADDRESS: | | | | | | |
| ADDRESS: | | | -,- | <u>-</u> : | | _ |
| CITY: | | STATE | . (b) (6) | | | _ |
| COUNTRY: | USA | ZIP COD | | | | _ |
| PHONE #: | (b) (6) | | | | | _ |
| E-MAIL: | | FOLLOWING E-MAIL ON 11/17/14 - I JUST | | | | |
| AND HE SHOT UP TO INGESTED. WE GOT AND I FEEL THAT YOU THAT THE CHILD HAD TABLETS BECAUSE HOUCES. THE FATHEI LETHARGIC AND HIS LATER THE FEVER C. TAKEN TO THE DOCT TRESCRIBED AN UNK | MM THEM. AN HOUR AND A HALF AFTI A 102°F IN A MATTER OF 20 MINUTES HIS FEVER DOWN WITH IBUPROFEN AU NEED TO KNOW ABOUT HIS REACTI OF THE TO THE TO THE THOUGHT IT WAS A TEETHING COUR GAVE 3 TABLETS AND THEN ABOUT FEVER WENT UP TO 102 DEGREES. 1 AME BACK. 4 DAYS AFTER GIVING THOR AND WAS DIAGNOSED WITH RSV | YOUR TEETHING TABLETS. I AM A FAN OF ER I GAVE HIM 3 TABLETS, HIS BREATHIN IS. MY WIFE STARTED FREAKING OUT AND AND HE IMMEDIATELY WENT TO SLEEP. I ION. ON 11/24/14 I WAS ABLE TO SPEAK W OUGH - COUGHING EVERY 30 SECONDS. JGH BECAUSE CHILD SOMETIMES COUG! 1.5 HOURS LATER THE CHILD'S BREATHI ITHE WIFE GAVE IBUPROFEN AND THIS HE IE HYLAND'S BABY TEETHING TABLETS, A (RESPIRATORY SYNCYTIAL VIRUS), A DO RAL STEROIDS. THE CHILD IS ON THE "U STA REFUND OR REPLACEMENT. | G BECAME LA O THIS WAS TH NEEDLESS TO VITH THE CUS FATHER PUF HS WHEN HE I NG WAS FAST ELPED THE SIVILLIBIE FAR INE | BORED, HE BEC HE ONLY THING ' O SAY SHE THREE STOMER BY PHO RCHASED THE B. IS TEETHING DU TER AND LABOR MPTOMS. A CO THE SAID LABOR, T | AME LETHARGIC, FHAT HE HAD W THEM AWAY NE. HE REPORTED ABY TEETHING E TO EXCESS ED, HE WAS UPLE OF DAYS HE CHILD WAS RIISH HE WAS | _ |
| | | | | | | _ |
| | FOR ADDITIONAL SPACE | PLEASE USE REVERSE OR ATTACH A SE | PARATE SHE | ET | | |
| PRODUCT RECEIVED INSPECTION: | FOR Y (CIRCLE ONE) | PRODUCT BEING RET | | | Y (CIRCLE ONE) | |
| | | DATE REQUESTED | PRODUCT BE | RETURNED: — | | _ |
| | | | UPS CALL | TAG ISSUED: | Y (N) (CIRCLE ONE) | |
| SECTION II: | INVESTIGATION | אָם יים | ATE PRODUCT | RECEIVED: | | _ |
| | | | | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INSPEC | CTION REPORT. | | | | _ |
| | | | | | | - |
| PPMARE WAS ARREST | 4-110 -110 | 1/2 Table 1/2 Ta | | | | |
| ADVERSE EVENT FOR | WARDED TO PHARMACIST / NURSE F | OR EVALUATION ON: | 11/17/14 | | | _ |
| ADVERSE EVENT FOR | WARDED TO PHARMACIST / NURSE F | OR EVALUATION BY: | EDYTA FR | ACKIEWICZ | | _ |
| SECTION III: | CORRECTIVE ACTION: | | | | | |
| CORRECTIVE ACTION(| S) COMPLETED BY: | | DATE: _ | | - Additional and the second se | |
| SECTION IV: | ADVERSE EVENT REPORTS | | AE#: _ | 1582 | | DSs |
| ADVERSE EVENT SERIO | | | | | DEC | DS <u>S</u> : 1 _{1 201} |
| SECTION V: | ORTED ON: | BY: ED | YTA FRACKIE | WICZ | | -5,- |
| REVIEWED BY MANAGE | EMENT BY: | that i ottler | DATE: | 12-01-1 | 4 | |
| BY: | Eruc Bo | UW | _ | 12-01-1 | , | |

cc: QA / QC Packaging Production Shipping / Receiving

DEC 1 0 F2014 D1





Serious Adverse Event SAE-0059-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty-one (131) Adverse Events (AE) which also included thirty-six (36) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

11/25/14

Date

DSS DEC 1 1 2014 DEC 1 0 2014

CaseID: 10648706



RSE EVENT DATA FORM



| CORRECTIVE ACT | ON(S) COMPLETED BY: | DATE: | DEC : |
|--|--|--|--|
| SECTION III: | CORRECTIVE ACTION: | | |
| SI PARE BELLADORN TO THE TOPACHO BENERAL SECURIOR CALLED BENERAL SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIOR CALLED BENERAL SECURIOR SECURIO | BELIEVE AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET AND STREET | A series of the | Teething Tablets Bit All Towns Bit |
| Intelligent Findings: Interpretation for interpretation of simple trailmenter and simple trailmenter and simple trailmenter and simple trailmenter and simple reduced and orderentation of game affected from the interpretation (Control of the Interpretation (Control of the Interpretation (Control of the Interpretation (Control of the Interpretation (Control of the Interpretation of the Interpretation (Control of the Interpretation (| the land. Bally B | Control of the party of the par | reething Tablets |
| AFF | X PACKAGING LABEL HERE | AFFIX COPY OF OUTER CAR (INCLUDE DRUG FACTS AND PRII PANELS) | |
| SECTION II: | PACKAGING INFORMATION: | | |
| E-MAIL: | | | |
| COUNTRY: PHONE #: | USA (b) (6) | ZIP CODE: | |
| | | STATE: | |



e by user-facilities, ributors and manufa DATORY reporting

| 4 | rm Approved: O | MB No. 09 | 10648708 10-0291, Expires: 6/30/201: OMB statement on reverse |
|---------------|----------------|-----------|---|
| Mfr Report # | 54973 | | |
| UF/Importer F | Report # | | |

| nanufacturers porting | UF/Importer Report # |
|--------------------------|----------------------|
| | |

| | FORM FDA 350 | 0A (2/13) | | | Pag | ge 1 |
|---------------|--|-------------------------------------|------------------|--------------------|---------------|----------|
| | A. PATIENT INF | ORMATION | | | | |
| | Patient Identifier (b) (6) | 2. Age at Time | | 3. Sex | 4. Weigh | ıt |
| | (b) (b) | of Event: 9 | Months | √ Female | | lbs |
| | | Date | | Male | or | |
| | In confidence | of Birth: | | | | kgs |
| | B. ADVERSE EV | ENT OR PRODUC | CT PROBLE | Vì | | |
| | 1. Adverse Event | | duct Problem (e. | .g., defects/malfu | ınctions) | ╝ |
| | 2. Outcomes Attribut (Check all that apply | | | | | |
| | Death: | | Disability or | r Permanent Dar | nage | - 1 |
| | Life-threatening | (mm/dd/yyyy) a | Congenital | Anomaly/Birth D | efect | |
| | | - initial or prolonged | | us (Important M | | nts) |
| | 1 - | vention to Prevent Perma | | | | |
| | 3. Date of Event (mm | /dd/yyyy) | 4. Date of This | Report (mm/dd/ | 'yyyy) | \dashv |
| | 11/1 | 5/2014 | | 11/19/2014 | | |
| | 5. Describe Event or I | | | | | ヿ |
| | | 9 MONTH OLD D | | | | |
| | 1. | TABLETS" FOR ' | | | | |
| | | E REPORTER STATE PURCHASED A NET | | | | - 1 |
| | | BEGAN GIVING HE | | | | - 1 |
| ĸ | I | HE NEW BOTTLE | | | | - 1 |
| Ž | | 15/14 AND ON 1: IG, TURN RED, AI | | | | . |
| X | WOULD BECOME L | | REPORTER D | | | Ί. |
| BLACK | | G IN AND OUT, | | | | |
| B | | PER THE REPORTE | | | | |
| USE | ABOUT 5 - 7 SE | CONDS. THE REI EETHING TABLET' | PORTER STAT | | | _ |
| | | SOMETIMES SHE | | | | 12 |
| $\frac{8}{2}$ | | IF THE CHILD W | | | | İ |
| TYPE | | NG THIS LAST BO | | | | |
| ΙŽ | | REPORTER GAVE F IN THE MORNING | | | | - |
| | | TABLETS ON 11/1 | | | | |
| Ä | TABLET ON 11/1 | 7/14. THE SHAR | CING EPISOD | ES OCCURED | ABOUT | |
| PLEASE | | R THE DOSES OF | | | ERE | -1 |
| - | GIVEN ON 11/15 | /14 AND 11/17/1 | 4, WITH ON | E EPISODE | | |
| | | | | (Continue on | page 3) | - |
| | 6. Relevant Tests/Labo | oratory Data, Including | Dates | | | 7 |
| | A PHYSICAL EXAM | | | | | - |
| | THEY DID NOT W | DOCTOR COULD NO | T GIVE A D | IAGNOSIS B | ECAUSE | ا ۸ |
| | TESTS WERE ORDE | | ZONO: FER | IND REPUR | - miss' - 140 | <u> </u> |
| | | | | | | |
| | | | | | | |
| ı | | | | | | |
| | | | | | | 1 |
| | The state of the s | | | Continue on | nage 3) | - |
| - 1 | 7. Other Relevant Historace, pregnancy, smo | xy, Including Preexisti | | | | 7 |
| | race, pregnancy, smo PER THE REPORTE | | | | | |
| | | THE REPORTER, | | | OI. | |
| ļ | EXPERIENCED A S | IMILAR EVENT/R | EACTION BEF | ORE. THE | CHILD | |
| | WAS PRESCRIBED | | | | | |
| | DISEASE, AND SH 2 MONTHS. THE | E HAS TAKEN A I CHILD HAS TAKEN | | | | |
| - 1 | IN THE PAST WIT | | A LIPRNOP W | MD WILIRIC | TICS | |
| | | | | | | |
| - 1 | | | | | | 1 |
| - [| | | | Continue on p | age 3) | |
| Š | ubmission of a rep | ort does not cons | | | | |

| s and manufactur ORY reporting | | JF/Importe | er Repo | ort# | | | |
|---------------------------------------|-------------|------------|----------|----------|--------------------|----------------------|-------------------------------|
| of 6 | | | | | | | FDA Use On |
| C. SUSPECT P | | | | | | | |
| 1. Name (Give labele #1 HYLAND'S E | • | | • | TETC | | | |
| | WDI IP | FIRING | IAL | DE13 | | | |
| #2 2. Dose, Frequency | º Pouto II | | 12 | Thorac | Date | #akaowa | give duration |
| #1 TAB BY M | | | | | o (or best | | give duración, |
| #2 | : | | _ | #2 | | . 1 | |
| 4. Diagnosis for Use | (Indication | 1) | 1 | | | Abated Aft | |
| #1 TEMP RELIE | F TEETH | | | | #14 [□] | | Doesn |
| #2 | | U | EC. | 102 | | | Apply Doesn |
| 6. Lot # | 7. E | Exp. Date | 2009 | eria ge | ×. | Yes No | LI Apply |
| #1A09314 | #1 | | Cont. | | 8. Event Reintr | Reappeare roduction? | d After |
| #2 | #2 | | | | _ | Yes No | Doesn' |
| 9. NDC# or Unique II | | | | | #2 F73 | [T] No | Dosen |
| 54973-3127-1 10. Concomitant Med | | | | l | | Yes No | LI Apply |
| D. SUSPECT MI | EDICAL | DEVICE | E | | (C | Continue o | n page 3) |
| 1. Brand Name | | | | | | | |
| 2. Common Device N | lame | | | | 2b. P | rocode | |
| 3. Manufacturer Nam | e, City and | d State | | | | | |
| 4. Model # | | Lot# | | | | 5. Operato | r of Device |
| Catalog # | | Expiration | on Dat | e (mm/d | d/yyyy) | | n Professional ser/Patient |
| Serial# | | Unique I | dentif | er (UDI) | # | Other: | |
| If Implanted, Give I | Date (mm/o | ld/yyyy) | 7. | If Expla | nted, Giv | e Date (mm/ | (dd/yyyy) |
| 3. Is this a Single-use | | at was Re | proce | ssed an | d Reusec | on a Patie | nt? |
| Yes No | | nd A | -1-d-nee | of Ban | | | |
|). If Yes to Item No. 8 | , Enter Na | me anu A | Odresa | of Kepi | rocessor | | |
| | | | | | | | |
| 0. Device Available f | ~ Evoluat | 12m2 (Do) | not non | dia EDA | | | |
| Ves No | percent | etumed to | | | | | |
| | | | - | | | (mm/dd/y) | 785 |
| 1. Concomitant Medi | cal Produc | cts and Ti | nerapy | Dates | Exclude (| reatment of | eveni) |
| | | | | | | DEC | 1 1 201 |
| | | | | | (Co | o ntinue on | |
| E. INITIAL REPO | RTER | | | | | | |
| Name and Address) (6) | | | | | | | |
| USA | | | | | DE | C 1 D | 2014 |
| hone #) (6) | | Em | nail Ad | dress | | | |
| Health Professional | 7 3. Occi | unation | | | 14. In | itial Reporte | er Also Sent |
| Yes No | NA | -pucoli | | | | eport to FD/ | |

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

2 LIFAmporter Report Number

1. Check One

ige 2 of 6

No (Attach page to explain why not) or provide code:

Patient Code Device Code Method Results

Conclusions 7. If Remedial Action Initiated, Check Type

10. Additional Manufacturer Narrative

Recall

Repair

Replace

Relabeling Other:

6. Event Problem and Evaluation Codes (Refer to coding manual)

Notification

Inspection

Modification/

Patient Monitoring

| • • • • • • • • • • • • • • • • • • • | CaseID: 10648708 | | | |
|---------------------------------------|-----------------------------|--|--|--|
| , | FDA USE ONLY | | | |
| f <u>6</u> | | | | |
| H. DEVICE MANUFACTURERS ONLY | | | | |
| Type of Reportable Event | 2. If Follow-up, What Type? | | | |
| ☐ Death | Correction | | | |
| Serious Injury | Additional Information | | | |
| Malfunction | Response to FDA Request | | | |
| | Device Evaluation | | | |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date | | | |
| Not Returned to Manufacturer | (mm/yyyy) | | | |
| Yes Evaluation Summary Attached | 1 1 | | | |

5. Labeled for Single Use?

☐ No

Yes

8. Usage of Device

Reuse

and / or

Unknown

Initial Use of Device

If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

11. Corrected Data

| User Facility | lm | porter | | | | |
|--|--|---|----------|-------------------|--|---|
| 3. User Facility or Imp | orter Nam | e/Address | | | | |
| | | | | | | |
| | | | | | | |
|] | | | | | | |
| | | | | | | |
| 4. Contact Person | | | 5. | Phone N | umber | |
| | | | | | | |
| 6. Date User Facility o | r | 7. Type of R | eport | | 8. Date | of This Report |
| Importer Became Aware of Event (mm | v/dd/yyyy) | ☐ Initial | | | (mm | (dd/yyyy) |
| i | | | | | | |
| 9. Approximate | 10 Event | Problem Cod | | | | ~f) |
| Age of Device | i _ | - Toblem Cou | es (Neic | or to cour | ny manua | · · · · · · · · · · · · · · · · · · · |
| | Patient Code | | 1-1 | | - | i |
| | Device [| | <u> </u> | | | |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEC 1 B 2014

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

NTINUATION PAGE)
se by user-facilities,
ributors, and manufacturers
NDATORY reporting
Page 3 of 6

CaseID: 10648708

FORM FDA 3500A (2/13) (continued)

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|-------------------|---|--|-------------|-------------------------|--------------|---|---------------------------------------|----------------------------|------------------|
| | B.5. Describe Event or Problem (continuous CCURING ON EACH DAY. 1) AFTERNOON, 11/18/14. | | HAS AN | APPOINTMENT | TO SEE | THE DOCTOR | REGARDING 1 | THESE SYMPTOMS | THIS |
| 40 | | | | | | | | | |
| Back to Item B.5 | | | | | | | | | |
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| | | | | | | | | | |
| | B.6. Relevant Tests/Laboratory Data, In | ncluding Dates (contin | nued) | | | | 9000 4 V | | |
| tem B.6 | | | | | | | | | |
| Back to Item B.6 | | | | | | | | | |
| | B.7. Other Relevant History, Including P | Preexisting Medical C | onditions (| (e.g., allergies, race, | pregnancy, | smoking and alcoho | ol use, hepatic/rena | l dysfunction, etc.) (cont | inued) |
| 1B.7 | | | | | | | | | |
| Back to Item B.7 | | | | | | | | | |
| .10 Ba | | | | | | | | | |
| Item C.1 | Concomitant Medical Products and The | rapy Dates (Exclude t | reatment of | event) (For continua | tion of C.10 | and/or D.11; please | e distinguish) | | |
| Back to Item C. | | and the state of t | | | | | | | (64 ₁ |
| Back to Item D.11 | | | | | | GRADA AND AND AND AND AND AND AND AND AND | | DEC 11 | |
| Back | Other Remarks | | | | | | · · · · · · · · · · · · · · · · · · · | | |
| | | | | | | | | DEC 1 0 2014 | • |

COMPLAINT RECORD



| PRODUCT: HY | | COMPLAINT #: | 2590 | |
|--|--|---|--|--|
| PRODUCT: HYL | | DATE OF COMPLAINT: | 11/18/14 | -114 |
| | LAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 | |
| SIZE: <u>135</u> | TABLETS | LOT NO.: | A09314 | |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | | | | |
| CITY: | | STATE: (b) (6) | VARI | |
| COUNTRY: USA | | ZIP CODE: | | |
| (b) (6) PHONE #: | | | | |
| E-MAIL: | | | | |
| PER THE REPORTER, ON 11/15/14 REPORTER, ABOUT 5 MINUTES FC SHAKING," AND THEN WOULD BEC RESPONSIVE." PER THE REPORTITEETHING TABLET! ONCE PER DAWAS ESPECIALLY "CRANKY". SINCTABLETS ON 11/15/14, IN THE MOR 11/17/14. THE SHAKING EPISODES 11/17/14, WITH ONE EPISODE OCC SYMPTOMS THIS AFTERNOON, 11/3 SUCH AS A RUNNY NOSE OR AN EFAMILY HISTORY OF SEIZURES, AITHE CHILD TAKES ZANTAC (RANIT MEDICATION DAILY SINCE THE AG ANTIBIOTICS IN THE PAST WITH NOTHE "TEETHING TABLETS". SHE SEVIDENCE IN COURT." | MONTHS WITH NO PROBLEMS. THE REPO 3 TABLETS' AND BEGAN GIVING HER DAUGE 4 AND ON 11/17/14, THE CHILD HAD EPISODE: DILLOWING A DOSE OF THE TEETHING TABL COME LETHARGIC. THE REPORTER DESCRI ER, EACH EPISODE LASTED FOR ABOUT 5 — AY WHEN SYMPTOMS WERE PRESENT; SOM CE PURCHASING THIS LAST BOTTLE OF 'BAI RNING AND ONE IN THE EVENING BEFORE B S OCCURRED ABOUT 5 MINUTES AFTER THE CURING ON EACH DAY. THE REPORTER HAS //18/14. PER THE REPORTER, THE CHILD HA: EARACHE, AND HAS NOT HAD A FEVER TO TI ND THE CHILD HAS NEVER HAD AN EPISODE IDIDINE) TWICE PER DAY FOR ACID REFLUX; TO ISSUES. THE REPORTER STATED THAT S TATED THAT SHE DOES NOT WISH TO RETU Y (CIRCLE ONE) | ITER DOSES OF THE TABLETS FROM SOF WHAT THE REPORTER DESCRIBETS," THE CHILD WOULD "STOP BRE BED THE CHILD AS "GOING IN AND C 7 SECONDS. THE REPORTER STATIETIMES SHE GAVE 2 OR 3 DOSES O BY TEETHING TABLETS", THE REPORTER STATIETIMES THE STATIETIME TABLETS ON 11/16/14 IN THE ME DOSES OF "TEETHING TABLETS" WE AN APPOINTMENT TO SEE THE DOCES NOT BEEN SICK, HAS NOT HAD AN HE REPORTER'S KNOWLEDGE. PER E OR REACTION LIKE THIS BEFORE. THIS WAS A PRESCRIPTION, AND THE CHILD HAS NO KNOWN ALLERGIES HE UNDERSTANDS THAT THESE EPIRN THE BOTTLE TO THE COMPANY" | I THE NEW BOTTLE BED AS "THE SHAKE ATHING, TURN RED JUT, COHERANT BU' ED THAT THE CHILD F 1 TABLET PER DA' RTER GAVE HER DA' RTER GAVE HER DA' RORNING, AND 1 TAE ERE GIVEN ON 11/19 CTOR REGARDING T Y CONCOMITANT SY THE REPORTER, TI THE REPORTER, TI THE REPORTER, ST E CHILD HAS BEEN ' AND HAS TAKEN TY SODES MAY BE UNE TIN CASE (SHE) NEE THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SEPORTER ST CONTROL OF THE SHAKE CONTROL OF THE | ON 11/15/14. SY. PER THE , AND START F NOT WAS GIVEN 1 YIF THE CHILD UGHTER 2 SLET ON 6/14 AND HESE //MPTOMS HERE IS NO ATED THAT TAKING THIS LENOL AND RELATED TO DS IT FOR |
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| | | UPS CALL T | AG ISSUED: (C | IRCLE ONE) |
| | | DATE PRODUCT | RECEIVED: | |
| SECTION II: INVESTIGA | ATION | | | |
| NVESTIGATION: PLEASE | SEE ATTACHED INVESTIGATION REPORT. | | | |
| ADVERSE EVENT FORWARDED TO | PHARMACIST / NURSE FOR EVALUATION OF | N. 4440/44 | | |
| | | (b) (6) | | |
| | PHARMACIST / NURSE FOR EVALUATION BY | r: | | |
| ECTION III: CORREC | CTIVE ACTION: | | | |
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| | A CONTRACTOR OF THE PART OF TH | | affects and a second se | |
| ORRECTIVE ACTION(S) COMPLETE | ED BY: | DATE: | districts as a second second second second | DSS |
| | ED BY: | DATE: | 1580 | DSS DEC 1 1 20 |
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| CORRECTIVE ACTION(S) COMPLETE SECTION IV: ADVERSE E DVERSE EVENT SERIOUS: DVERSE EVENT REPORTED ON: ECTION V: EVIEWED BY MANAGEMENT BY: | EVENT REPORTS Y / N | AE #: | 1580 2-01-14 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0057-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A09314, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A09314 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A09314. The Baby Teething bulk lot # 122448 was tested for total Atropine and Scopolamine and the results were with in specification of $s_{(4)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured two other complaints (CC-0382-2014 & CC-0421-2014) has been received for Hyland's Baby Teething Tablets lot # A09314. The complaints were reviewed and the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A09314.

Manufacture and processing occurred within established procedures to ensure product quality.

11 | 25| 14 ared by Date

> DSS DEC 1 1 2014

CaseID: 10648708

DEC 1 0 2014



RSE EVENT DATA FORM



| AE #:1 | 1580 | | COMPLAIN | T#: 2590 | *** |
|--|---|--|--|--|--------------|
| SECTION I: | PATIENT INF | ORMATION (IF DIFFEREN | T FROM REPORTER ON FO | RM VD1) | |
| NAME: | (b) (6) - | | | | |
| ADDRESS: | *************************************** | | | | 172 |
| CITY: | | | STATE | (b) (6) | |
| COUNTRY: | USA | | ZIP COD | | |
| PHONE #: | (b) (6) | | | | |
| E-MAIL: | | | | | |
| SECTION II: | PACKAGING | NFORMATION: | | | |
| | AFFIX PACKAGING LA | BEL HERE | (INCLUDE DRUG FACT | OUTER CARTON HERE IS AND PRINCIPAL DISPLA ANELS) | Y |
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| SECTION III: | CORRECTIVE | ACTION: | | | |
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| CORRECTIVE | ACTION(S) COMPLETE | ED BY: | | DATE: | — DSS |
| SECTION IV: | | | | | DEC 1 1 2014 |
| | | - HAST | ZOAA. | 10 -4 | |
| KEVIEWED BY | MANAGEMENT BY: | Thai | rullum | DATE: 12-01-14 | · . |
| BY: | QA/QC | DIRECTOR | | DATE: 12-01-14 | |
| | | | | | DEC 1 A 201 |



by user-facilities, outors and manufacturers for MANUATORY reporting

C. SUSPECT PRODUCT(S) 1. Name (Give labeled strength & mfr/labeler) #1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

#1 1-2TABS, 1-2XDAY PRN

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

Therapy Dates (If unknown, give duration) from/to (or best estimate)

CaseID: 10656951

FDA Use Only

| UE/Incomedes | 54973 | | |
|--------------|----------|------|--|
| JF/Importer | Report # | | |

#1

MEDWATCH

| FORM F | OA 3500 | A (2/13) | | | Page 1 |
|--|---|---|--|---|--|
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| (b) (6) | entiner 12 | of Event: | Months | | 4. Weight |
| | ' | Date | | ✓ Female | or lbs |
| In confid | | of Birth: | | Male | kgs |
| B. ADVE | RSE EV | ENT OR PROD | JCT PROBLE | М | |
| 1. 📝 Adve | | - | roduct Problem (| e.g., defects/malfi | unctions) |
| | s Attribute I that apply) | d to Adverse Event | | | |
| Deal | h: | (mm/dd/yyyy) | Disability | or Permanent Da | mage |
| ✓ Life- | threatening | (minuca yyyy) | Congenita | il Anomaly/Birth D | Defect |
| Hosp | oitalization - | initial or prolonged | Other Seri | ious (Important M | ledical Events) |
| | | intion to Prevent Per | | | |
| 3. Date of E | | /2014 | 4. Date of This | Report <i>(mm/dd</i> 11/20/2014 | |
| 5. Describe | | · | 1 | 11/20/2014 | · |
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| DIAGNOSE | D WITH | FEBRILE SEIZ | URE. | | - 1 |
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| | | | | (Continue on | page 3) |

| H. Diagnosis for Ose (more | Stopp | ed or Dose R | | |
|--------------------------------------|---------------------------------------|---------------------|---------------------------------|---------------|
| #1 TEMP RELIEF OF | TEETHING PA | IN #1 □ Y | _ | Doesn't Apply |
| #2 | T7 F = | #2 TIY | es No | Doesn't |
| 6. Lot# | 7. Exp. Date | | | After |
| #1A27113 | #1 | Reintre | Reappeared oduction? | |
| #2 | #2 | #1 🗆 Y | es No | Doesn't Apply |
| 9. NDC# or Unique ID 54973~3127~2 | | #2 Y | es No | Doesn't Apply |
| 10. Concomitant Medical F | roducts and Therac | y Dates (Exclude | treatment of e | |
| | | | | |
| | | | | |
| | | | | |
| D. SUSPECT MEDIC | AL DEVICE | (C | ontinu e on | page 3) |
| D. SUSPECT MEDIC 1. Brand Name | ME DEVICE | | | |
| | | - TAL - | rocode | |
| 2. Common Device Name | Newsonia and the second | 20. P | | |
| 3. Manufacturer Name, Cit | y and State | | | |
| | | | | |
| 4. Model # | Lot# | | 5. Operator | of Device |
| Catalog # | Expiration De | ite (mm/dd/yyyy) | | Professional |
| | priorition UE | , | | er/Patient |
| Serial# | Unique Identi | fier (UDI) # | Other: | |
| 6. If Implanted, Give Date (| mm/dd/yyyv) Tz | . If Explanted, Giv | e Date (mm/r | id/yyyv) |
| , sive Date (| · · · · · · · · · · · · · · · · · · · | | ;;;n;t)(| |
| 8. Is this a Single-use Devi | ce that was Reproc | essed and Reused | on a Patien | t? |
| Yes No 9. If Yes to Item No. 8, Ente | r Name and Addres | s of Reprocessor | | |
| | | | DS | S |
| | | _ | | |
| 10. Device Available for Ev | aluation? (Do not se | nd to FDA) | EC 1 | 2014 |
| Yes No [| Returned to Manu | - | | |
| 11. Concomitant Medical P | | | (mm/dd/yy treatment of e | |
| Somewhalk medical P | and i nerap | , Jules (EXCIUDE) | Service Of 6 | . 4-11/ |
| | | | | |
| E. INITIAL REPORTE | R | (C | ontinue on | page 3) |
| 1. Name and Address | | | 1 | |
| (b) (6) | | DEC | 1 5 20 | 14 |
| b) 6) USA | | とし | 1 J ZU | 17 |
| | | | | |
| Phone # | Email A | ddress | | |
| (b) (6) | | | | |
| | Occupation | 4. tr | nitial Reporte Report to FDA | r Also Sent |
| Yes No N | IA . | | | lo 🔽 Unk. |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.



F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report Initial Follow-up #

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Study

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

Report Source (Check all that apply)

Health Professional

FORM FDA 3500A (2/13) (continuea)

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4 Contact Person

9. Approximate Age of Device

Yes

☐ No

Yes

☐ No

Address

11. Report Sent to FDA?

Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

11/20/2014

30-day

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

7-day Periodic

✓ 15-day Follow-up# 9. Manufacturer Report Number

10-day 📝 initial

54973 AE # 1581

7. Type of Report

5-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

i uge 2

| | | FDA USE ONLY |
|--|--------------------------|---|
| _ | | |
| of <u>5</u> | | |
| H. DEVICE MANUFAC | TURERS ONLY | |
| 1. Type of Reportable Event | | 2. If Follow-up, What Type? |
| ☐ Death | | Correction |
| Serious Injury | | Additional Information |
| Malfunction | | Response to FDA Request |
| | | Device Evaluation |
| 3. Device Evaluated by Mans | ufactures? | 4. Device Manufacture Date |
| 1 _ | | (mm/yyyy) |
| Not Returned to Manu | Summary Attached | |
| 1 = - | • | 5. Labeled for Single Use? |
| No (Attach page to ex provide code: | tpiam why noty or | |
| | | Yes No |
| 6. Event Problem and Evalua | ation Codes (Refer to co | ding manual) |
| Patient | | |
| Code | | |
| Device Code | | |
| Code | | production production |
| Method | | |
| Results | 1_[| |
| Thesautis | | |
| Conclusions | - | - |
| 7. If Remedial Action Initiates | d, Check Type 8. | Usage of Device |
| Recall N | otification | Initial Use of Device |
| | spection | Reuse |
| | atient Monitoring | Unknown |
| | odification/ 9, 1 | f action reported to FDA under |
| | diverment | 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | |
| <u> </u> | | |
| 10. Additional Manufactu | rer Narrative and | 1 / or 11. Corrected Data |
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| | | DEC 1 5 2014 |
| * | | 1 7 2017 |
| | | |

CaseID: 10656951

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k) #

Combination Product

OTC Product Yes

8. Adverse Event Term(s) FEBRILE SEIZURE

Pre-1938

Yes

Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@Ma.hhs.gov valid OMB control numb

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



OMPLAINT RECORD

CaseID: 10656951



| | | COMPLAINT #: | 2591 | *************************************** |
|--|--|--|--|---|
| TAKEN BY: | TUTTI GOULD | DATE OF COMPLAINT: | 11/20/14 | ************************************** |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT250 | |
| SIZE: | 250 TABLETS | LOT NO.: | A27113 | |
| REPORTER: (b) | (6) | | | |
| ADDRESS: | | | | |
| Anamagemen | | | | - |
| CITY: | | STATE: (b) (6) | | - |
| COUNTRY: US | The state of the s | ZIP CODE: | - In the trade the second of t | |
| PHONE #: | (6) | | | - |
| E-MAIL: | | | | - |
| CAUSE. THAT MORNING OUT. SHE WAS TAKEN TYLENOL. THE DAUGHT WAS TREATED WITH AN 4 – 12 MONTHS OF AGE, | MOTHER CALLED ABOUT HER 20 MONTH C SHE WANTED TO KNOW IF HAVING GIVEN BIZURE. AT THE TIME OF THE INCIDENT, HER DAUGHTE SHE GAVE HER DAUGHTER IBUPROFEN AND 6 HOUR TO THE HOSPITAL WITH A FEVER OF 103.9°F AND DIAC TER AND MOTHER HAVE A HISTORY OF HIGH FEVER DI TIBIOTICS IMMEDIATELY AFTER BEING BORN. BABY T DEPENDING ON WHEN SHE WAS 'GNAWING ON HER F DID USE IBUPROFEN FROM TIME TO TIME. | HER DAUGHTER BABY TEETHING T ER HAD HAD A FEVER OF 102°F FOR S LATER HER DAUGHTER STOOD L GROSED WITH FEBRILE SEIZURE, JURING DAUGHTER'S BIRTH DUE TO EETHING TABLETS WERE USED INT | ABLETS 8 MONTHS PRIOR, COULI R 2 – 3 DAYS, OF UNKNOWN JP FROM HER BATH AND "PASSED IND GIVEN IBUPROFEN AND O CHORIOAMNIONITIS. DAUGHTER TERMITTENTLY AS NEEDED FROM | |
| | FOR ADDITIONAL SPACE PLEASE USE REVE | RSE OR ATTACH A SEPARATE SHE | £ī | |
| | _ | | | |
| PRODUCT RECEIVED FO | OR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR I | INSPECTION: Y (CIRCLE ONE) |) |
| | | DATE REQUESTED PRODUCT BE | RETURNED: | |
| | | UPS CALL 1 | TAG ISSUED: (CIRCLE ONE) |) . |
| | | D. (T. T. D. D.) () | | |
| SECTION II: | INVESTIGATION | DATE PRODUCT | T RECEIVED: | |
| SECTION II: | INVESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | namen de des la Maria de Maria de Maria de Maria de Maria de La Maria de La Maria de La Maria de La Maria de L | |
| | | An other to the same to the sa | | |
| | | | | |
| ADVERSE EVENT FORW | ARDED TO PHARMACIST / NURSE FOR EVALUATION OF | N: 11/20/14 | | |
| | ARDED TO PHARMACIST / NURSE FOR EVALUATION BY | - Minary and a superior and | UID | manufic. |
| SECTION III: | CORRECTIVE ACTION: | | | enthrough. |
| | Some Market Market | | | |
| | | 1907 - Marine and American Control of the Control o | CONTRACTOR OF THE STATE OF THE | - |
| | | | · · · · · · · · · · · · · · · · · · · | DSS |
| | | | 8 | Promoter Common |
| CORRECTIVE ACTION(S) | COMPLETED BY: | DATE: | | C 1 6 2014 |
| | | | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: _ | 1581 | |
| ADVERSE EVENT SERIOL | JS: Y/ N | | | |
| ADVERSE EVENT REPOR | TED ON: 11/20/14 | BY: TUTTI GOULD | DE | C 1 5 2014 |
| SECTION V: | . 1 | , / | | G 1 J 2011 |
| REVIEWED BY MANAGEM | MENT BY: | DATE: | 12-02-14 | |
| BY: | QA OC DIRECTOR | | 12-02-14 | |





Serious Adverse Event SAE-0058-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A27113, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A27113 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A27113. The Baby Teething bulk lot # 118748 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no related issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A27113. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A27113.

Manufacture and processing occurred within established procedures to ensure product quality.

12 - 01 - 14 Date

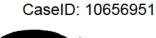
Date

DEC 1 6 2014

CaseID: 10656951

DEC 1 5 2014







SERIOUS ADVERSE EVENT DATA FORM

| AE #: | 1581 | COMPLAINT #: 2591 | |
|---|--|--|--------------|
| SECTION I | <u>l:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: ADDRESS: | : | (b) (6) | namen. |
| CIFY: | | STATE: (b) (6) | |
| COUNTRY: PHONE #: E-MAIL: | - | USA ZIP CODE: | |
| SECTION I | Ŀ | PACKAGING INFORMATION: | Base . |
| | AFFI | X PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) | |
| elle without into the child program of a dispersion of a dispersion of a dispersion of the second of the second of the child program of dispersion of the programmer, a Child programmer, a Child programmer, a Child programmer, a Child programmer, a Child programmer, a Child programmer, and | per la company la comp | | |
| SECTION II | <u>ll:</u> | CORRECTIVE ACTION: | - DSS |
| | | | DEC 1 6 2014 |
| CORRECTI | VE ACT | ION(S) COMPLETED BY: DATE: | _ |
| | | NAGEMENT BY: DATE: 12-02-14 | |
| BY: | - constant of the section of the sec | QA / QC DIRECTOR DATE: 12-02-14 | |



by user-facilities, ibutors and manufacturers DATORY reporting

| (CaseID: 10678285 |
|--|
| Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse |

| Form Approved: OMB No. 0910-0291, | Expires: 6/30/2015 |
|-----------------------------------|----------------------|
| See OMB sta | atem ent on reverse. |

| | See OMB statem ent on reverse |
|----------------------|-------------------------------|
| Mfr Report # 54973 | |
| UF/Importer Report # | |
| | |

| | AILH | | | |
|---|---|---|--|--|
| FORM FDA 3500 | | | | Page |
| A. PATIENT INF | ORMATION | | | |
| 1. Patient Identifier (b) (6) | 2. Age at Time of Event: 8 | Months | 3. Sex | 4. Weight |
| | or Date | | Female | or los |
| In confidence | of Birth: | | ✓ Male | kgs |
| B. ADVERSE EV | ENT OR PRODUC | CT PROBLE | VI | |
| 1. Adverse Event | and/or Pro | duct Problem (e. | .g., defects/malf | unctions) |
| Outcomes Attribut (Check all that apply | | | | |
| Death: | | Disability o | r Permanent Da | mage |
| Life-threatening | (<i>mm/dd/yyyy</i>) g | Congenital | Anomaly/Birth D | Defect |
| ✓ Hospitalization | - initial or prolonged | | ous (Important M | |
| Required Interv | vention to Prevent Perma | anent Impairment | /Damage (Devic | es) |
| 3. Date of Event (mm | /dd/yyyy) | 4. Date of This | Report (mm/dd | (yyyy) |
| 11/15 - | 30/2014 | | 12/08/2014 | |
| VOMITING EVERY CALLED FOR AN IIMES IN THE A WAS SEVERELY DEBEN AN INFECT DID NOT GET AN UNSURE OF DIAG FETHING TABLE MOTHER GAVE PE MORNING. DOCT BABY TEETHING | EHYDRATED. DO 'ION. TRANSFER I ANTIBIOTIC ON MOSIS. AT A L TS AGAIN AND T | DRY HEAVING LD LOST CON TE COUNT WA CTORS THOUG RED TO CHIL LY FLUIDS. ATER DATE S HE CHILD ST TO THE DOG SYMPTOMS TO ON THE SYME | G, NOT RES NSCIOUSNES AS ELEVATE GHT IT COU LDREN'S HO THE DOOT SHE GAVE TO CARTED VOM CTOR THE NO D BELLADONI PTOMS. CH | PONDING. S 3 D AND HE LD HAVE SPITAL. ORS HE BABY ITING. EXT NA IN ILD HAD |
| fi. Relevant Tests/I ab | oratory Data, Including | Dates | (Continue on | page 3) |
| o. Netevalit Tests/Lab | | ECEI | VED | |
| | | DEC 23 | 2014 | |
| | | CD | R | |
| | | | (Continue on | page 3) |
| Other Relevant Hist race, pregnancy, smo | ory, Including Preexist oking and alcohol use, he | ing Medical Con epatic/renal dysfu | ditions (e.g., all nction, etc.) | ergies, |
| | 95.7 - 96.1F R | | | T |
| | | | | |

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

(Continue on page 3)

| RY reporting | | UF/Importer Report # | | |
|-----------------------------|------------------|------------------------------|--------------|--|
| of 5 | | | | EDA Has Onl |
| C. SUSPECT PRO | DUCT(S) | | | FDA Use Onl |
| 1. Name (Give labeled st | | eler) | | |
| #1 HYLAND'S BAB | Y TEETHING | TABLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & R | oute Used | | | (If unknown, give duration) |
| #1 2TABS HS X 1 | DOSE | #1 | o (or best e | rsunate) |
| #2 | | #2 | | |
| 4. Diagnosis for Use (Inc | dication) | | | Abated After Use |
| #1 TEMP RELIEF T | REETHING PA | AIN | Stopp | ed or Dose Reduced? Yes No Doesn |
| #2 | | | "' ' ' ' | Apply |
| 6. Lot# | 7. Exp. Date | | #2 🗌 \ | res ☐ No ☐ Doesn Apply |
| #1114193 | #1 | | | Reappeared After |
| #2 | #2 | | #1 🗸 Y | roduction? res No Doesn' |
| 9. NDC# or Unique ID | | | | Арріу |
| 54973-3127-1 | | | #2 🗌 Y | es No Doesn' |
| 10. Concomitant Medica | Products and | Therapy Dates | (Exclude | treatment of event) |
| | | | | |
| | | | | |
| | | | (0 | Continue on page 3) |
| D. SUSPECT MED | ICAL DEVIC | E | Į | oranue on page 3) |
| 1. Brand Name | | | | |
| 2. Common Device Nam | e | | 2b. P | rocode |
| 3. Manufacturer Name, C | New and State | | | |
| o. manufacturer Name, C | Aty and State | | | |
| 4. Model# | 11 | | | 15.4 |
| +. Model # | Lot # | | | 5. Operator of Device |
| Catalog # | Expirati | Expiration Date (mm/dd/yyyy) | | Lay User/Patient |
| Serial# | Unique | Identifier (UD | 1) # | Other: |
| Oct lat # | Oinque | identine (OD | 1)# | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Expl | anted, Giv | e Date (mm/dd/yyyy) |
| 8. Is this a Single-use De | vice that was R | enrocessed a | nd Pausa | d on a Pation#2 |
| Yes No | wice that was it | epiocesseu a | ilu neusei | u on a Facienti |
| 9. If Yes to Item No. 8, Er | nter Name and A | Address of Re | processor | |
| | | | | |
| | | | | 000 |
| 10. Device Available for I | Evaluation? (Do | not send to FL | DA) | ngo |
| Yes No | Returned to | o Manufacture | r on: | ™DEC 22 4 20 |
| 1. Concomitant Medical | Products and T | herapy Dates | (Exclude | <u> </u> |
| | | | | , |
| | | | | antinua an mara a |
| E. INITIAL REPORT | TER | | (C | ontinue on page 3) |
| . Name and Address | | | | |
| b) (6) | | | | |
| | | | | |
|)(6) USA | | | DE | C 2 3 2014 |
| Phone # b) (6) | | mail Address | | |
| | |) (6) | | |
| P. Health Professional? | | | | nitial Reporter Also Sent Report to FDA |
| _ Yes [√] No | NA | | 1 [| Yes No Unk. |



Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

Approximate Age of Device

11. Report Sent to FDA?

Yes

☐ No

Yes

☐ No

Address

6. Date User Facility or

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

12/01/2014

30-day

Periodic

9. Manufacturer Report Number

Follow-up #

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

10-day 📝 Initial

54973 AE # 1586

7. Type of Report

5-day

7-day

√ 15-day

EDYTA FRACKIEWICZ

HYLAND'S, INC. 154 W. 131ST STREET

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Study

Literature √ Consumer

User Facility

Company Representative

Distributor

Other:

3. Report Source (Check all that apply)

Health Professional

(mm/dd/yyyy)

ige 2 c

| of <u>5</u> | |
|--|--|
| H. DEVICE MANUFACTURERS ONL 1. Type of Reportable Event | |
| Death Serious Injury Malfunction | 2. If Follow-up, What Type? Correction Additional Inform ation Response to FDA Request |
| Device Evaluated by Manufacturer? Not Returned to Manufacturer | 4. Device Manufacture Date (mm/yyyy) |
| Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| 6. Event Problem and Evaluation Codes (Refer | Yes No |
| Patient Code - Device Code | - |
| 7. If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification Repair Inspection Replace Patient Monitoring | ☐ Initial Use of Device ☐ Reuse ☐ Unknown |
| Relabeling Modification/ Adjustment Other: | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
| | 200 |
| | DSS DEC 2 4 2014 |
| | DEC 2 3 2014 |

CaseID: 10678285

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(A)NDA#

IND#

BLA# PMA/

510(k) #

Product

Pre-1938

Combination

OTC Product Yes

8. Adverse Event Term(s)

Yes

Yes

VOMITING, LETHARGY, DEHYDRATION,

LOSS CONSCIOUSNESS, ELEVATED WHITE BLOOD CELL COUNT, HOSPITALIZATION

> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

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OMPLAINT RECORD



| 10678 | 8285-01-00-03 | COMPLAINT #: | 2596 |
|--|---|---|--|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 12/01/14 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT135 |
| SIZE: | 135 TABLETS | LOT NO.: | 114193 |
| REPORTER: | (b) (6) | | |
| ADDRESS: | | | |
| | - | (L) (C) | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: | USA (b) (6) | ZIP CODE: | THE REAL PROPERTY OF THE PERSON OF THE PERSO |
| PHONE #; | | VANA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA TARANTA T | |
| E-MAIL: NATURE OF COME | CUSTOMER SENT THE FOLLOWING E-MAIL ON PURCHASED YOUR TEETHING TABLETS ON 2 D | 12/1/14: I AM DISAPPOINTED IN YOUR | RTEETHING TABLETS PRODUCT. 1 |
| IF MY CHILDREN NE APPROXIMATELY 6 THEM TO HIM AFTE (b) (6) I GAVE MY SC DEHYDRATED FROI WITH, AND HE HAD AMBULANCE TO TAI IT MAY JUST BE A V HOSPITAL THE NEXT TEETH POSSIBLY PI THE NEXT MORNING WAS THE BELLADO SUDDEN THERE BE EACH DOSE FOR IN CHILD DUE TO THIS OUNCES. VOMITED RESPONDING. THIS WHITE COUNT WAS CHILDREN'S HOSPIT SHE GAVE THE BAB | EEDED SOME, AND THEN A BOTTLE TO HAVE AT HOME. I STARTED MONTHS. I WOULD USUALLY ONLY GIVE IT ONCE MAYBE TWICE AS R ABOUT 2 WEEKS, AS HE WAS NOT SHOWING SIGNS OF TEETHIN DIV 2 TABLETS AS HE WAS FUSSING AND TEETHING. WE ENDED UP MY VOMITING SO MUCH. I HAD NURSED HIM FOR THE HOUR PRIOR, RECEIVED A BOTTLE THE PRIOR FEEDING. HE HAD NOT HAD ANY KE US TO THE HOSPITAL, AND HE LOST CONSCIOUSNESS 3 TIMES (FRUS RUNNING THROUGH HIS SYSTEM AND THAT AFTER HE RECEIT MORNING. ABOUT 2 WEEKS LATER, I GAVE HIM 2 MORE TEETHIN OKING THROUGH. WE ENDED UP WITH THE SAME RESULT EXCEP TO THE HAVE HIM CHECKED OUT. THEY WERE ABLE TO MAKE THE DENAIN IN THE TEETHING TABLETS. HE HAD NEVER SHOWN A PROBLEAM A PROBLEM. I AM WONDERING IF THIS PRODUCT NEEDS TO FANTS / TOODLERS. I DO NOT WANT ANOTHER PARENT TO GO THE FANTS / TOODLERS. I DO NOT WANT ANOTHER PARENT TO GO THE HAPPENED AROUND (10) (6) E HAPPENED AROUND (10) (6) E LEVATED AND HE WAS SEVERELY DEHYDRATED. DOCTORS THE LEVATED AND HE WAS SEVERELY DEHYDRATED. DOCTORS THE TALL DID NOT GET AN ANTIBIOTIC, ONLY FLUIDS. THE DOCTORS OF THE PARENT TO BABY TEETHING TABLETS. HE HAS USED BABY FOR ADDITIONAL SPACE PLEASE USE REVERSALED. | O GIVING MY SON YOUR TEETHING TA A WEEK AND GIVE HIM ONLY 2 TABLE IG, AND DID NOT NEED THEM. AT ARR IN THE HOSPITAL AS HE BECAME SE, SO THERE WAS NO POSSIBLE WAY! NEW MEDICATIONS AND NOTHING N 6 ON THE WAY TO THE HOSPITAL. TH EIVED FLUIDS, HE WOULD BE FINE. W NG TABLETS BEFORE BED, AS HEWA PT WE DID NOT END UP AT THE HOSPI BETERMINATION FROM THE SYMPTON LEM PRIOR TO THESE 2 TIMES BEING D BE RE-EVALUATED TO ENSURE THE ROUGH WHAT WE HAVE HAD TO EN UMITED 15 MINUTES AFTER GETTING THIS TIME. WAS VOMITING EVERY FE JLANCE, CHILD LOST CONSCIOUSNEE OUGHT IT COULD HAV VITHER GAVE PEDIALYTE. WENT TO TI VITER THOST WIN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI TEETHING TABLETS IN THE PAST WI | BLETS WHEN HE WAS IS AT A TIME. I STOPPED CIVING DUND 8 MONTHS OLD. (b) (6) EVERELY LETHARGIC AND HE WAS DEHYDRATED TO BEGIN EW IN HIS DIET. WE HAD TO CALL AN E DOCTORS AND MYSELF THOUGHT FE WERE DISCHARGED FROM THE S FUSSY AND I HAD FELT SOME TAL. I TOOK HIM TO THE DOCTOR AS BOTH TIMES, THAT THE CAUSE GIVEN TO HIM, AND NOW ALL OF A IRE ISN'T TOO MUCH BELLADONNA IN DURE AND POSSIBLY LOSE THEIR TABLETS. VOMITED UP ABOUT 4 – 6 EW MINUTES, DRY HEAVING, NOT SS 3 TIMES IN THE AMBULANCE. ECTION. TRANSFERRED TO I'VE BEEN. COUPLE OF NIGHTS LATER I'VE DOCTOR THE NEXT MORNING. TH NO PROBLEMS. ET |
| | | UPS CALL T | |
| | | DATE PRODUCT | RECEIVED: |
| SECTION II: | INVESTIGATION | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| ADVERSE EVENT F | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | 12/01/14 | |
| | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | ACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | EDITATE | ACNEWICZ |
| | | | DSS |
| CORRECTIVE ACTION | ON(S) COMPLETED BY: | DATE: _ | DEC 2 4 2014 |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: _ | 1586 |
| ADVERSE EVENT S | ERIOUS: Y / N | | |
| ADVERSE EVENT R | EPORTED ON: 12/01/14 | BY: EDYTA FRACKIE | WICZ |
| SECTION V: | | 211 | DEC 2 3 2014 |
| REVIEWED BY MAN | AGEMENT BY: | Mus_ DATE: _ | 12-18-14 |
| BY: | Cyc Brien | DATE: | 12-12-14 |
| | OA LOC DIPECTOR | DATE: | 16 1 1 1 |





Serious Adverse Event SAE-0063-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # 114193, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (STET) and (STET) are currently in the Standard Homeopathic Co. (SHC) warehouse.

Review of Records:

The Hyland's Baby Teething Tablets lot # 114193 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # 114193. The Baby Teething bulk lot # 114193 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC # 2338) has been received for Hyland's Baby Teething Tablets lot # 114193. The reports were reviewed and they do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # 114193.

Manufacture and processing occurred within established procedures to ensure product quality.

| 007 | 12/10/14 | DSS |
|-------------|----------|-------------|
| Prepared by | Date | DEC 2 4 20M |

DEC 2 3 2014

CaseID: 10678285





CaseID: 10678285

ERSE EVENT DATA FORM

| AE #:158 | 36 | COMPLAINT #: 2596 |
|--|---|--|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM | REPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | | STATE: (b) (6) |
| COUNTRY: | USA | ZIP CODE: |
| PHONE #: | (b) (6) | |
| E-MAIL: | | |
| SECTION II: | PACKAGING INFORMATION: | AFFIX COPY OF OUTER CARTON HERE |
| | | NCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| Indications: Improving the property of the pro | Could by County of the County | Comment of the commen |
| SECTION III: | CORRECTIVE ACTION: | |
| | | 200 |
| | | DSS |
| CORRECTIVE A | CTION(S) COMPLETED BY: | DEC 2 4 2014 |
| SECTION IV: | Per Dan | ^ . |
| REVIEWED BY M | MANAGEMENT BY: | DATE: 12-15-14 |
| BY: | Que Main QAT QC DIRECTOR | DATE: 12-15-14 DEC 2 3 201 |



TO TO

| _ | See OMB statem ent on r |
|---|-------------------------|
| ser-facilities, rs and manufacturers | Mfr Report # 54973 |
| ORY reporting | UF/Importer Report # |
| _ | |

CaseID: 10678309 orm Approved: OMB No. 0910-0291, Expires: 6/30/2015

Page 1 of FORM FDA 3500A (2/13) A. PATIENT INFORMATION 1. Patient Identifier 2. Age at Time 3. Sex 4. Weight of Event: (b) (6) 4 Months ✓ Female 1bs or Date Male In confidence of Birth: kgs **B. ADVERSE EVENT OR PRODUCT PROBLEM** Product Problem (e.g., defects/malfunctions) 1. Adverse Event and/or 2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) ✓ Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) ✓ Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 08/00/2010 12/03/2014 5. Describe Event or Problem CHILD HAD A SEIZURE IN 2 WEEKS LATER SHE HAD ANOTHER SEIZURE. DIAGNOSIS: RULE-OUT DEHYDRATION. A WEEK LATER CHILD HAD A STROKE FROM A BRAIN BLEED AND TAKEN TO THE HOSPITAL. BRAIN SCAN SHOWED FLUID BETWEEN BRAIN AND SKULL. INCARCERATED FOR SHAKEN BABY SYNDROME BUT CHILD HAD NO OTHER PHYSICAL SIGNS OF BEING SHAKEN. CHILD ALSO HAD HEMORRHAGING AND HEMATOMA BEHIND THE EYES AND NOW HAS CORTICAL VISUAL IMPAIRMENT. RECEIVED DEC 23 2014 (Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates (Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) ALLERGIC TO AMOXICILLIN

PLEASE TYPE OR USE BLACK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

(Continue on page 3)

| and manufacturers RY reporting | UF/Importer Re | 4973 port # | | | |
|---|-------------------|-----------------------|--------------|-------------------------|---------------|
| f 5 | | Of Importal Toport II | | | |
| C SUSPECT PROD | UCT/S) | | | | DA Use Only |
| SUSPECT PROD Name (Give labeled stren | | | | | |
| #1 HYLAND'S TEETH | | | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Rou | te Used | 3. Therapy D | | | ive duration) |
| #1 #1 | | | Jeal 6 | | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Indic | ation) | | | Abated After | |
| #1 TEMP RELIEF TE | ETHING PAIN | #1 | | ed or Dose R es V No | Doesn't |
| #2 | | | | | Apply Doesn't |
| 6. Lot # | 7. Exp. Date | #2 | | es No | L Apply |
| #1 | #1 | | | Reappeared oduction? | After |
| #2 | #2 | #1 | Y | es 🗌 No | Doesn't Apply |
| 9. NDC# or Unique ID | | #2 | | es \square No | Doesn't |
| 54973-7504-1 10. Concomitant Medical P | Producte and The- | | | | Apply Apply |
| | | | | | |
| | | | (C | ontinue on | page 31 |
| D. SUSPECT MEDIC | AL DEVICE | | ,0 | | page o) |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 2b. P | rocode | |
| 3. Manufacturer Name, Cit | y and State | | | | |
| | | | | | |
| 4. Model# | Lot # | | | 5. Operator | of Device |
| Catalan " | P | -4- / :::: | | Health | Professional |
| Catalog # | Expiration D | Date (mm/dd/y | yyy) | Lay Us | er/Patient |
| Serial# | Unique Iden | tifier (UDI) # | | Other: | |
| 6. If Implanted, Give Date (| /mm/dd/yyyy) | 7. If Explante | d, Giv | e Date (mm/c | dd/yyyy) |
| 8. Is this a Single-use Devi | ce that was Renn | cessed and F | Reuser | on a Patien | t? |
| Yes No | | - Coooga and F | | . on a raciety | `` |
| 9. If Yes to Item No. 8, Ente | r Name and Addr | ess of Reprod | essor | | |
| | | | | | ا م |
| | | | | D | SS |
| 10. Device Available for Ev | | | | חבר פ | 4 2014 |
| Yes No [| Returned to Ma | | | (mm/dd/yy | yy) |
| 11. Concomitant Medical P | roducts and Thera | apy Dates (E) | kclude i | treatment of e | event) |
| | | | | | |
| | | | (C | ontinue on | page 3) |
| E. INITIAL REPORTE 1. Name and Address | R | | | | |
| b) (6) | | | | | |
|) (6) USA | | | DE(| 232 | 014 |
| V 0/1 | | | | - | |
| Phone # b) (6) | Email (b) (6) | Address | | | |
| | Occupation | | 14 1- | nitial Reporte | r Also Sont |
| nearth Professional? 3. | occupation | | 7. 11 | miai neporte | n AISU SENII |
| Yes No N | IA | | | eport to FDA | ` I |



Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

Yes _

☐ No

Name

Address

☐ No

Date User Facility or Importer Became

11. Report Sent to FDA?

Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

___ Initial Follow-up # 10. Event Problem Codes (Refer to coding manual)

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Study

Literature ✓ Consumer

User Facility

Report Source (Check all that apply)

Health Professional

ge 2 of

| f <u>5</u> | |
|---|--|
| H. DEVICE MANUFACTURERS ONLY | |
| Type of Reportable Event Death Serious Injury Malfunction | 2. If Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation |
| 3. Device Evaluated by Manufacturer? | 4. Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? Yes No |
| 6. Event Problem and Evaluation Codes (Refer to | - coding manual) |
| Patient Code Device Code Method Results | - |
| Results | |
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type Recall Notification Repair Inspection | 8. Usage of Device Initial Use of Device Reuse |
| Replace Patient Monitoring | 9. If action reported to FDA under |
| Relabeling Modification/ Adjustment Other: | 21 USC 360i(f), list correction/ removal reporting number: |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
| | DSS DEC 2 4 2014 |
| | DEC 2 3 2014 |

CaseID: 10678309

FDA USE ONLY

 Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 12/01/2014 Distributor IND# 6. If IND, Give Protocol# Other BLA# PMA/ 7. Type of Report 510(k)# (Check all that apply) Combination 5-day 30-day Yes Product 7-day Periodic Pre-1938 Yes 10-day

√ Initial OTC Product √ Yes ✓ 15-day Follow-up # 9. Manufacturer Report Number 8. Adverse Event Term(s) SEIZURE, BRAIN BLEED, STROKE, 54973 AE # 1584 SHAKEN BABY SYNDROME, CORTICAL VISUAL IMPAIRMENT This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



COMPLAINT RECORD



10678309-01-00-03

| 1001.0000.0 | | COMPLAINT #: | 2594 | |
|---|--|---|--|---|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 12/01/2014 | |
| PRODUCT: | HYLAND'S TEETHING TABLETS | ITEM CODE: | TEET | |
| SIZE: | UNKNOWN | LOT NO.: | UNKNOWN | |
| REPORTER: (b) (6) | | | | |
| ADDRESS: | | | | *************************************** |
| | | | | <u>.</u> |
| CITY: | | STATE: (b) (6) | | |
| COUNTRY: USA | | ZIP CODE: | | |
| PHONE #: (b) (6) | | | | |
| E-MAIL: | CUSTOMED STATE THE FOLLOWING F MALLON | HANNAMONA MESSAGE HELLO | S EIDOT LET ME OTAD | OSE BY |
| CHILDREN. WAS THIS EVEN AND STILL HAS SEIZURES. | CUSTOMER SENT THE FOLLOWING E-MAIL ON SAYING I'M NOT INTERESTED IN COLLECTING IE HOMEOPATHIC TEETHING TABLETS WERE RECALLEIR PROVEN? I'M ASKING BECAUSE MY DAUGHTER SUFF BUT SOMEONE WAS INCARCERATED BECAUSE THESE IS ALL I WANT TO KNOW. I CAN'T LIVE WITH THE POSS | ANYTHING OR LAWSUITS. I JU: D IN 2010. THAT THEY CAUSED FERED FROM BOTH. IN 2010, S E SYMPTOMS SEEMED ALMOST | ST HAVE A QUESTION BRAIN BLEEDS AND S HE IS NOW BLIND FRO DENTICAL TO SHAKE | I SAW EIZURES IN M STROKE N BABY |
| SPOKE WITH THE CUSTOMER HAD A SEIZURE. 2 WEEKS LA FROM A BRAIN BI FFD - CHIL AND SKULL. (b) (6) WAS IN | R ON 12/02/2014: CUSTOMER REPORTED CHILD TAKING THE ATER SHE HAD ANOTHER SEIZURE. RULE OUT DEHYDRATIC D WAS MOANING AND NERVES WERE GOING OFF. IN THE H ICARCERATED FOR SHAKEN BABY SYNDROME FOR (b) (5) AND HEMATOMA BEHIND THE EYES AND NOW HAS CORTICA FOR ADDITIONAL SPACE PLEASE USE REVERSE | ETABLETS IN 2010. INJURY OCCU IN BY DOCTORS AT THE TIME. A 1 IOSPITAL THERE WAS A SCAN TH. BUT CHILD HAD NO OTHER PH' NL VISUAL IMPAIRMENT. | IRRED IN (b) (6) WEEK LATER CHILD HAE IAT SHOWED FLUID BETV YSICAL SIGNS OF BEING | WHEN SHE A STROKE |
| | ,,, | ON ATTAON A GET ANATE OFFE | | |
| PRODUCT RECEIVED FOR INSPECTION: | Y (CIRCLE ONE) | DDUCT BEING RETURNED FOR | | RCLE ONE) |
| | D | ATE REQUESTED PRODUCT BE | E RETURNED: | |
| | | | , | RCLE ONE) |
| | | DATE PRODUC | T RECEIVED: | |
| SECTION II: IN | VESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | · · | | | |
| ADVERSE EVENT FORWAR | DED TO PHARMACIST / NURSE FOR EVALUATION ON: | 12/01/201 | 4 | |
| ADVERSE EVENT FORWAR | DED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDYTA FI | RACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | |
| | | | | |
| | | | | DSS |
| CORRECTIVE ACTION(S) CO | DMPLETED BY: | DATE: | | DEC 2 4 201 |
| SECTION IV: ADV | VERSE EVENT REPORTS | AE #: | 1584 | |
| | | · · · · · · · · · · · · · · · · · · · | | |
| ADVERSE EVENT SERIOUS: | Y / N | | | |
| ADVERSE EVENT REPORTE | ED ON: 12/01/14 | BY: EDYTA FRACKI | EWICZ | |
| SECTION V: REVIEWED BY MANAGEMEN | NT BY: | Dlu DATE: | 12-12-14 | DEC 2 3 2014 |
| BY: | Ence Boun | | 12-12-14 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0061-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Teething Tablets (TEET) but no lot number, location of purchase or date of purchase for the units involved.

Hyland's Teething Tablets (TEET) was subject to an SHC recall and withdrawn from the market in 2010.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred and eight (8) Adverse Events (AE) which also included six (6) Serious Adverse Events (SAE) reported for Hyland's Teething Tablets (TEET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

12/8/14

CaseID: 10678309

DEC 2 3 2014





CaseID: 10678309

≟RSE EVENT DATA FORM

| AE #: | 1584 | | COMPLAINT #:2594 |
|---------------------|--|--|--|
| SECTION | <u>l:</u> | PATIENT INFORMATION (IF DIFFER | ENT FROM REPORTER ON FORM VD1) |
| NAME: | | (b) (6) | |
| ADDRESS | : | | |
| CITY: | | | STATE: (b) (6) |
| COUNTRY | ' ; | USA (b) (6) | ZIP CODE: |
| PHONE #: E-MAIL: | | - | |
| | | - | |
| SECTION | <u>II:</u> | PACKAGING INFORMATION: | |
| | AFF | X PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| | bell, on or risk of the or risk tarries tarries | to the second of | Tablets |
| | description of the second of t | Techning Tables Techni | Teething Tablets Tabletas para la Dentición |
| | | Communication control | - Suppressed: Relief to Technique Collifore Co |
| | • | Secretary and the secretary an | * Toursenant February Tracking Colders No. 18th 18th 18th 18th 18th 18th 18th 18th |
| | | | |
| | | | |
| SECTION | <u>II:</u> | CORRECTIVE ACTION: | |
| | | | 200 |
| | | | USS |
| | | | DEC 2 4 201 |
| CORRECT | IVE AC | FION(S) COMPLETED BY: | DATE: |
| SECTION I | <u>v:</u> | ART. | DEC 2 3 2014 |
| REVIEWED | BY MA | NAGEMENT BY: | DATE: 12-12-14 |
| BY: | | QUU POUM QA/QC DIRECTOR | DATE: 12-12-14 |



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FORM FDA 3500A (2/13)

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| ov user-facilities, |
| utors and manufacturers |
| utors and manufacturers |
| ATORY reporting |
| The state of the s |

| Mfr Report # | 54973 | | | |
|---------------|----------|--|--|--|
| UF/Importer I | Report # | | | |
| | | | | |

CaseID: 10678313 Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

Page 1 of ⁵

FDA Use Only

| A. PATIENT INFORMATION | | | C. SUSPECT PRO | DUCT(S) | | |
|--|-------------------------------------|-----------|----------------------------|----------------------|------------------|--|
| Patient Identifier 2. Age at Time | 3. Sex | 4. Weight | 1. Name (Give labeled str | ength & mfr/labeler) | | |
| (b) (6) of Event: | Years | lbs | #1 HYLAND'S BABY | TEETHING TA | ABLETS | |
| Date | | or | #2 | | | |
| In confidence of Birth: | Male | kgs | 2. Dose, Frequency & Ro | oute Used | 3. Therapy Dat | es (If unknown, give duration) |
| B. ADVERSE EVENT OR PRODUC | CT PROBLEM | | #1 2 TABLETS PO | x 1 DOSE | from/to (or be | est estimate) |
| 1. Adverse Event and/or Pro | oduct Problem (e.g., defects/malfu. | nctions) | | | | |
| Outcomes Attributed to Adverse Event (Check all that apply) | | | #2 | | #2 | |
| Death: | Disability or Permanent Dam | nage | 4. Diagnosis for Use (Inc | • | Ste | ent Abated After Use opped or Dose Reduced? |
| (mm/ad/yyyy) Life-threatening | Congenital Anomaly/Birth Do | | #1 TEMP RELIEF T | EETHING PAIR | #1 [| ✓ Yes No Doesn' Apply |
| | Other Serious (Important Me | | #2 | | #2 [| Yes No Doesn' |
| Required Intervention to Prevent Perma | C. | | 6. Lot # | 7. Exp. Date | L. | — С Арріу |
| 3. Date of Event (mm/dd/yyyy) | 4. Date of This Report (mm/dd/ | | #1A52214 | #1 | | rent Reappeared After eintroduction? |
| 09/00/2014 | 12/08/2014 | "" | #2 | #2 | 1 - | Yes No Doesn' |
| 5. Describe Event or Problem | <u> </u> | | 9. NDC# or Unique ID | | | Doesn' |
| CHILD TOOK 2 TABLETS IN THE | DUDUTNO TUD DUE NEVO | MODNITHE | 54973-3127-1 | | #2 [| Yes No Apply |
| AROUND, EYES ROLLING BACK. | | CAUSE. | | | | (Continue on page 3) |
| | | | D. SUSPECT MED | ICAL DEVICE | | |
| | | | 1. Brand Name | | | |
| _ | *a | | 2. Common Device Nam | е | 2 | 2b. Procode |
| Re | ceived | | 3. Manufacturer Name, 0 | City and State | | |
| | | 1 | 1 | | | |
| Re | C 2 3 2014 | | 4. Model # | Lot# | | 5. Operator of Device |
| 1 | .0 20 2011 | 1 | 4. Inodern | 200 | | Health Professional |
| | | 1 | Catalog # | Expiration | Date (mm/dd/yy) | |
| | CDR | 1 | Serial # | Halaus Id. | entifier (UDI) # | Other: |
| | | 1 | Serial # | Ollique los | entiner (ODI)# | |
| | /O# | | 6. If Implanted, Give Date | e (mm/dd/yyyy) | 7. If Explanted | , Give Date (mm/dd/yyyy) |
| 6. Relevant Tests/Laboratory Data, Including | (Continue on | page 3) | | | 1 | |
| Street and testing and the street an | g - utes | 1 | 8. Is this a Single-use De | evice that was Rep | rocessed and Re | used on a Patient? |
| EEG AND MRI WERE NORMAL. | | | 9. If Yes to Item No. 8, E | nter Name and Add | ress of Reproce | ssor |
| | | | | | • | |
| | | | | | | |
| | | | | | | 799 |
| | | 1 | 10. Device Available for | , | • | D 30 |
| | | i | Yes No | Returned to N | nanulacturer on | (meryy 4 201 |
| | (Continue on | page 3) | 11. Concomitant Medica | Products and The | erapy Dates (Exc | lude treatment of event) |
| 7. Other Relevant History, Including Preexis race, pregnancy, smoking and alcohol use, it | sting Medical Conditions (e.g., all | ergies, | | | | |
| race, programoy, amoning and discinal use, i | nepatarena dysianoton, etc.) | | 1 | | | (Continue on page 3) |
| NONE | | | E. INITIAL REPOR | TER | | , |
| | | | 1. Name and Address | | | |
| | | | (b) (6) | | | |
| | | - 1 | | | | DEC 2 3 2014 |
| | | 1 | | | _ | -0 2 3 2014 |
| | | | Phone # | Em: | ail Address | |
| | (Continue on | page 3) | Phone # (b) (6) | | | |
| Submission of a report does not con | stitute an admission that i | medical | 2. Health Professional? | 3. Occupation | | 4. Initial Reporter Also Sent |
| personnel, user facility, importer, dis caused or contributed to the event. | stributor, manufacturer or | product | Yes V No | NA | | Report to FDA Yes No V Unk. |
| THE PARTY OF THE PARTY IN THE PARTY. | | | | ı | | |



F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

☐ Hospital

Nursing Home

Facility

Other:

Outpatient Treatment

Home

12. Location Where Event Occurred

Initial Follow-up #

Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

Approximate Age of Device

Yes

No

Yes

No

Name

Address

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

12/04/2014

30-day

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

☐ 10-day
✓ Initial

54973 AE # 1585

✓ 15-day ☐ Follow-up # 9. Manufacturer Report Number

7. Type of Report

5-day

7-day

EDYTA FRACKIEWICZ

HYLAND'S, INC. 154 W. 131ST STREET

Email Address

1. Contact Office (and Manufacturing Site for Devices)

2. UF/Importer Report Number

5. Phone Number

Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

✓ Consumer

User Facility

Company

Distributor

Other:

Study Literature

3. Report Source (Check all that apply)

Health Professional

Representative

(mm/dd/yyyy)

e 2 of

| | | | FDA USE ONLY | |
|------------------------------------|----------------------------|----------|---|---|
| | | | | _ |
| 5 | | | | |
| H. DEVICE MANUFAC | TURERS ON | ILY | | |
| 1. Type of Reportable Event | | | 2. If Follow-up, What Ty pe? | |
| Death | | | Correction | |
| Serious Injury | | | Additional Information | |
| Malfunction | | | Response to FDA Reques | t |
| | | | Device Evaluation | |
| 3. Device Evaluated by Man | ufactur or? | | Device Manufacture Date | _ |
| _ | | | (mm/yyyy) | |
| Not Returned to Man | | and . | | |
| | Summary Attach | iea | 5. Labeled for Single Use? | |
| No (Attach page to exprovide code: | xprain why not) or | | | |
| | | | Yes No | |
| 6. Event Problem and Evalu | ation Codes (Ref | er to co | odina manual) | _ |
| Patient | 1 | 0, 10 00 | ong manua) | |
| Code | - | | - | |
| Device | 1_ | | | |
| Code | | | | |
| Method | - | | - - | |
| | === | | | |
| Results | | |]-[] | |
| Conclusions |]_[| | - | |
| <u> </u> | | 10. | | |
| 7. If Remedial Action Initiate | а, спеск гуре | 8. | Usage of Device | |
| | otification | | Initial Use of Device | |
| Repair In | spection | | Reuse | |
| | atient Monitoring | 0.1 | Unknown | _ |
| | lodification/ djustment | 1 4 | If action reported to FDA under 21 USC 360i(f), list correction/ | |
| Other: | | ' | removal reporting number: | |
| | | | | |
| 0. Additional Manufact | uror Narrativo | l | d / or 11. Corrected Data | _ |
| Additional mandiacti | arer Harrative | anc | or or Tr Corrected bata | |
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| | | | DEC 2 3 2014 | |
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CaseID: 10678313

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA

510(k)#

Product

Pre-1938

SEIZURE

Combination

OTC Product

8. Adverse Event Term(s)

Yes

Yes

√ Yes

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



COMPLAINT RECORD



10678313-01-00-03 COMPLAINT #: 2595 TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 12/04/14 HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET----T135 PRODUCT: SIZE: LOT NO.: A52214 135 TABLETS REPORTER: (b) (6) ADDRESS: (b) (6) CITY: STATE: COUNTRY: USA ZIP CODE: (b) (6) PHONE #: E-MAIL: 3 MONTHS AGO CHILD TOOK 2 TABLETS FOR THE FIRST TIME EVER IN THE EVENING AND THE NEXT MORNING
NATURE OF COMPLAINT: SHE HAD A SEIZURE SHORTLY AFTER WAKING. WENT TO THE HOSPITAL AND STAYED 3 DAYS. EEG AND MRI
WERE NORMAL AND PEDIATRIC NEUROLOGIST COULD NOT DETERMINE A CAUSE. ONLY HAD THAT ONE SEIZURE. SYMPTOMS WERE FLOPPING AROUND, EYES ROLLING BACK, WANTS A REFUND – SEND SRP. IS CONSIDEREING SEEING A LAWYER. WANTS TO KNOW WHY FACEBOOK INFORMATION SAYS THAT BABY TEETHING TABELTS CAUSES SEIZURES. CUSTOMER ALSO SENT THE FOLLOWING E-MAIL ON 12/04/14 TO MARY BORNEMAN: THIS IS JUST TO INFORM YOU THAT MY DAUGHTER HAD A SEIZURE ON YOUR TEETHING TABELTS AND I THINK YOU NEED TO PUT A RECALL ON YOUR TABLETS AND I AM GOING TO CONSULT A LAWYER. FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET PRODUCT RECEIVED FOR PRODUCT BEING RETURNED FOR INSPECTION: (CIRCLE ON INSPECTION: (CIRCLE ONE DATE REQUESTED PRODUCT BE RETURNED: UPS CALL TAG ISSUED: (CIRCLE ONE DATE PRODUCT RECEIVED: SECTION II: INVESTIGATION INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/04/14 ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: DATE: SECTION IV: ADVERSE EVENT REPORTS AE #: 1585 ADVERSE EVENT SERIOUS: EDYTA FRACKIEWICZ ADVERSE EVENT REPORTED ON: 12/04/14 BY: DEC 2 3 2014 SECTION V: REVIEWED BY MANAGEMENT BY: BY:

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





Serious Adverse Event SAE-0062-2014

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A52214, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A52214 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A52214. The Baby Teething bulk lot # 123494 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A52214. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A52214.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by Date

DEC **2 4** 2014

CaseID: 10678313

DEC 2 3 2014







| AE #: | 1585 | | | COMPLAIN | T#: 2595 | 5 | |
|---|---|---|--|---|--|--|--------------|
| SECTION | <u>l:</u> | PATIENT INFORMATIO | N (IF DIFFERENT F | ROM REPORTER ON FO | RM VD1) | | |
| NAME: | (| (b) (6) | | | | | |
| ADDRESS | 3: | | **** | | | | |
| CITY: | | | | STATE | (b) (6) | | |
| COUNTRY | Y: | USA | | ZIP COD | | | |
| PHONE #: | | (b) (6) | | | | | |
| E-MAIL: | - | | | | | | |
| SECTION | | PACKAGING INFORMA X PACKAGING LABEL HER | | AFFIX COPY OF (INCLUDE DRUG FAC | | | |
| Principality dates or residents and enter shirt and enter shirt and enter the same of the manufactured or washed, I seeker recommended to a washed, I seeker recommended to a washed to same enter soft and show for temporary principality (ALC) 1975, OwnACMI, St. 1975, St. | instant 2 m 3 lathert order for der 9 year greder sall et werdpoor in saver ger chief. If the chief is merben mers have for 5 desert or mers have for the plates is felle almost orderely grade CAREA PRESPACES, COPPER CIE. DANS AREA FRESPACES. | HONE DEATHIC TECHNIC TANK AND PROPERTY OF THE | gat the set and empression of an empirical set of the s | distributed American Company of the | The state of the s | Teething Tablets Tablets Tablets Teething Teething Tablets Teething Tablets Teething Tablets | |
| SECTION | <u>III:</u> | CORRECTIVE ACTION | <u>l:</u> | | | | |
| | | | | | | | _DSS |
| | | | | | BING ALL | | DEC 2 4 2014 |
| CORRECT | IVE ACT | TION(S) COMPLETED BY: | | | DATE: | | |
| SECTION REVIEWED | | NAGEMENT BY: | Partie | Hh. | | 12-15-14 | |
| BY: | | QA/QC DIRECT | au IOR | | DATE: _ | 12-15-1 | <u></u> |

mer Report

CaseID: 10684780

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

THE FUA Salety Information and Adverse Event Reporting Program

Y reporting of uct problems and product use errors

| | FDA USE ONLY | |
|------------------------|--------------|--|
| Triage unit sequence # | 577223 | |
| | | |
| | | |

| A. PATIENT INFORMATION | | #4 | Frequency | | |
|---|--|---|--------------------------|---|---|
| Patient Identifier 2. Age at Time of Event (a) (6) Date of Birth: | | #1 | | Taken by | / mouth |
| 11 Months | Female 20 lb | #2 | | | |
| (b) (6) | Male or kg | | | | |
| In confidence B. ADVERSE EVENT, PRODUCT I | PROBLEM OR ERROR | 3. Dates of Use (If unknown) | own, give duration) from | om/to 5. Event | Abated After Use |
| heck all that apply: | RODELIN OR ERROR | (or best estimate) | | Stopped | or Dose Reduced? |
| Adverse Event Product Problem | n (e.g., defects/malfunctions) | #1 09/01/2014 - 1 | 2/29/2014 | #1 🗸 Y | es No Doesn't |
| Product Use Error Problem with Dif | fferent Manufacturer of Same Medicin | | for the dedication | #2 🗆 Y | es No Doesn't |
| . Outcomes Attributed to Adverse Event (Check all that apply) | | 4. Diagnosis or Reason #1 Teething | for Use (Indication) | 8. Event | Reappeared After |
| | Disability or Permanent Damage | #2 | | | roduction? /es \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ |
| (mm/dd/yyyy) | Congenital Anomaly/Birth Defect | | | | Apply Apply Doesn't |
| Hospitalization - initial or prolonged | | 6. Lot# #1 | 7. Expiration D | | Apply |
| Required Intervention to Prevent Perman | | #2 | #2 | 9, NDC 7 | # or Unique ID |
| | Date of this Report (mm/dd/yyyy) | E. SUSPECT MEI | | | |
| | 12/29/2014 | 1. Brand Name | SIGAL DEVICE | | |
| See page 2 for complete text. | | I. Diana name | | | |
| while in the stringstree select | | 0.00 | | | |
| | | 2. Common Device Nam | 118 | | |
| | | | | | CTU |
| | | 3. Manufacturer Name, | City and State | | |
| | | | | DE | C 3 0 2014 |
| | | 4. Model # | Lot# | ((2011-2017-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1- | 5. Operator of Device |
| | | | | | Health Professional |
| | | Gatalog # | Expiration D | ate (mm/dd/yyyy) | Lay User/Patient |
| | | Atmint a | Espiration o | (uayyyy) | |
| Polarizat Tooled observed Date Inches | - Pates | - | | | Other: |
| Relevant Tests/Laboratory Data, including | A ruga | Serial # | Other# | | |
| | | | | ' | |
| | | 6. If Implanted, Give Da | ite (mm/dd/yyyy) | 7. If Explanted, G | live Date (mm/dd/yyyy) |
| | | 8. Is this a Single-use I | Device that was Rep | rocessed and Re | used on a Patient? |
| | | Yes No | | | : |
| | | 9. If Yes to Item No. 8, Er | nter Name and Addres | ss of Reprocessor | • |
| Other Relevant History, Including Preexis | ting Medical Conditions (e.g., | 7 | | | |
| allergies, race, pregnancy, smoking and alco See page 4 for complete text | onoi use, liver/kidney problems, etc.) | F 071155 40040 | OMITANT | ICAL PROPI | ICTS |
| h | | F. OTHER (CONC | | | |
| \mathcal{I} | | Froduct names and the | app auto (and au | a James II OF THE | y |
| | | | | | |
| | | | | | |
| | | | ee confidentiality | section on b | ack) |
| | | G. REPORTER (Se | | | - 23 C S C S C S C S C S C S C S C S C S C |
| PRODUCT AVAILABILITY | · | 1. Name and Address | | | |
| | end product to FDA) | 1. Name and Address Name: (b) (6) | | | DEC 9 A |
| roduct Available for Evaluation? (Do not se | 46.) | 1. Name and Address | | 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - | DEC 8 0 |
| roduct Available for Evaluation? (Do not se | 46.) | 1. Name and Address Name: (b) (6) Address. | <u> </u> | State: 78 | |
| roduct Available for Evaluation? (Do not se Yes No Returned to Manufa SUSPECT PRODUCT(S) | cturer on: (mm/dd/yyyy) | 1. Name and Address Name: (b) (6) Address. City: | /\ | State: Zi E-mail | |
| roduct Available for Evaluation? (Do not see Yes No Returned to Manufact SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from produ | cturer on: (mm/dd/yyyy) | 1. Name and Address Name: (b) (6) Address. | / \. | State: Zi E-mail | |
| roduct Available for Evaluation? (Do not see Yes No Returned to Manufacture). SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product Name: Hyland Teething Tablets | cturer on: (mm/dd/yyyy) uct label) | 1. Name and Address Name: (b) (6) Address. City: Phone # | | E-mail | P: |
| Product Available for Evaluation? (Do not see Yes No Returned to Manufactor). SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product Name: Hyland Teething Tablets Strength: Hyland Teething Tablet Manufacturer: | cturer on: (mm/dd/yyyy) uct label) | 1. Name and Address Name: (b) (6) Address. City: Phone # | | E-mail | P: Also Reported to: |
| D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product 1 Name: Hyland Teething Tablets Strength: Hyland Teething Table | cturer on: (mm/dd/yyyy) uct label) | 1. Name and Address Name: (b) (6) Address. City: Phone # | 3. Occupation | E-mail 4 | |

B.5. Describe Event or Problem (continued)

I've been giving my son Hyland Teething Tablets for the past few days and his cheeks have turned bright red and slightly swollen.

Individual Case Safety Report

10684780-01-00-02

DSS DEC **3 0** 2014 B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., ellergies, race, pregnancy, amoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race: White Medical Conditions:

Allergies:

Important Information:

RX Meds: OTC Meds:

Individual Case Safety Report



10684780-01-00-03

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

ser-facilities, rs and manufacturers ORY reporting

| / | Form Approved: OMB | No. 0910-0291, Expires: 6/30/201 See OMB statement on reverse |
|-------|--------------------|--|
| Mfr R | eport# 54973 | |
| UF/Im | porter Report # | |

CaseID: 10691018

Page 1 of 5

| | 1. Patient Identifi | er 2 | 2. Age at Time | | | 3. Sex | 4. Weigt | nt |
|------------------------------|--|-------|-------------------|----------|------------------|--------------------|--------------------|----------|
| | (b) (6) | | of Event: | 9 | Months | Female | | ibs |
| | | | Date | | | ✓ Male | or | |
| | In confidence | | of Birth: | ODLI | T DDODLE | | | kgs |
| | B. ADVERSE | EV | | | PROBLE | VI | | |
| | 1. Adverse E | | and/or [| | duct Problem (e | .g., defects/malfu | unctions) | |
| | 2. Outcomes Attr (Check all that a | | | vent | | | | |
| | Death: | | (mm/ad/yyyy) | | Disability o | r Permanent Dar | mage | |
| | Life-threat | ening | | | Congenital | Anomaly/Birth D | efect | |
| | | | initial or prolon | • | • | ous (Important M | | ents) |
| | | | | nt Perma | anent Impairment | | | _ |
| | 1 | | | | i . | | | |
| | | | | | | 12/10/2014 | | \dashv |
| PLEASE TYPE OR USE BLACK INK | 3. Date of Event (mm/dd/yyyy) 10/00/2014 5. Describe Event or Problem SON WAS HAVING SEIZURES IN (b) (6) BABY TEETHING TABLETS. ON THE DAY OF THE SEIZURE CHILD TOOK 1 TABLET IN THE MORNING. MOTHER PUT CHILD IN THE SWING AND THEN SHE FOUND HIM STIFF, ARMS WERE OUT, EYES ROLLED IN THE BACK OF THE HEAD, NOT RESPONDING TO MOTHER, SHAKING X 30 SECONDS. WHEN THE SEIZURE STOPPED THE CHILD VOMITED AND STARTED CRYING. TOOK HIM TO THE BATHROOM TO CLEAN HIM OFF AND HE HAD ANOTHER SEIZURE THAT LASTED 15 MINS. WENT TO THE HOSPITAL. IN THE HOSPITAL DID BLOODWORK (NORMAL) AND CHILD HAS AN MRI AND EEG SCHEDULED FOR NEXT MONTH. SPECIALIST SAID THE CHILD LOOKS NORMAL. (Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates | | | | | | S D ND LD | |
| | MRI AND EEG | SCI | HEDULED FO | OR NE | Rece | eived | | |
| | | | | | DEC \$ | 3 1 2014 | | |
| | | | | | C | DRinue on | page 3 | , |
| | 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) FAMILY HISTORY OF AUTISM ON THE FATHER'S SIDE. | | | | | | | |
| | | | | | | (Continue on | page 3, |) |

| RY reporting | UF/Importer F | Report # | | |
|---------------------------------|-----------------|----------------|--|---|
| f <u>5</u> | | | | EDA Hea Only |
| C. SUSPECT PRODU | UCT(S) | | | FDA Use Only |
| Name (Give labeled stren | | er) | | |
| #1 HYLAND'S BABY | TEETHING T | TABLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & Rou | ite Used | 3. Thera | ov Dates (| If unknown, g ive duration) |
| | | from/to | o (or best e | |
| #1 1TAB RUBBD ON | GUMBAORRS | _ #1 | | |
| #2 | | #2 | | |
| 4. Diagnosis for Use (Indica | , | | | Abated After Use ed or Dose Reduced? |
| #1 FEMP RELIEF OF | TEETHING | PAIN | | es No Doesn't |
| #2 | | 1 | | Apply Doesn't |
| 6. Lot # | 7. Exp. Date | | #2 🗌 Y | es No Doesn't |
| #1 | #1 | | | Reappeared After oduction? |
| #2 | #2 | | #1 TY | es No Doesn't |
| 9. NDC# or Unique ID | 1 | | <u>" </u> | — С Арріу |
| 54973-3127-3 | | ! | #2 🗌 Y | 'es No Doesn't |
| 10. Concomitant Medical P | roducts and Th | nerapy Dates | (Exclude | freatment of event) |
| SUSPECT MEDIC | - DEVICE | | (C | ontinue on page 3) |
| D. SUSPECT MEDIC 1. Brand Name | AL DEVICE | | | |
| | | | | |
| 2. Common Device Name | | | 2b. P | rocode |
| 3. Manufacturer Name, Cit | y and State | | | |
| 4. Model# | Lot # | | | 5. Operator of Device |
| | | | | Health Professional |
| Catalog # | Expiratio | on Date (mm/ | dd/yyyy) | Lay User/Patient |
| Serial # | Unique k | dentifier (UDI | 4) # | Other: |
| VI. 12. 1 | | , | ,, | |
| 6. If Implanted, Give Date (| (mm/dd/yyyy) | 7. If Expl | anted, Giv | ve Date (mm/dd/yyyy) |
| 8. Is this a Single-use Devi | ice that was Re | processed a | nd Reuser | d on a Patient? |
| Yes No | | | | |
| 9. If Yes to Item No. 8, Ente | er Name and Ad | idress of Re | processor | |
| | | | | DSS |
| 10. Device Available for Ev | _ | | | N 0 5 2015 |
| Yes No | Returned to | Manufacturer | | (mm/dd/yyyy) |
| 11. Concomitant Medical P | roducts and Th | nerapy Dates | (Exclude | |
| | | | | |
| | | | (C | ontinue on page 3) |
| E. INITIAL REPORTE | ER | | | Vining 11. p-g- , |
| 1. Name and Address (b) (6) | | | | JAN 0 2 2015 |
| Phone # (b) (6) | En | nail Address | | |
| | - Castination | | 14 1 | nitial Reporter Also Sent |
| . | . Occupation | | | Report to FDA |
| ☐ Yes 🕢 No 🕴 | NA. | | 11 | Yes No V Unk. |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| F. FOR USE BY | USER FAC | HLII Y/IIV | (POF | KTEK (υ | evices Only) | |
|---|----------------|---------------------|--------------------------|-----------------------|---|---|
| 1. Check One | | | 2. UF | /Importer R | Report Number | |
| User Facility | ∐ Impor | | | | | |
| 3. User Facility or Imp | orter Name/i | Address | | | | |
| 4. Contact Person | | | | 5. Phone N | umber | |
| Date User Facility of Importer Became Aware of Event (mn) | | Type of R | | | 8. Date of This Report (mm/dd/yyyy) | |
| 9. Approximate | 10. Event P | | | | ng manual) | |
| Age of Device | Patient | | | | | |
| | Code | | | | | |
| | Device Code | | | |]-[| |
| 11. Report Sent to FDA | | 12. Location | on Wh | ere Event (| Occurred | |
| Yes(mm/dd | √ <i>уууу)</i> | Ho | ospital ome orsing | Home nt Treatmen | Outpatient Diagnostic Facility Ambulatory Surgical Facility | у |
| □ No (mm/dd | /уууу) | | her: | | | |
| 14. Manufacturer Nam | | | | | (Specify) | _ |
| G. ALL MANUFA | CTURERS | 5 | | | | |
| 1. Contact Office (and | Manufacturi | ng Site for | Devic | es) | 2. Phone Number | |
| Name | | | | | 310-768-0700 | |
| EDYTA FRACKIEW: Address | ICZ | | | | 3. Report Source (Check all that apply) | , |
| HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA | | | | | Foreign Study Literature Consumer | |
| STANDARD@HYLANI | DS.COM | | | | Health Professional | 1 |
| 4. Date Received by | | 5. | | | User Facility | |
| Manufacturer (mm/d | | (A)NDA# | | | Company Representative | |
| 12/08/20 | | IND# | | | Distributor | |
| 6. If IND, Give Protoco | # | BLA# | | | Other: | |
| | | PMA | | | | |
| 7. Type of Report (Check all that apply) | | 510(k) # | | | | |
| 5-day 30-da | ву | Combinat Product | ion | Yes | | _ |
| 7-day Perio | | Pre-1938 | | Yes | | _ |
| 10-day Initial | | OTC Proc | duct | √Yes | | |
| <u> </u> | w-up # | | . = | | | |
| 9. Manufacturer Repor | | I . | | nt Term(s) VOMITIN | IG | |
| | | | | | | |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| | FDA USE ONLY |
|---|--|
| _F 5 | |
| · | |
| H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| | |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request Device Evaluation |
| | Device Evaluation |
| 3. Device Evaluated by Manufacturer? | Device Manufacture D ate (mm/yyyy) |
| Not Returned to Manufacturer | (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| Yes Evaluation Summary Attached | L |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | Yes No |
| | |
| 6. Event Problem and Evaluation Codes (Refer to | coding manual) |
| Patient Code - | - |
| Device | |
| Code | |
| Method - |]_[|
| | |
| Results | - - |
| | |
| Conclusions | |
| 7. If Remedial Action Initiated, Check Type | 3. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Treatenty Information | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| Adjustment | removal reporting number: |
| Other: | |
| | |
| 10. Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
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CaseID: 10691018

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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OMB Statement: "An agency may not conduct or sponsor, and a person is not required to responsit to a collection of information of info

Individual Case Safety Report

_AINT RECORD



| T. 1 T. T. T. T. T. T. T. T. T. T. T. T. T. | 91018-01-00-03 | COM | IPLAINT #: | 2597 | |
|---|---|---|---|---|--|
| IDDEN DI. | LU I TA I INDUNICIYIUA | DATE OF CO | | | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | | | BTETT135 | |
| SIZE: | 135 TABLETS | | | CAN'T FIND BO | OTTLE |
| REPORTER: (b) | (6) | | | | |
| ADDRESS: | | | | | West Control of the C |
| | | | | | |
| CITY: | | STATE: | (b) (6) | | |
| | JSA | ZIP CODE: | | | |
| PHONE #: |) (6) | | | | |
| E-MAIL: | SON WAS HAVING SEIZURES IN | b) (6) WHILE TAKING BAI | | | |
| SWING, STIFF, ARMS V SEIZURE STOPPED TH SEIZURE THAT LASTEI SCHEDULED FOR NEX ON THE FATHER'S SID | 1 TABLET IN THE MORNING. THEN CHILD ATE VERE OUT, EYES ROLLED IN THE BACK OF THE IE CHILD VOMITED AND STARTED CRYING. TO 15 SECONDS. WENT TO THE HOSPITAL. IN 1 THONTH. SPECIALIST SAID THE CHILD LOOK. IE. OFFERED A REFUND AND SHE ACCEPTED SECAUSE I WANTED THE LOT#. SHE SAID THA | E HEAD, NOT RESPONDING TO MC OK HIM TO THE BATHROOM TO C 'HE HOSPITAL HAD BLOODWORK S NORMAL. NO FAMILY HISTORY - PAID AROUND \$ 5.00. CALLED M | THE SWING THER, SHA LEAN HIM O (NORMAL) OF SEIZURI NOTHER ON | G. MOTHER SAV AKING X 30 SECO OFF AND HE HAD AND CHILD HAS ES. FAMILY HIST I 12/09/14 TO ASK | V CHILD IN THE NDS. WHEN THE ANOTHER AN MRI AND EEG ORY OF AUTISM I HER IF SHE |
| | FOR ADDITIONAL SPACE PLEASE U | SE REVERSE OR ATTACH A SEPA | RATE SHE | ET | |
| PRODUCT RECEIVED I | FOR Y N (CIRCLE ONE) | PRODUCT BEING RETUR | RNED FOR | INSPECTION: | Y N (CIRCLE ONE) |
| | | DATE REQUESTED PR | RODUCT BE | RETURNED: | |
| | | | UPS CALL | TAG ISSUED: | Y (CIRCLE ONE) |
| | | DAT | E PRODUC | T RECEIVED: | |
| SECTION II: | INVESTIGATION | | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INSPECTION REF | PORT. | | | |
| | | | | | _ |
| | WARDED TO PHARMACIST / NURSE FOR EVALU | | 12/08/14 EDYTA FF | RACKIEWICZ | · |
| SECTION III: | CORRECTIVE ACTION: | | | | |
| | | | | | DSS |
| | | | | | UAN 0 5 2015 |
| CORRECTIVE ACTION(| S) COMPLETED BY: | | DATE: | | |
| SECTION IV: | ADVERSE EVENT REPORTS | | AE #: | 1587 | - |
| ADVERSE EVENT SERI | ous: Y N | | | | |
| ADVERSE EVENT REPO | DRTED ON: 12/08/14 | BY: EDY | TA FRACKI | EWICZ | |
| SECTION V: | | 2 1.// | | | |
| REVIEWED BY MANAGE | EMENT BY: | walt | DATE: | 12-19 | -14 |
| BY: | Que 1/20 DIRECTOR | | DATE: | 12-19 | -14 |

JAN 0 2 2015

Individual Case Safety Report

10691018-01-00-04



Serious Adverse Event SAE-0065-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty (130) Adverse Events (AE) which also included forty (40) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

<u>\2 /17/14</u> Date

USS 2015

CaseID: 10691018



EVENT DATA FORM

| AE #: _ | 1587 | COMPLAINT #: |
|---------------------------------|--------------------------------|--|
| SECTION I | PATIENT INFORMATION (IF DIFFER | RENT FROM REPORTER ON FORM VD1) |
| NAME: ADDRESS: | (b) (6) | |
| CITY: COUNTRY: PHONE #: E-MAIL: | USA (b) (6) | STATE: ZIP CODE: |
| SECTION II | : PACKAGING INFORMATION: | |
| | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Toothing Tablets Toothing Tablets Toothing Tablets Toothing Toothing Toothing Tooling To |
| SECTION II | I: CORRECTIVE ACTION: | 200 |
| | | DSS |
| | | SAIR & 9 (0) |
| CORRECTI | VE ACTION(S) COMPLETED BY: | DATE: |
| SECTION IN | BY MANAGEMENT BY: | JAN 0 2 2015 DATE: 12-19-14 |
| BY: | QA/QC DIRECTOR | DATE: 12-19-14 |



y user-facilities utors a **ATOR**

| | Eorm Approved: O | MB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
|------|-------------------|---|
| Mfr | Report # 54973 | |
| 115/ | Importer Penart # | |

CaseID: 10723317

| FORM | FDΔ | 3500A | (2/13) |
|------|-----|-------|--------|
| | FDA | 3300M | 121131 |

Page 1 of A. PATIENT INFORMATION 1. Patient Identifier Age at Time 3. Sex 4. Weight of Event: Months Female or Date Male In confidence of Birth: kgs B. ADVERSE EVENT OR PRODUCT PROBLEM Adverse Event and/or Product Problem (e.g., defects/malfunctions) 2. Outcomes Attributed to Adverse Event (Check all that apply)
(b) (6)

✓ Death: Life-threatening

Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)

PLEASE TYPE OR USE BLACK

4. Date of This Report (mm/dd/yyyy) 07/09/2014 12/30/2014

Disability or Permanent Damage

Congenital Anomaly/Birth Defect Other Serious (Important Medical Events)

5. Describe Event or Problem (b) (6) CHILD PASSED AWAY AT THE AGE OF 9 MONTHS. WAS CHILD'S FIRST TIME USING THE BABY TEETHING TABLETS. MOTHER GAVE 2 TABLETS CRUSHED IN CHILD'S MOUTH. PUT CHILD TO BED AND THEN SHE GOT A BOTTLE, WHEN SHE FINISHED THE BOTTLE THEN THE BOTTLE WAS TAKEN AWAY BY THE MOTHER AND THE MOTHER LEFT HER. 45 MINUTES LATER MOTHER CHECKED ON HER AND SHE WAS DEAD IN THE CRIB. CHILD WAS FOUND WITH A PUDDLE OF VOMIT NEXT TO HER AT THE TIME OF DEATH. CAUSE OF DEATH UNKNOWN. ON THE DAY THIS HAPPENED CHILD WAS "FUSSING REALLY BAD" AND MOTHER FELT A TOOTH COMING IN ON THE BOTTOM.

(Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) CHILD BORN 5 WEEKS PREMATURE

(Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| and manufacturers | 54973 | | | | | |
|---|----------------------|----------------|----------------|---------------------------------|---------------|--|
| Y reporting | UF/Importer Report # | | | | | |
| 5 | | | | | FDA Use Only | |
| C. SUSPECT PRODUC | CT(S) | | | | | |
| Name (Give labeled strengti | | DIEMO | | | | |
| #1 HYLAND'S BABY TE | EETHING TA | BLETS | | | | |
| #2 | | 1 | | | | |
| 2. Dose, Frequency & Route | | from/to (or | | if unknown, gr estimate) | we duration) | |
| #1 2 TABS CRUSHED I | IN MOUTH | #1 | | | | |
| #2 | | #2 | | | | |
| Diagnosis for Use (Indication #1 TEMP RELIEF TEET | * | | | Abated After ed or Dose R | Reduced? | |
| - DEA | FILL SAIN | #1 | □ Y | es No | Doesn't Apply | |
| #2 REC 5. Lot # 7. | Exp. Date | #2 | Y | 'es No | Doesn't Apply | |
| #1 #A N # | | 8. 1 | Event | Reappeared | | |
| "' JAN ": | 1 4 2015 | | Reintre | oduction? | Doesn't | |
| NDC# or Unique ID | Service Military | #1 | 니 ^Y | es No | Apply | |
| 54973-3127-3 | DR | #2 | | es No | Doesn't Apply | |
| 0. Concomitant Medical Pro | ducts and Ther | apy Dates (Ex | clude | treatment of e | event) | |
| | | | | | | |
| | | | | | | |
| | | | 10 | ontinue on | pade 3) | |
| D. SUSPECT MEDICA | L DEVICE | | Ų | | F-90 0/ | |
| Brand Name | | | | | | |
| . Common Device Name | | | 2b. P | rocode | | |
| Manufacturer Name, City a | ind State | | <u></u> | | | |
| | State | | | | | |
| . Model # | Lot# | | | 5. Operator | of Device | |
| | | | | l' | Professional | |
| Catalog # | Expiration I | Date (mm/dd/y | ууу) | | er/Patient | |
| Serial # | Unique Ider | ntifier (UDI)# | | Other: | | |
| If implement of the second | n/dd/ | 7 1/2 | لبِ | n Post d | idl | |
| If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) | | | | | | |
| Is this a Single-use Device | that was Repro | ocessed and R | leused | on a Patien | t? | |
| Yes No | Vamo and Add | pge of Da | 000 | | | |
| If Yes to Item No. 8, Enter I | June dila Addr | ⊶a ∪r Keproc | -ess Or | | | |
| | | | | | l | |
| Device Available for Fort | iation? /De | sand to FDA | | | | |
| Device Available for Evalue Yes No | Returned to Ma | • | | |] | |
| | | | | (mm/dd/yy) | | |
| Concomitant Medical Proc | uucts and Ther | αpy Dates (Ελ | ciude | reatment of 6 | event) | |
| | | | | | 1 | |
| . INITIAL REPORTER | | | (C | ontinue on | page 3) | |
| Name and Address | | | | - O | | |
|) (6) | | | L | AN 15 | 2015 | |
| | | | J | mi t I 9 , | EUIJ | |
| USA | | | | | | |
| none # | Email | Address | | | | |
|) (6) | | | | | | |
| Health Professional? 3. O | JAN 1 | 4 204E | | nitial Reporte Report to FDA | | |
| Yes No NA | AUIT 1 | 7 (01) | 1 [| Yes N | _ | |



F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

7. Type of Report

Follow-up #

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial

☐ Importer

3. User Facility or Importer Name/Address

User Facility

4. Contact Person

9. Approximate

Yes

☐ No

No.

Name

Address

Age of Device

11. Report Sent to FDA?

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

Patient

Code Device

Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

12/30/2014

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

7. Type of Report

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

2. UF/Importer Report Number

5. Phone Number

8. Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Study

Literature ✓ Consumer

User Facility

Distributor

Other:

Company Representative

3. Report Source (Check all that apply)

Health Professional

2 of 5

H. DEVICE MA

1. Type of Reportal

3. Device Evaluated Not Returne

7. If Remedial Actio

10. Additional M

6. Event Problem a

| | CaseID: 10723317 |
|--|--|
| | FDA USE ONLY |
| | |
| DEVICE MANUFACTURERS ONL | v |
| ype of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Inform ation |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| Device Evaluated by Manufacturer? | 4. Device Manufacture Date (mm/yyyy) |
| Not Returned to Manufacturer | (111111))))) |
| Yes Evaluation Summary Attached | |
| No (Attach page to explain why not) or | 5. Labeled for Single Use? |
| provide code: | Yes No |
| vent Problem and Evaluation Codes (Refer t | to coding manual) |
| Patient Code - | - |
| Device Code - | - |
| Method | |
| Results | - |
| Conclusions |]-[|
| Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | 9. If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| Additional Manufacturer Narrative | and / or 11. Corrected Data |
| | |
| | |
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| | |

JAN 1 5 2015

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DSS

| | Product Yes Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(s) DEATH | |
|--|--|--|
| This section applies only to require public reporting burden for this collinates per response, including the tinources, gathering and maintaining the finformation. Send comments regard offection of information, including suggi | lection of information has been ne for reviewing instructions, s data needed, and completing ing this burden estimate or an | n estimated to average 66 searching existing data g and reviewing the collection y other aspect of this |

(A)NDA#

IND#

BLA# PMA/

510(k) #



MPLAINT RECORD



| 10723 | 3317-01-00-03 | COMPLAINT #: | 2601 | |
|---|---|---|---|--|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 12/26/14 | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT40 | |
| SIZE: | 40 TABLETS | LOT NO.: | THREW AWAY | BOTTLE |
| REPORTER: | (b) (6) | | | |
| ADDRESS: | | | | |
| - | | | | <u>.</u> |
| CITY: | | STATE: (b) (6) | | |
| COUNTRY: | USA | ZIP CODE: | | |
| PHONE #: | b) (6) | | | |
| E-MAIL: | CUSTOMER SENT THE FOLLOWING E-MAIL | MESSAGE, LOAVE MY DALIGHTED | THE LIVE AND D | TEETLING |
| MONTHS. WAS HER THEN SHE GOT A BO 45 MINUTES LATER M MOTHER THINKS BAH HAS BEEN DOING REBABIES. SHERIFF IS CHILD WAS FOUND Y RESUCITATE HER FODAY THIS HAPPENED | LLED THE CUSTOMER ON 12/30/2014 TO OBTAIN MORE INFO FIRST TIME USING THE BABY TEETHING TABLETS. GAVE 20 ITTLE, WHEN SHE FINISHED THE BOTTLE THEN THE BOTTL MOTHER CHECKED ON HER AND SHE WAS DEAD IN THE CEPTOR OF THE SEARCH ON THE INTERNET ABOUT BABY TEETHING TABLE SEARCH ON THE INTERNET ABOUT BABY TEETHING TABLE LOOKING THROUGH MEDICAL FILES AND LOOKING INTO THE WITH A PUDDLE OF VOMIT NEXT TO HER AT THE TIME OF DOOR AN HOUR BUT WERE UNSUCCESSFUL. MOTHER DOES IN CHILD WAS "FUSSING REALLY BAD" AND MOTHER FELT A DOOR REPLACEMENT. | TABLETS CRUSHED IN CHILD'S ME WAS TAKEN AWAY BY THE MOTING ALL KINDS AND DIE. MOTHER DID NOT CONTETS AND READING THAT BELLADONE BABY TEETHING TABLETS TO INFORMED THE BABY TEETHING TABLETS TO INFORMED TO THE WORLD AMENOT HAVE A CAUSE OF DEATH OF TOOTH COMING IN ON THE BOTTO, JUST RECEIVED A BOTTLE OF MI | OUTH. PUT CHII HER AND THE M OF TESTS FOR ACT HYLAND'S S NNA IS CAUSING DETERMINE A CA ULANCE CAME (DEATH CERTIFI DM. CHILD WAS LK. CUSTOMER | LD TO BED AND OTHER LEFT HER. CAUSE OF DEATH. GOONER BUT SHE G SEIZURES IN AUSE OF DEATH. OUT AND TRIED TO ICATE. ON THE |
| | TON ADDITIONAL STAGE FELAGE USE NEVERS | SE ON ATTACITÀ SEPANATE SHE | _, | |
| PRODUCT RECEIVED | FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR I | NSPECTION: | Y (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT BE | RETURNED: | |
| | | UPS CALL | TAG ISSUED: | Y (CIRCLE ONE) |
| | | DATE PRODUC | RECEIVED: | |
| SECTION II: | INVESTIGATION | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | |
| | | | | |
| MANAGEMENT | | | | |
| ADVERSE EVENT FOR | RWARDED TO PHARMACIST / NURSE FOR EVALUATION ON | : 12/26/14 | | |
| | | | | |
| ADVERSE EVENT FOR | RWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | ACKIEWICZ | |
| | RWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | | ACKIEWICZ | |
| | | | ACKIEWICZ | |
| | | | ACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | ACKIEWICZ | |
| SECTION III: | CORRECTIVE ACTION: | | | Dec |
| SECTION III: | CORRECTIVE ACTION: | EDYTA FR | | DSS |
| SECTION III: CORRECTIVE ACTION SECTION IV: | CORRECTIVE ACTION: W(S) COMPLETED BY: ADVERSE EVENT REPORTS | EDYTA FR | | |
| SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT SEF | CORRECTIVE ACTION: N(S) COMPLETED BY: ADVERSE EVENT REPORTS RIOUS: Y N | EDYTA FR | 1591 | |
| SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT SER | CORRECTIVE ACTION: N(S) COMPLETED BY: ADVERSE EVENT REPORTS RIOUS: Y / N | DATE: | 1591 | JAN 1 5 20 |
| ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTION SECTION IV: ADVERSE EVENT SER ADVERSE EVENT REF SECTION V: REVIEWED BY MANAGE | CORRECTIVE ACTION: N(S) COMPLETED BY: ADVERSE EVENT REPORTS RIOUS: PORTED ON: 12/26/2014 | DATE: | 1591 | |

cc: QA / QC Packaging

Production Shipping / Receiving JAN 1 4 2015

Form # VD1





Serious Adverse Event SAE-0069-2014

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that since the reported occurrence of the incident in July 2014 that there have been a total of two hundred sixty seven (267) complaints received, of those one hundred sixty-six (166) were further classified as Adverse Events (AE) and of those forty-six (46) Serious Adverse Events (SAE) have been reported for Hyland's Baby Teething Tablets (BTET). None of those other reports indicated any "death" related to the use of our products. The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

Date

12/31/14

DSS JAN 1 5 2015

CaseID: 10723317







| AE #: | 1591 | | COMPLAINT #: 2601 | |
|---------------------------|------------|---|--|--|
| SECTION I | <u>:</u> | PATIENT INFORMATION (IF DIFFERENT FI | ROM REPORTER ON FORM VD1) | |
| NAME: ADDRESS | : | (b) (6) | | |
| CITY: | | | STATE: (b) (6) | |
| COUNTRY: PHONE #: E-MAIL: | | USA (b) (6) | ZIP CODE: | |
| SECTION I | <u>l:</u> | PACKAGING INFORMATION: | | |
| | AFFI | X PACKAGING LABEL HERE THE PACKAGING LABEL | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Identification Identificat | |
| SECTION II | <u>li:</u> | CORRECTIVE ACTION: | | |
| CORRECTI | VE ACT | ION(S) COMPLETED BY: | DATE: | |
| SECTION IN | | NAGEMENT BY: Pro Baum QA/QC DIRECTOR | DATE: <u>01-02-15</u> DATE: <u>01-02-15</u> | |



y user-facilities, utors and manufacturers ATORY reporting CaseID: 10792549

| OMB No. 09 | 10-0291, Expire | s: 6/30/2015 |
|------------|-----------------|---------------|
| See | OMB statemen | t on reverse. |

| | | TOTAL DISTORTION | 1010130 |
|--------------|----------|------------------|---------|
| Afr Report # | 54973 | | |
| F/Importer F | Report # | | |
| | | | |

| FORM FDA | 3500A | (2/13) |
|----------|-------|--------|
|----------|-------|--------|

PLEASE TYPE OR USE BLACK

Page 1 d A. PATIENT INFORMATION 1. Patient Identifier 2. Age at Time 3. Sex 4. Weight (b) (6) of Event: 5 Months Female or Date ✓ Male In confidence of Birth: kgs B. ADVERSE EVENT OR PRODUCT PROBLEM 1. 📝 Adverse Event and/or Product Problem (e.g., defects/malfunctions) Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) Date of This Report (mm/dd/yyyy) 01/16/2015 01/28/2015 5. Describe Event or Problem CHILD HAD ASPHYXIA AT BIRTH AND WAS DELIVERED VIA EMERGENCY C-SECTION RESULTING IN BLEEDING ON THE BRAIN WHICH PREDISPOSES HIM TO SEIZURES. CHILD HAD A SEIZURE AND HE WAS REALLY TIRED PRIOR TO THIS TIME. HE STARTED HAVING 3 - 4 SEIZURES PER DAY. TREATED WITH KEPPRA AND TOPAMAX. CT SCAN WAS NORMAL. EEG WAS ABNORMAL (UNKNOWN RESULTS). CURRENTLY HAVING 1 - 2 SEIZURES PER DAY EVEN WHILE ON ANTI-SEIZURE MEDICATION. Received FEB 11 2015 COR (Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates EEG WAS ABNORMAL (UNKNOWN RESULTS). CT SCAN WAS NORMAL. (Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) CHILD HAD ASPHYXIA AT BIRTH AND WAS DELIVERED VIA EMERGENCY C-SECTION RESULTING IN BLEEDING ON THE BRAIN WHICH PREDISPOSES HIM TO SEIZURES. (Continue on page 3)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| oki reporting | O / / / / / / / / / / / / / / / / / / / | epui i ir | | | |
|--|---|-----------------|-------------------------|-------------------------|----------------|
| of ⁵ | | | | | |
| C. SUSPECT PROD | | | | | FDA Use Only |
| 1. Name (Give labeled stre #1 HYLAND'S BABY | , | | | | |
| | 100111110 17 | ADDETS | | | |
| #2 | | 16 = | | | |
| 2. Dose, Frequency & Ro | | 3. Therapy | y Dates ((or best e | lf unknown, stimate) | give duration) |
| #1 2TABSINFORMUL | AX1MONTH | #1 | | | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Indi | | - 1 | | Abated Afted or Dose | |
| #1 TEMP RELIEF O | F TEETHING S | SX . | #1 Y | _ | Doesn't |
| #2 | | - | | | Apply Doesn't |
| 6. Lot# | 7. Exp. Date | | #2 Y | es No | Apply |
| #1A63714 | #1 | | | Reappeared | After |
| #2 | #2 | [; | #1 🔲 Y | | Doesn't |
| 9. NDC# or Unique ID | | | <u> </u> | | Apply Doesn't |
| 54973-3127-2 | | - 1 | #2 Y | | ☐ Apply |
| Concomitant Medical KEPPRA, TOPAMAX, | AND TYLENOL | rapy Dates (| Exclude | reatment of | event) |
| , | | - | | | |
| | | | | | |
| | | | (C | ontinu e oi | n page 3) |
| D. SUSPECT MEDIC | CAL DEVICE | | , | | , page o |
| 1. Brand Name | | | | | |
| 2. Common Device Name | | | 2b. P | rocode | |
| 3 Manufacturer Name Ci | tr and Ctate | | | | |
| 3. Manufacturer Name, Ci | ty and State | | | | |
| | | | | | |
| 4. Model # | Lot # | | | 5. Operato | |
| Catalog # | Expiration | Date (mm/do | l/yyyy) | | Professional |
| 0.114 | | | | | ser/Patient |
| Serial# | Unique Ider | ntifier (UDI) i | # | Other: | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explan | nted, Give | e Date (mm | /dd/yyyy) |
| | | | | | |
| 8. Is this a Single-use Dev Yes No | ice that was Repro | ocessed and | l Reused | on a Patie | nt? |
| 9. If Yes to Item No. 8, Ent | er Name and Addr | ess of Repr | ocessor | | |
| | | | | | |
| | | | | | |
| 10. Device Available for Ex | valuation? (Do not | send to EDA |) | | |
| | Returned to Ma | | | | İ |
| | | | | (mm/dd/y) | |
| 11. Concomitant Medical F | roducts and Thera | apy Dates (| ⊏xciud o f | realment of | event) |
| | | | | | |
| | | | (Co | ontinue on | page 3) |
| E. INITIAL REPORT | ER | | | HE | |
| 1. Name and Address | | 4 | | D2 | <u>ح</u> |
| (b) (6) | | | _ | EB 12 | 2015 |
| | | | | ED I A | , 2013 |
| | | | | | |
| Phone # (b) (6) | Email (b) (6) | Address | | | |
| 2. Health Professional? 3. | Occupation | | [4, In | itial Report | er Also Sent |
| 1 | √A | * " | | port to FD | A _ |
| u | | | 1 L | Yes 🗸 N | lo Unk. |

1. Check One 2. UF/Importer Report Number User Facility Importer 3. User Facility or Importer Name/Address 4. Contact Person 5. Phone Number Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) 7. Type of Report 8. Date of This Report Initial Follow-up # Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) Patient Device Code 11. Report Sent to FDA? 12. Location Where Event Occurred Outpatient
Diagnostic Facility Hospital Yes _ (mm/dd/yyyy) Home ☐ No Ambulatory
Surgical Facility Nursing Home 13. Report Sent to Manufacturer? Outpatient Treatment Yes Facility (mm/dd/yyyy) ☐ No Other: (Specify) 14. Manufacturer Name/Address G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number Name 310-768-0700 EDYTA FRACKIEWICZ 3. Report Source (Check all that apply) Address Foreign HYLAND'S, INC. Study 154 W. 131ST STREET LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 01/22/2015 Distributor IND# 6. If IND, Give Protocol # Other: BLA# PMA/ 7. Type of Report 510(k)# (Check all that apply) Combination Product 5-day 30-day Yes Periodic 7-day Pre-1938 Yes 10-day 📝 Initial OTC Product √ Yes 15-day Follow-up# 9. Manufacturer Report Number 8. Adverse Event Term(s) ATONIC SEIZURES, LETHARGY 54973 AE # 1596

This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| 1 | | FDA USE ONLY |
|------------------------------------|------------------------|--|
| . 5 | | |
| 5 | | |
| H. DEVICE MANUFAC | URERS ONLY | |
| Type of Reportable Event | | 2. If Follow-up, What Type? |
| Death Serious Injury | | Correction Additional Information |
| Malfunction | | Response to FDA Reques |
| | | Device Evaluation |
| 3. Device Evaluated by Manu | cturer? | 4. Device Manufacture Date |
| Not Returned to Manu | | (mm/yyyy) |
| Yes Evaluation | ımmary Altached | |
| No (Attach page to exprovide code: | nin why not) or | 5. Labeled for Single Use? |
| provide dede. | | Yes No |
| 6. Event Problem and Evalua | n Codes (Refer to d | coding manual) |
| Patient | | |
| Code | | |
| Device Code | | |
| Method | -[|]_ |
| | _ | |
| Results | |]-[] |
| Conclusions | - |]- |
| 7. If Remedial Action Initiated | Check Type 8. | Usage of Device |
| Recall No | cation | Initial Use of Device |
| Repair | ection | Reuse |
| | nt Monitoring | Unknown |
| | fication/ 9. stment | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: |
| Other: | | removarreporting number: |
| | | |
| 0. Additional Manufactur | Narrative an | d / or 11. Corrected Data |
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CaseID: 10792549

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@jda.hhs.gov

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Please DO NOT RETURN this form to the above PRA Staff email address.

PLAINT RECORD



| 107925 | 549-01-00-03 | COMPLAINT #: | 2606 |
|---|---|---|--|
| TAKEN BY: | EDYTA FRACKIEWICZ | DATE OF COMPLAINT: | 01/22/15 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTETT250 |
| SIZE: | 250 TABLETS | LOT NO.: | A63714 |
| REPORTER: _(b) (6) | | | |
| ADDRESS: | | | |
| _ | | | |
| CITY: | | STATE: (b) (6) | |
| COUNTRY: USA | | ZIP CODE | |
| PHONE #: (b) (6) | | | |
| E-MAIL: | | | |
| THE CHILD'S FORMULA EV LAST DOSE OF BABY TEET TAKEN TO (D) (6) AND (MOTHER DOES NOT KNOW GIVEN BABY TEETHING TA SENT THE FOLLOWING E-N TEETHING FOR A COUPLE HERE RECENTLY WITHIN T SEIZURES 3 – 4 TIMES A D. | SPOKE WITH CUSTOMER ON 01/27/2015. O PREDISPOSES HIM TO SEIZURES. HAD AS TEETHING TABLETS COULD HAVE CAUSED CHILD'S ERY OTHER FEEDING X 1 MONTH. CHILD HAD A SEI HING TABLETS WAS ON 01/15/15. STARTED HAVING HEWAS HOSPITALIZED THERE AND WAS GIVEN AN N THE RESULTS). CURRENTLY HAVING 1 – 2 SEIZUF BLETS SINCE 01/15/15 AND GIVES TYLENOL FOR TE MAIL MESSAGE: DEAR SIR OR MADAM: I AM WRITIN OF MONTHS NOWI INQUIRED FROM SEVERAL PEO OF MONTHS NOWI INQUIRED FROM SEVERAL PEO THE LAST 2 WEEKS MY SON HAS BECOME SUPER SI AYI WILL NO LONGER USE THIS PRODUCT ON MY EMMY SON SPENT 3 DAYS IN THE PEDIATRIC NEU | SPHYXIA AT BIRTH WITH EMERGENC ATONIC SEIZIIPES, WAS GIVING T IZURE ON (b) (6) AND HE WAS RE. 63 - 4 SEIZURES PER DAY. TOOK H EEG AND CT SCAN. CT SCAN WAS RES PER DAY EVEN WHILE ON ANTI ETHING PAIN. WOULD LIKE A REFU G AS A CONCERNED PARENT OF A IPLE ON TEETHING TABLETS AND T LEEPY AND LETHARGICWELL THE CHILD EVEN THOUGH I AM NOT 100 | CY C-SECTION. MOTHER HE TEETHING TABLETS 2 TABS IN ALLY TIRED PRIOR TO THIS TIME. IIM TO THE ER AND THEN HE WAS NORMAL. EEG WAS ABNORMAL SEIZURE MEDICATION. HAS NOT ND. PAID \$9.98. CUSTOMER 5MO OLD BOY WHO HAS BEEN HEY HAVE WORKED GREAT BUT N CAME SEIZURES AND HE HAD % SURE IF THE TEETHING |
| | FOR ADDITIONAL SPACE PLEASE USE REVE | DSE OD ATTACH A SEDADATE SHE | - |
| | TON ADDITIONAL SPACE FEEASE USE NEVER | SE OR ATTACH A SEPARATE SHE | =1 |
| PRODUCT RECEIVED FOR INSPECTION: | Y (CIRCLE ONE) | PRODUCT BEING RETURNED FOR I | NSPECTION: Y N (CIRCLE ONE) |
| | | DATE REQUESTED PRODUCT BE | RETURNED: |
| | | UPS CALL 1 | Y N (CIRCLE ONE) |
| | | DATE PRODUCT | RECEIVED: |
| SECTION II: IN | VESTIGATION | | |
| IN TOTAL | | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | - Vertical Control of the Control of |
| | | | |
| ADVERSE EVENT FORWAR | DED TO PHARMACIST / NURSE FOR EVALUATION OF | N: 01/22/15 | |
| ADVERSE EVENT FORWAR | DED TO PHARMACIST / NURSE FOR EVALUATION BY | EDYTA FR | ACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| | T-717-0-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1 | | |
| | 7-7-4-5-4-5-4-5-4-5-4-5-4-5-4-5-4-5-4-5- | 77.48 | |
| CORRECTIVE ACTION(S) CO | OMPLETED BY: | DATE: | ——DSS |
| SECTION IV: ADV | VERSE EVENT REPORTS | AE #: | 1596 |
| | | | FEB 1 2 2015 |
| ADVERSE EVENT SERIOUS: | | | |
| ADVERSE EVENT REPORTE | ED ON: 01/22/15 | BY: EDYTA FRACKIE | WICZ |
| SECTION V: | \mathcal{O}_{a} | 11 | Mars ² |
| REVIEWED BY MANAGEMEN | VT BY: | DATE: | 02-02-18 |
| BY: | Gun Bam | DATE: | 02-02-15 |

cc: QA / QC Packaging

Production Shipping / Receiving FEB 1 1 2015

Form # VD1





Serious Adverse Event SAE-0005-2015

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A63714, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A63714 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A63714. The Baby Teething bulk lot # 118748 was tested for total Atropine and Scopolamine and the results were with in specification of ≤(4) opm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

A review of the Customer Complaint system found one other complaint (CC-0896-2014) related to this lot. The complaints were reviewed and they do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A63714.

Manufacture and processing occurred within established procedures to ensure product quality.

Prepared by

14-14-15 01. 29-15

Date

v2001-30-15 (EE)

DSS FEB 1 2 2015

CaseID: 10792549



SE EVENT DATA FORM



| AE #: | 1596 | COMPLAIN | T#: 2606 | |
|--|--|--|---|------------------|
| SECTION | I: PATIENT INFORMATI | ON (IF DIFFERENT FROM REPORTER ON FO | <u>RM VD1)</u> | |
| NAME: | (b) (6) | | | |
| ADDRESS | : : | | | |
| | | | (b) (6) | |
| CITY: | | STATE | | |
| COUNTRY PHONE #: | (b) (6) | ZIP CODE | E: | |
| E-MAIL: | | | | |
| | - | | | |
| SECTION | II: PACKAGING INFORM | ATION: | | |
| | AFFIX PACKAGING LABEL HE | (INCLUDE DRUG FACT | OUTER CARTON HERE 'S AND PRINCIPAL DISPLAY ANELS) | |
| Fe Secretary for a Secretary for the Secretary f | The principle of the property of the principle of the pri | man part and man and and and and and and and and and a | | |
| SECTION I | II: CORRECTIVE ACTIO | ł <u>:</u> | | |
| | | | | , 1 .3 |
| CORRECTI | VE ACTION(S) COMPLETED BY: | | DATE: DS | S |
| 00/11/2011 | TENOTION (C) COM LETER BY. | | FEB 12 | |
| SECTION I | <u>/:</u> | 1 | 16014 | LUIJ |
| REVIEWED | BY MANAGEMENT BY: | DUM | DATE: 02-03-15 | |
| BY: | QUA / QC DIRECT | Paul | DATE: 02-03-15 DATE: 02-02-15 | |
| | | | EED 4.4.000 | |



UIU

THE FUA Safety Information and

sumer Report

CaseID: 10855443

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

| RY reporting of | FDA USE ONLY |
|--------------------|------------------------|
| duct problems and | Triage unit sequence # |
| product use errors | 583620 |

| Adv | erse Event F | Reporting Prog | Jra m | | 101 | | | | | りとク | 64 |) |
|---------------|---|---|------------------------------|--|----------------------------|----------------|---|--------------|----------------|-------------|-------------------|-------------------------|
| Α. | PATIENT IN | FORMATION | | | | 2. 1 | Dose or Amount | _ | Frequency | | oute | _ |
| 3 | | 2. Age at Time of | Event or | 3. Sex | 4. Weight | #1 | 2-3 tablets | 4x/ | Four tim | nes Ta | ken by m | outh |
| yns | pecified | Date of Birth: 4.5 Months | | Female | 14.5 _{lb} | | day | | daily | | | |
| | | (b) (6) | | [2] | or . | #2 | | | | | | |
| | n confidence | | | ✓ Male | Kg | | | | | L | | |
| | ADVERSE E ck all that apply: | EVENT, PRODI | JCT PRO | BLEM OR EF | RROR | (or | tes of Use (If unki best estimate) | | | s | topped or | Dose Reduced? |
| . [√ | Adverse Event | Product P | roblem (e.g | ., defects/malfunc | tions) | | 2/07/2015 - | 02/14/ | 2015 | | 1 [∠] Yes | No Doesn' |
| | Product Use E | rror 🔲 Problem v | ith Differer | t Manufacturer o | of Same Medicine | #2 | | | | # | 2 Yes | No Doesn |
| | Outcomes Attribu Check all that app | ited to Adverse Ev | ent | | | 1 | ignosis or Reaso Teething in it | | (Indication) | L | | Apply appeared After |
| ,, | Death: | ny) | ☑ Dicab | ility or Permanent | Damaga | " ' | reeching in it | manc | | ١ | Reintrod | uction? |
| _ | (r | mm/dd/yyyy) | | • | • | #2 | | | | # | 1 Nes | No ✓ Doesn |
| L | Life-threatening | • | | enital Anomaly/Bir | | | | | | | 2 Yes | |
| _ | - | - initial or prolonge | | | | 6. Lot | t# 21114 | 7. E #1 | xpiration Da | _ | | Apply |
| L |] Required Interv | rention to Prevent P | ermanent Ir | npairment/Damag | e (Devices) | #2 | | _ | | | | Unique ID |
| | ate of Event (mr | n/dd/yyyy) | - 1 | of this Report (r | mm/dd/yyyy) | | | #2 | | ١ | 4973-31 | 127-1 |
| | 2/15/2015 | | - | 15/2015 | | | SUSPECT ME | DICAL | DEVICE | | | |
| | | Problem or Production complete | | | | 1. Bra | and Name | | | | | |
| 3 | ce bade v r | or comprete | cent. | | | _ | | | | | | |
| | | | | | | 2. Co | mmon Device Na | me | | | | CTU |
| | | | | | | | | | | | | ~10 |
| | | | | | | 3. Ma | nufacturer Name | , City and | d State | | EED | 1 0 2045 |
| | | | | | | | | | | | LEB | 1 8 2015 |
| | | | | | | | | | | | | |
| | | | | | | 4. Mo | del # | Т | _ot # | | 5. | Operator of Device |
| | | | | | | | | | | | l | Health Professions |
| | | | | | | | -l# | | | -4 ·· | | |
| | | | | | | Ca | talog # | - ' | Expiration Da | ate (mm/de | ועעעעים | Lay User/Patient |
| | | | | | , , | | | 1 | | | | Other: |
| 6. R | elevant Tests/La | aboratory Data, Inc | cluding Dat | es | | Sei | rial # | • | Other# | | | |
| | | | | | | | | | | | | |
| | | | | | | 6. If Ir | mplanted, Give D | ate (mm/ | dd/yyyy) 7 | . If Explai | nted, Give | Date (mm/dd/yyyy) |
| | | | | | | <u></u> | | | | | | |
| | | | | | | | his a Single-use | Device th | iat was Repr | ocessed a | and Reuse | ed on a Patient? |
| | | | | | | _= | es to Item No. 8, E | nter Nam | e and Addres | s of Repro | cessor | |
| | | | | | | | • | | | | | |
| 7. O | ther Relevant Hi llergies, race, pre | story, Including P gnancy, smoking a | reexisting I nd alcohol u | Medical Conditio se, <i>liver/kidney pr</i> | ns (e.g., oblems, etc.) | | | | | | | |
| S | See page 4 f | or complete | text. | | , , | F. O | THER (CONC | COMITA | NT) MED | ICAL PE | RODUCT | rs |
| | | | | | | | uct names and th | | | | | |
| | | | | | | | | | | | - | |
| | | | | | | | | | | | | |
| | | | | | | | 1 | | | | · . | |
| | | | | | | | EPORTER (S | ee com | fidentiality | section | on back | () |
| C. | PRODUCT A | VAILABILITY | | | | 1. Ma i | me and Address | | | | | D - |
| Pro | duct Available fo | or Evaluation? (Do | not send pr | oduct to FDA) | | , | | | | | | US |
| 4 | Yes No | Returned to M | lanufacturer | | | | | | | | | ED - |
| $\overline{}$ | | | | | /dd/yyyy) | | | | | | | DS EB18 |
| _ | SUSPECT P | RODUCT(S) Manufacturer (from | product to | ol) | | Phone | e # | | F | -mail | | |
| | ame, Strength, N Name: teethir | , | product IBD | ei) | | (b) (6) | | | |) (6) | | |
| | | ds teething | tablets | | | | | | | | | |
| | Manufacturer: | | | | | 2. He a | alth Professional | ? 3. Occ | upation | | 4. Als | so Reported to: |
| 2 1 | Name: | | | | | | Yes No | | | | | Manufacturer |
| | Strength: | | | | | - | ou do NOT want y | | - | | \dashv \vdash | User Facility |
| ٨ | Manufacturer: | 1/1/00\ Si | hmission of | | | to t | the manufacturer, | place an ' | 'X" in this bo | k: 🗌 | \sqcup | Distributor/Importer |

CaseID: 10855443

B.5. Describe Event or Problem (continued)

Severe constipation in infant Severe agitation

Individual Case Safety Report

10855443-01-00-02

DSS FEB 1 8 2015 CaseID: 10855443
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race:White Medical Conditions: N/a

Allergies: Nka

Important Information:

RX Meds: Zantac

OTC Meds: Infant Tylenol, polysivol

Individual Case Safety Report



10855443-01-00-03

DSS FEB 1 8 2015



ors and manufacturers ORY reporting

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| | | | | | 1 | 9 |
|---|-----|------|-------|------|---|---|
| J | sei | r-fa | cilit | ies, | | |

| Pag. | CaseID: 10862441 Form Approved: OMB No. 0910-0291, Expires: 6/30/201: See OMB statement on reverse |
|-----------|--|
| fr Report | # 54973 |

| | FORM FDA 350 | 0A (2/13) | | | Page | | |
|------------------------------|--|---|--------------------|--------------------|-----------|--|--|
| | A. PATIENT INF | ORMATION | | | | | |
| | 1. Patient Identifier (b) (6) | 2. Age at Time of Event: 7 | Months | 3. Sex | 4. Weight | | |
| | In confidence | Date of Birth: | | ✓ Male | or kg | | |
| | B. ADVERSE EV | VENT OR PRODU | ICT PROBLE | M | | | |
| | 1. Adverse Even | t and/or Pr | oduct Problem (6 | .g., defects/malfi | unctions) | | |
| | Outcomes Attribut (Check all that appl) | | 361 | | | | |
| | Death: | (mm/dd/yyyy) | Disability o | r Permanent Da | mage | | |
| | Life-threatenin | 9 | | Anomaly/Birth D | | | |
| | | - initial or prolonged | | ous (Important M | | | |
| | | vention to Prevent Perr | | | | | |
| | 3. Date of Event (mn | | 4. Date of This | Report (mm/dd | | | |
| | | 7/2015 | | 01/29/2015 | | | |
| PLEASE TYPE OR USE BLACK INK | CHILD CARE CENTER REPORTS CHILD EXPERIENCED SEIZURES THIS PAST WEEKEND WHILE TAKING TEETHING TABLETS. ACCORDING TO THE REPORTER, THE MOTHER STATED THE CHILD'S SEIZURES STOPPED AFTER THE MOTHER DISCONTINUED ADMINISTERING THE TEETHING TABLETS. FOLLOW-UP CONVERSATION WITH THE CHILD'S MOTHER ON 01/28/15: MOTHER STATES THE CHILD HAS BEEN TEETHING FOR SEVERAL MONTHS. SINCE THE TEETHING SYMPTOMS WERE MILD, SHE DID NOT OFFER THE CHILD ANY MEDICATION. HOWEVER, OVER THE PAST FEW WEEKS THE CHILD SEEMS TO HAVE BECOME MORE IRRITABLE, FUSSY AND TROUBLED BY THE TEETHING PROCESS PARTICULARLY IN THE LATE AFTERNOON AND EARLY EVENING. SO HAVING USED THE TEETHING TABLETS WITH HER OLDER CHILD WITH GOOD RESULTS, SHE WENT TO WALMART AND "PICKED UP A BOTTLE OF TEETHING TABLETS". APPROXIMATELY TWO WEEKS AGO, SHE ADMINISTERED 2 TEETHING TABLETS TO THE CHILD EVERY DAY IN THE LATE AFTERNOON / EVENING WHEN THE CHILD BECAME FUSSY. WITHIN ONE HOUR OF THE DOSE SHE OBSERVED THE CHILD EXPERIENCING SYMPTOMS OF "TWITCHING, MOVING HIS HEAD FAST FROM SIDE TO SIDE, MOVING HIS HEAD BACKWARDS, AND HIS EYES WENT UP". THE CHILD CARE STAFF (Continue on page 3) | | | | | | |
| | | | EB 1 9 20 | | | | |
| | | | | | | | |
| | | | CDR | (Continue or | , , , | | |
| | race, pregnancy, sn | story, Including Preex noking and alcohol use, OF ANAPHYLAX | hepatic/renal dyst | function, etc.) | iergies, | | |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

(Continue on page 3)

| K1 reporting | or amporter ive | , , , , | | | |
|---|--|---|--|--|--|
| of 6 | | | | EDATIO | |
| C. SUSPECT PRODU | JCT(S) | | | FDA Use Onl | |
| Name (Give labeled strength & mfr/labeler) | | | | | |
| #1 HYLAND'S BABY TEETHING TABLETS | | | | | |
| #2 | | | | | |
| 2. Dose, Frequency & Rout | e Used | 3. Therapy from/to | y Dates (If (or best est | unknown, give duration) timate) | |
| #12 TABS DAILY BY | Y MOUTH | #1 | | - | |
| #2 | | #2 | | | |
| 4. Diagnosis for Use (Indication) 5. Event Abated After Use Stopped or Dose Reduced? | | | | | |
| #1 TEMP RELIEF TEETHING SYMPTO | | TOMS | #1 | - December | |
| #2 | | #2 T Voc T No T Do | | s DNo Doesn' | |
| 6. Lot# | 7. Exp. Date | | #2 Yes No Apply 8. Event Reappeared After | | |
| #1A22214 | #1 | | Reintro | duction? | |
| #2 9. NDC# or Unique ID | #2 | | #1 Yes No Doesn't Apply | | |
| 54973-3127-3 | | | #2 Ye | s No Doesn' | |
| 10. Concomitant Medical Pr | roducts and Ther | apy Dates | (Exclude tre | | |
| | | | | | |
| | | | | | |
| | | | (Ca | ntinue on page 21 | |
| D. SUSPECT MEDIC | AL DEVICE | | (00 | ntinue on page 3) | |
| 1. Brand Name | THE DISCHARGE STATE OF THE STAT | SECULIAR SECTION | APPENDING THE PROPERTY. | A CONTRACTOR OF THE PARTY OF TH | |
| 2. Common Device Name | | | 2b. Pro | ocode | |
| 3. Manufacturer Name, City | and State | | | | |
| o. manufacturer Name, City | and State | | | | |
| 4. Model# | Lot# | | 10 | . Operator of Device | |
| mount | LOC IF | | ľ | Health Professional | |
| Catalog # | Expiration [| Expiration Date (mm/dd/yyyy) | | Lay User/Patient | |
| Serial# | Unique Ider | ntifier (UDI) | # | Other: | |
| | | , | | | |
| 6. If Implanted, Give Date (1 | mm/dd/yyyy) | 7. If Expla | nted, Give | Date (mm/dd/yyyy) | |
| 8. Is this a Single-use Device | ce that was Repro | cessed an | d Reused | on a Patient? | |
| Yes No | - Name | Yes No | | | |
| 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor | | | | | |
| | | | | | |
| | r Name and Addr | ess of Rep | rocessor | | |
| 10 Davidson 11 | | | | | |
| 10. Device Available for Eva | aluation? (Do not | send to FD/ | 4) | | |
| Yes No [| aluation? (Do not Returned to Ma | send to FD/ anufacturer | 4) on: | (mm/dd/yyyy) | |
| | aluation? (Do not Returned to Ma | send to FD/ anufacturer | 4) on: | | |
| Yes No [| aluation? (Do not Returned to Maroducts and There | send to FD/ anufacturer | 4) on: | | |
| Yes No 11. Concomitant Medical Pr | aluation? (Do not Returned to Ma roducts and There | send to FD/ anufacturer | A) on: (Exclude tr | | |
| Yes No 11. Concomitant Medical Property FEB E. INITIAL REPORTE | aluation? (Do not Returned to Ma roducts and There | send to FD/ anufacturer | A) on: (Exclude tr | eatment of event) | |
| Yes No 11. Concomitant Medical Property E. INITIAL REPORTE 1. Name and Address | aluation? (Do not Returned to Ma roducts and There | send to FD/ anufacturer | A) on:(Exclude tr | eatment of event) ntinue on page 3) | |
| Yes No 11. Concomitant Medical Property E. INITIAL REPORTE 1. Name and Address | aluation? (Do not Returned to Ma roducts and There | send to FD/ anufacturer | A) on:(Exclude tr | eatment of event) ntinue on page 3) | |
| Yes No 11. Concomitant Medical Property E. INITIAL REPORTE 1. Name and Address (b) (6) | aluation? (Do not Returned to Ma roducts and There 192015 | send to FD/ anufacturer | A) on:(Exclude tr | eatment of event) ntinue on page 3) | |
| Yes No 11. Concomitant Medical Property FEB E. INITIAL REPORTE 1. Name and Address (b) (6) (D) (b) | aluation? (Do not Returned to Ma roducts and Ther. 1 9 2015 R | send to FD/ anufacturer | A) on:(Exclude tr | eatment of event) ntinue on page 3) | |
| Yes No 11. Concomitant Medical Property FEB E. INITIAL REPORTE 1. Name and Address (b) (6) (D) (b) | aluation? (Do not Returned to Ma roducts and Ther. 1 9 2015 R | send to FD/ anufacturer apy Dates | A) on: (Exclude tr | ntinue on page 3) | |
| Yes No 11. Concomitant Medical Property of the second of | aluation? (Do not Returned to Ma roducts and Ther. 1 9 2015 R | send to FD/ anufacturer apy Dates | (Exclude tr | eatment of event) ntinue on page 3) | |

Yes No V Unk.

7. Type of Report

Initial Follow-up # 10. Event Problem Codes (Refer to coding manual)

Importer

3. User Facility or Importer Name/Address

2. UF/Importer Report Number

5. Phone Number

12. Location Where Event Occurred

Outpatient Treatment Facility

Hospital

Nursing Home

Home

Other:

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

(mm/dd/yyyy)

1. Check One

User Facility

4. Contact Person

9. Approximate Age of Device

Yes

No

Yes

No

6. Date User Facility or

11. Report Sent to FDA?

Importer Became Aware of Event (mm/dd/yyyy)

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

2 of

| 6 | | | |
|--|--|--|----|
| H. DEVICE MANUFAC | TURERS ONLY | | |
| . Type of Reportable Event Death Serious Injury Malfunction | | If Follow-up, What Type? Correction Additional Information Response to FDA Reques Device Evaluation | st |
| . Device Evaluated by Manu | ufacturer? | 4. Device Manufacture Date | |
| Not Returned to Manu | ıfacturer . | (mm/yyyy) | |
| = - | Summary Attached | E Labeled for Single Head | |
| No (Attach page to exprovide code: | or (cplain why not | 5. Labeled for Single Use? | |
| | | | |
| Patient Code Device Code Method Results Conclusions | ation Codes (Refer to | coding manual) | |
| . If Remedial Action Initiate | d, Check Type | 8. Usage of Device | |
| Recall N | otification spection atient Monitoring | ☐ Initial Use of Device ☐ Reuse ☐ Unknown | |
| | odification/ djustment | If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: | |
| 0. Additional Manufacto | urer Narrative | and / or 11. Corrected Data | a |
| | | | |
| | | DSS | |
| | | FEB 2 0 20 | 15 |
| anadment of Health and Hum | an Sonices | OMB Statement: "An agency may no | of |

CaseID: 10862441

FDA USE ONLY

G. ALL MANUFACTURERS 2. Phone Number 1. Contact Office (and Manufacturing Site for Devices) 310-768-0700 EDYTA FRACKIEWICZ 3. Report Source (Check all that apply) Address Foreign HYLAND'S, INC. Study 154 W. 131ST STREET LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 01/27/2015 Distributor IND# 6. If IND, Give Protocol # Other: BLA# PMA 7. Type of Report 510(k)# (Check all that apply) Combination 30-day Yes 5-day Periodic 7-day Pre-1938 Yes 10-day ✓ Initial OTC Product √ Yes Follow-up # √ 15-day 8. Adverse Event Term(s) 9. Manufacturer Report Number SEIZURES 54973 AE # 1595 This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov Please DO NOT RETURN this form to the above PRA Staff email address.

conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Back to Item B.5

Back to Item B.6

Back to Item B.7

Back to Item D.11 Back to Item C.10

NUATION PAGE) by user-facilities, CaseID: 10862441

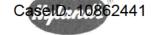
utors, and manufacturers JATORY reporting

| FORM FDA 3500A (2/13) (continued) | rage 3 of |
|--|---|
| THE CONVERSATION WITH THE CHILD CARE STAFF, TH | HERED BY THE TAG IN HIS CLOTHES. HOWEVER, SUBSEQUENT TO E MOTHER NOTICED THE SAME SYMPTOMS AFTER ADMINISTERING S MOTHER DISCONTINUED ADMINISTERING THE TEETHING TABLETS |
| THE CHILD HAS AN APPOINTMENT WITH HIS HEALTHCA | RE PRACTITIONER ON 2/2/15. |
| | |
| | |
| | |
| * | |
| | |
| | |
| | |
| | |
| B.6. Relevant Tests/Laboratory Data, Including Dates (continued) | |
| | |
| * | |
| , | |
| | |
| 2 9 | |
| , | |
| B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., | allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) |
| | |
| | |
| | |
| | 1 |
| , | |
| | |
| Concomitant Medical Products and Therapy Dates (Exclude treatment of ever | nt) (For continuation of C.10 and/or D.11; please distinguish) |
| , | |
| | |
| , , | |
| | |
| | |
| | |
| Other Pewarite | nee |
| Other Remarks | 1799 |

FEB 1 9 2015

FEB 2 0 2015

OMPLAINT RECORD



| 10862441-01-00-04 | | COMPLAINT #: | 2605 | | |
|---|--|--|--|---|-----|
| | | DATE OF COMPLAINT: | 01/27/2015 | | |
| PRODUCT: HYLAND'S BABY TE | ETHING TABLETS | ITEM CODE: | BTETT135 | | |
| SIZE: 135 TABLETS | | LOT NO.: | A22214 | | |
| REPORTER: (b) (6) | | | | | |
| ADDRESS: | | | | | |
| | | (b) (6) | | - | |
| CITY: | | STATE: | | | |
| COUNTRY: USA (b) (6) | | ZIP CODE: | | | |
| PHONE #: | | | | | |
| E-MAIL: | ATIVE OF A CHILD CARE CENTER CALL | ED TO INQUIRE ABOUT THE ST | TATUS OF OUR TER | THING TABLETS | |
| THE MOTHER OF ONE OF THE CHILDREN ATTENDING TABLETS. I PROVIDED OUR SAFETY INFORMATION A CONVERSATION WITH THE CHILD'S MOTHER ON 1/28 SYMPTOMS WERE MILD, SHE DID NOT OFFER THE CI MORE IRRITABLE, FUSSY AND TROUBLED BY THE TE THE TEETHING TABLETS WITH HER OLDER CHILD WITH APPROXIMATELY TWO WEEKS AGO, SHE ADMINISTE CHILD BECAME FUSSY. WITHIN ONE HOUR OF THE EFROM SIDE TO SIDE, MOVING HIS HEAD BACKWARDS THE SYMPTOMS AND REPORTED THE SYMPTOMS TO ADMINISTERING TWO TEETHING TABLETS. ON 01/24. CHILD HAS NOT EXPERIENCED ANY OF THE SYMPTOM THE TEETHING TABLETS SINCE SHE LEARNED THER | IND REFERRED HER TO HYLANDSTEETH /15: MOTHER STATES THE CHILD HAS E HILD ANY MEDICATION. HOWEVER, OVE ETHING PROCESS - PARTICULARLY IN' HI GOOD RESULTS, SHE WENT TO WAL RED 2 TEETHING TABLETS TO THE CHILD OSE SHE OBSERVED THE CHILD EXPEL S, AND HIS EYES WENT UP'. ACCORDIN HER. THE CHILD CARE STAFF ATTRIB HECONVERSATION WITH THE CHILD '15, THE CHILD'S MOTHER DISCONTINUI MS DESCRIBED ABOVE SINCE. THE MO | ENCED SEIZURES THIS WEEK HING.COM FOR ADDITIONAL IN BEEN TEETHING FOR SEVERAL THE PAST FEW WEEKS THE THE LATE AFTERNOON AND E. MART AND "PICKED UP A BOT D EVERY DAY IN THE LATE AF RIENCING SYMPTOMS OF "TW G TO THE MOTHER, THE CHILL UTED THE SYMPTOMS TO THE LARE STAFF, THE MOTHER NO ED ADMINISTERING THE TEET ITHER STATES SHE BELIEVES D FORMULA." MOTHER REQU | END WHILE TAKING FORMATION. FOLL MONTHS. SINCE CHILD SEEMS TO ARLY EVENING. STILE OF TEETHING THE NOON, EVENING TO CARE STAFF INITICHING, MOVING TO CHILD BEING BOTTICED THE SAME SHING TABLETS ANITHE SYMPTOMS A ESTS REFUND. | G THE TEETHING .OW UP THE TEETHING HAVE BECOMRE D HAVING USED TABLETS". NG WHEN THE HIS HEAD FAST IALLY NOTICED HERED BY THE SYMPTOMS AFTER D REPORTS THE | |
| PRODUCT RECEIVED FOR Y INSPECTION: (CIRC | CLE ONE) | ICT BEING RETURNED FOR | | Y (CIRCLE ONE) | |
| | | | _ | y (N) | |
| | | UPS CALL | TAG ISSUED: | (CIRCLE ONE) | |
| | | DATE PRODUC | T RECEIVED: | | |
| SECTION II: INVESTIGATION | | | | | |
| 3 | | | | | |
| INVESTIGATION: PLEASE SEE ATTACH | ED INVESTIGATION REPORT. | | | | |
| ADVERSE EVENT FORWARDED TO PHARMACIST ADVERSE EVENT FORWARDED TO PHARMACIST SECTION III: CORRECTIVE ACTION | / NURSE FOR EVALUATION BY: | | NE DOW | | |
| | | | | | |
| CORRECTIVE ACTION(S) COMPLETED BY: | | DATE: | | | |
| SECTION IV: ADVERSE EVENT REPOR | TS C | AE #: | 1595 | | |
| ADVERSE EVENT SERIOUS: | Y)/ N | | FEB 1 9 | 2015 DS | 2 |
| ADVERSE EVENT REPORTED ON: | 01/27/15 | BY: CATHERINE DO | | FED a a | - |
| SECTION V: | 02/1/4 | / | | · FD Z () | 201 |
| REVIEWED BY MANAGEMENT BY: | POW | DATE: | <i>02-09</i> 02-06- | -15 | |
| BY: QA/QC DIREC | DOULL TOR | DATE: _ | 02-06- | 15 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1



1NDARD DPATHIC E USA SINCE 1903 CaseID: 10862441

Serious Adverse Event SAE-0004-2015

Product in Inventory:

No units of Hyland's Baby Teething Tablets (BTET), lot # A22214, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot's (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A22214 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A22214. The Baby Teething bulk lot # 122944 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(6)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product.

Of the units manufactured one other complaint (CC-0617-2014) has been received for Hyland's Baby Teething Tablets lot # A22214. The complaints were reviewed and the complaints do not appear to be related. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A22214.

Manufacture and processing occurred within established procedures to ensure product quality.

02-05-15

Date

DSS FEB **2** 0 2015



SE EVENT DATA FORM



| AE #:159 | 595 | COMPLAINT #: |
|--|--|---|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM RE | EPORTER ON FORM VD1) |
| NAME: | (b) (6) | |
| ADDRESS: | · | |
| | | /IAV (CV |
| CITY: | | STATE: |
| COUNTRY: | USA (b) (6) | ZIP CODE: |
| PHONE #: | | |
| E-MAIL; | | |
| SECTION II: | PACKAGING INFORMATION: | |
| AF | | AFFIX COPY OF OUTER CARTON HERE LUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| And Countries an | THE THE LIFE TO A PAN AND CONTROL FOR TH | Raby |
| SECTION III: | CORRECTIVE ACTION: | |
| | | * |
| | | |
| CORRECTIVE A | ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: | PalalA | DSC. |
| REVIEWED BY | MANAGEMENT BY: | DATE: 02-09-15-03 |
| BY: | QA/QC DIRECTOR | DATE: 02-09-15 DSS DATE: 02-06-15 DSS |

DISTRIBUTION: FDA

ADVERSE EVENT FILE

FORM SAE01

umer Report

CaseID: 10866401

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse.

ONLY

| RY reporting of | |
|-------------------|--|
| luct problems and | |
| ica arrore | |

| 10866401-01-00-01 | luct problems and | Triage unit sequence # |
|---------------------------------|-------------------|------------------------|
| Adverse Event Reporting Program | dse errors | 584023 |
| A DATIENT INFORMATION | 2 Dags on Amount | Francisco Bauta |

| A. PAHENTIN | | | | Z. Dose of A | | Frequency | Route | | |
|----------------------------------|--|--------------------------|------------------|--------------------------|--------------------|--------------------------------------|------------------------|------------------------------|-----------------|
| 1. Patient Identifier (b) (6) | 2. Age at Time of Event Date of Birth: | or 3. Sex | 4. Weight | | 2 tabs hour x6d | As needed | dissolved | on tongue | 9,50 |
| | 8 Months | ✓ Female | 17.5 lb | #2 | | | 1 | | |
| In confidence | (b) (6) | ☐ Male | or kg | | | | | | |
| | EVENT, PRODUCT I | PROBLEM OR EL | RROR | 3. Dates of Use | e (If unknown, aiv | L | 5. Event Al | bated After Us | e |
| Check all that apply: | | | | (or best estir | mate) | | | r Dose Reduce | d? |
| 1. Adverse Event | t Product Problem | n (e.g., defects/malfund | ctions) | - | of 2 tabs th | en hx3d | #1 Ves | | Doesn' Apply |
| Product Use E | rror Problem with Di | fferent Manufacturer | of Same Medicine | #2 | | | #2 TYes | | Doesn' |
| | uted to Adverse Event | | | 4. Diagnosis o | r Reason for Us | e (Indication) | | eappeared Afte | Apply |
| (Check all that app Death: | | Disability or Permanent | Damage | #1 teethin | 3 | | Reintrod | | |
| (1) | mm/dd/yyyy) | | | #2 | | | #1 Yes | | Doesn' Apply |
| Life-threatening | | Congenital Anomaly/Bir | | 0.1-1# | 1- | Fiti D-t- | #2 Yes | | Doesn' |
| process. | - initial or prolonged 🗸 (| | | 6. Lot # #1 | #1 | Expiration Date | | Δ Δ | Apply |
| | vention to Prevent Perman | | | #2 | #2 | | B01614 | r Unique ID | |
| 3. Date of Event (mr | 1.2.7.2.1 | Date of this Report (| mm/dd/yyyy) | | CT MEDICAL | | B01014 | | |
| 02/18/2015 | | 02/18/2015 | | 1. Brand Name | | DEVICE | 1534/2832 | | 4000 |
| | Problem or Product Use for complete text | | * , | iii biana itam | | | | | |
| , and project | | | | | | 3" NO N | 10.00 | | - |
| | | | 3.12 | 2. Common De | vice Name | | | | |
| | | | 4 | | | | | | |
| | | | 100 g | 3. Manufacture | er Name, City an | d State | | | |
| | | | | | | | | CTU | |
| | | | * 2. ° | | | | 200 | | |
| | | | | 4. Model # | -7 200 | Lot# | | Operator of D | |
| | | | | | | | - L | Health Profes | ssiona |
| | | | | Catalog # | | Expiration Date (n | nm/dd/yyyy) | Lay User/Pati | ient |
| | | | | | | | - | Other: | |
| 6. Relevant Tests/L: | aboratory Data, Including | g Dates | | Serial # | | Other# | | _ Other. | |
| | | | | 00110111 | | | | | |
| | | | | | 01 - D 4 / | | | D 4 ((14) | |
| | | | 12 1 5 2 | 6. If implanted | , Give Date (mm | /dd/yyyy) /. If E | kplanted, Give | Date (mm/dd/) | YYYYI |
| | | | | 8. Is this a Sin | gle-use Device t | hat was Reproces | sed and Reus | ed on a Patien | t? |
| | | | | Yes | | | | | |
| 1 W 2 | | | | 9. If Yes to Item | No. 8, Enter Nan | ne and Address of R | eprocessor | | |
| 7. Other Relevant H | listory, Including Preexis | ting Medical Condition | ons (e.g., | | | | | | |
| | egnancy, smoking and alco for complete text | | robiems, etc.) | E OTHER | CONCOMIT | ANT MEDICAL | BBOBLIO | T0 | - |
| | | | | | | ANT) MEDICAL ates (exclude treatn | NAME OF TAXABLE PARTY. | 15 | e feet |
| | | | | Product name. | s and therapy de | ates (exclude treath | ient or event) | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | G. REPORT | ER (See con | fidentiality sec | tion on bac | k) | |
| C. PRODUCT A | VAILABILITY | | | 1. Name and A (b) (6) | ddress | | | | 2: |
| CONTRACTOR DESCRIPTION OF STREET | or Evaluation? (Do not se | end product to FDA) | and the state of | | | | | | |
| ✓ Yes No | Returned to Manufac | | | | | | | 319 |) 2h |
| | | (mm | n/dd/yyyy) | | | | | | 1.0 |
| D. SUSPECT PI | | et la hall | | Phone # | | E-mail | | V | |
| | Manufacturer (from produ s Baby Teething T | | | (b) (6) | 100 | (b) (6) | | | |
| Strength: 135 t | tab/bottle | | . Ad | | 177 | | | 24 8 7 | |
| Manufacturer: Hy | ylands Inc. | | | | essional? 3. Oc | cupation | | Iso Reported to | |
| #2 Name: | | 2 1 2 2 3 | | Yes | | | <u> </u> | Manufacturer | |
| Strength: Manufacturer: | | | | | T want your ident | | - E | User Facility Distributor/Im | node- |
| Manufacturer. | 0 (4(00) | | | to the manuf | acturer, place an | v iii qiis box: | _ _ | וויוסווימוויפוט L | poner |

B.5. Describe Event or Problem (continued)

CaseID: 10866401

I bought Hylands Teething Tablets today at the local Rite Aid. I gave my 8 month old foster child 2 tabs then 1 tab every two hours for teething. On the package it says may give 2 tabs every hour for up to 6 doses. After the first dose I noticed her flushing. She seemed to get some relief. I gave her 1 more dose, she acted cranky and tired but stopped chewing on anything she could fit in her mouth. I gave her a third dose. She acted "weird", like slow, drugged.I noticed she seemed to have trouble breathing, just for a few seconds. I didn't know if I had imagined it. I didn't relate it to the medicine as the package says it is a SAFE SOLUTION and homeopathic. I gave her one more dose. Within 10 minutes she was flushed and her pupils were dilated and then she did the breathing thing again. All symptoms relieved after about 30 min and I did not feel the need to get medical intervention. I have been checking her breathing frequently. I found a video from the FDA on the dangers of giving this product. I will not give it again. Why is it still being sold?

Individual Case Safety Report

10866401-01-00-02

DSS FEB 1 9 2015

CaseID: 10866401

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Medical Conditions: Was born with addictions to opiates and benzodiazipans. Wonder if this is related.

Allergies: none known at this time.

Important Information: She is my foster child.

RX Meds: None

OTC Meds: Tylenol/ motrin

Individual Case Safety Report

10866401-01-00-03

DSS FEB 1 9 2015



PLEASE TYPE OR USE BLACK INK

iser-facilities, ors and manufacturers ORY reporting

| CaseID: 10877680 | |
|---|---|
| Form Approved: OMB No. 0910-0291, Expires: 6/30/201 See OMB statement on reverse | |
| Report# EAD72 | 7 |

UF/Importer Report #

| FORM FDA 3500A (2 | 2/13) | | | Page 1 | of 5 | | | | 1 | 1 1 | DA Use Only |
|---|---------------------|--------------------|------------------|-----------|--------------|------------------|--------------------|--------------|---------------|----------------------------------|---------------|
| A. PATIENT INFORM | MATION | | | | C. SUSF | ECT PROD | DUCT(S) | | | | |
| 1. Patient Identifier 2. Age | | | 3. Sex | 4. Weight | 1. Name (G | ive labeled stre | ength & mfr/labele | rr) | | | |
| (b) (6) of E | Event: | | | lbs | #1 HYLA | ND'S BABY | TEETHING ' | FABLETS | | | |
| Dat | te | | - | or | #2 | | | | | | |
| | Birth: | | Male | kgs | | equency & Ro | ute Used | 3. Ther | rapy Dates | (If unknown, giv | ve duration) |
| B. ADVERSE EVENT | OR PRODUC | T PROBLE | Λ | | #4 IINKN | OWN DOSAGI | E | from | to (or best | | |
| 1. ✓ Adverse Event and | nd/or Prod | duct Problem (e. | g., defects/malf | unctions) | | OWN DOSAGI | | - #1 | | | |
| Outcomes Attributed to A (Check all that apply) | Adverse Event | | | | #2 | | | #2 | le e | | |
| Death: | | ☐ Disability o | r Permanent Dar | mage | | is for Use (Indi | - | | | t Abated After ped or Dose Re | |
| Life-threatening | v/dd/yyyy) | Congenital | Anomaly/Birth D | Defect | #1 1EMP | KELLET I | EETHING PA | IN | - #1 √ | Yes No | Doesn't Apply |
| Hospitalization - initia | al or prolonged | | ous (Important M | | #2 | | | | | V | Doesn't |
| Required Intervention | | | | | 6. Lot # | | 7. Exp. Date | | | Yes No | ☐ Apply |
| 3. Date of Event (mm/dd/yy) | | 4. Date of This | | | #1 | | #1 | | | t Reappeared / roduction? | , |
| 08/12/20 | | | 02/05/2015 | | #2 | | #2 | | | Yes THO | Doesn't |
| 5. Describe Event or Proble | em | | | | 9. NDC# or | Unique ID | | | | JB 02-10-1 | |
| ON AUGUST 6, 2012, | , DAUGHTER : | | | | 54973 | -3127-1 | | | #2 | Yes No | Apply |
| TEETHING TABLETS. LASTING 20 MIN. (| | | | | 10. Concon | nitant Medical | Products and TI | nerapy Dat | es (Exclude | treatment of ev | vent) |
| USING THE TABLETS. | . CHILD CO | NTINUED US: | ING TABLET | S AND | | | | | | | |
| HAD 4 MORE SEIZURE DISCONTINUING THE | | | | AFTER | | | | | | | |
| HAD ANY MORE SEIZU | | ING INDLEIS | O CUITO UV | 5 NOI | | | | | | | |
| | | | | | D CHEE | ECT MEDI | CAL DEVICE | | (0 | Continue on | page 3) |
| | DE | CEIV | FD | | 1. Brand N | | CAL DEVICE | GALL HA | | | |
| | | Chair W | Barn Stars | | Draile it | | | | | | |
| | | 0 4 00 | 45 | - 1 | 2. Commor | Device Name | | | 2b. l | Procode | |
| | F | EB 2 4 20 | 113 | 1 | 3. Manufac | turer Name, C | ity and State | | | | |
| | | on many 1930) | | - 1 | | | | | | | |
| | | CDR | | | 4. Model# | | Lot # | | | 5. Operator | of Davice |
| | | Sile som a | | | 4. model# | | Lot # | | | | Professional |
| | | | | - 1 | Catalog | # | Expiration | n Date (m | m/dd/yyyy) | | |
| | | | | | | | | | | Lay Use | errratient |
| | | | | | Serial # | | Unique I | dentifier (L | JDI) # | Other: | - 1 |
| | | | | | 6. If Implan | ted, Give Date | (mm/dd/yyyy) | 7. If Ex | planted, Gi | ive Date (mm/d | ld/yyyy) |
| | | - | (Continue or | n page 3) | | | | | | | |
| Relevant Tests/Laborator | ory Data, Including | Dates | | | | | vice that was Re | processed | and Reuse | ed on a Patient | t? |
| | | | | | 9 If Yes to | No No. 8. En | ter Name and A | ddress of I | Reprocesso | or | |
| | | | | | 0 | | | | , | | - |
| | | | | | | | | | | | DSG |
| | | | | | | | | | | | 200 |
| | | | | 1 | | | Evaluation? (Do I | | | F | B 2 5 2 |
| | | | | | Yes | ∐ No | Returned to | Manufactu | irer on: | (mm/dd/yy) | |
| | | | (Continue or | n page 3) | 11. Concor | nitant Medical | Products and T | herapy Dat | es (Exclude | e treatment of e | event) |
| 7. Other Relevant History, I race, pregnancy, smoking | Including Preexis | ting Medical Co | • | , , , | | | | | | | |
| race, pregnancy, smoking UNKNOWN | and alcohol use, h | iepatic/rėnai dyst | unction, etc.) | | | | | | (| Continue on | page 3) |
| | | | | | E. INITIA | L REPORT | TER | 184 | 2. 10. | | |
| | | | | | 1. Name ar | | 3 | 0 | 16 | 6/1 | |
| | | | | | (b) (6) | | | 7/ | 1. 7. | 1 | |
| | | | | | | | | | | | - 1 |
| | | | | | | | | | | | |
| | | | | | Phone # | | Te. | mail Addres | | | |
| | | | (Continue or | n page 3) | Frione # | | | nan Addres | | | - 1 |
| Submission of a report | does not con | stitute an ad | nission that | medical | 2. Health P | rofessional? | 3. Occupation | | 4. | Initial Reporte | er Also Sent |
| personnel, user facility caused or contributed | , importer, dis | tributor, mar | ufacturer or | product | | | NA | | | Report to FDA | |
| aused or contributed t | to the event. | | | | | | | | | | E |



of

| 4 Observation | | and the same | C LIE | | Marie Ballet Control of the Control |
|--|---|--|---------------|--------------------|---|
| 1. Check One | | | 2. UF/Impo | orter Repor | t Number |
| User Facility | Impo | | | | |
| 3. User Facility or Imp | orter Name/ | Address | | | |
| | | | | | |
| 4. Contact Person | | | 5. Pho | one Numbe | r |
| Date User Facility of Importer Became Aware of Event (mn) | n/dd/yyyy) | Type of R | ıp# | (n | ate of This Report nm/dd/yyyy) |
| Approximate Age of Device | 10. Event P | roblem Cod | les (Refer to | coding ma | nual) |
| Age of Device | Patient | | | | |
| | Code | | | |]- |
| | Device Code | 1 | - | | 1- |
| 44 5 40 44 55 | | 10.1 | | | |
| 11. Report Sent to FDA | 47 | | on Where E | vent Occur | |
| Yes | // | | spital | | Outpatient Diagnostic Facility |
| □ No (mm/dd | yyyyy) | | me | | Ambulatory |
| 13. Report Sent to Mar | nufacturer? | - | rsing Home | | Surgical Facility |
| Yes | | | tpatient Tre | atment | |
| □ No (mm/dd | /уууу) | | ner: | | |
| | | | | (Sp | pecify) |
| | | | | | |
| , | | | | | |
| G. ALL MANUFA | CTURERS | 5 | | | |
| G. ALL MANUFA 1. Contact Office (and | | Certification Contraction | Devices) | 2. P | hone Number |
| A DESCRIPTION OF THE PARTY OF T | | Certification Contraction | Devices) | | hone Number -768-0700 |
| Contact Office (and Name EDYTA FRACKIEW) | Manufacturi | Certification Contraction | Devices) | 310 3. R | -768-0700 eport Source |
| Contact Office (and Name | Manufacturi | Certification Contraction | Devices) | 310 3. R | -768-0700 eport Source Check all that apply) |
| Contact Office (and Name EDYTA FRACKIEW) | Manufacturi | Certification Contraction | Devices) | 310 3. R | -768-0700 eport Source Check all that apply) Foreign |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST ST | Manufacturi | Certification Contraction | Devices) | 310 3. R | -768-0700 eport Source Check all that apply) Foreign Study |
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| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND | Manufacturi | Certification Contraction | Devices) | 310 3. R (0 | eport Source Check all that apply) Foreign Study Literature Consumer Health Professional User Facility |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLANG 4. Date Received by Manufacturer (mm/d) | Manufacturi CZ TREET A 90061 DS.COM | ng Site for | Devices) | 310 3. R (0 | eport Source Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND | Manufacturi CZ TREET A 90061 DS.COM | 5. (A)NDA# | | 310 3. Re ((| eport Source Check all that apply) Foreign Study Literature Consumer Health Professional User Facility |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLANG 4. Date Received by Manufacturer (mm/d) | Manufacturi ICZ IREET A 90061 DS.COM Id/yyyy) 015 | 5. (A)NDA# | | 310 3. Re ((| -768-0700 eport Source theck all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, C. Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d 01/31/20 | Manufacturi ICZ IREET A 90061 DS.COM Id/yyyy) 015 | 5. (A)NDA # IND # BLA # | | 310 3. Re ((| eport Source Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor |
| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST ST. LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 01/31/20) 6. If IND, Give Protoco | Manufacturi ICZ TREET A 90061 DS.COM Id/yyyy) D15 | 5. (A)NDA# | | 310 3. Re ((| eport Source Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor |
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| 1. Contact Office (and Name EDYTA FRACKIEW) Address HYLAND'S, INC. 154 W. 131ST St. LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 01/31/20) 6. If IND, Give Protoco 7. Type of Report (Check all Ihal apply) 5-day Perio 10-day Initial 15-day Follow | Manufacturi ICZ IREET A 90061 DS.COM Id/yyyy) D15 I# | 5. (A)NDA # BLA # PMA/ 510(k) # Combinat Product Pre-1938 OTC Proc | ion Y | 310 3. R (() | eport Source Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor |
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| Little Harris Charles | FDA USE ONLY |
|---|--|
| 5 | |
| H. DEVICE MANUFACTURERS ONL | Y |
| . Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| . Device Evaluated by Manufacturer? | Device Manufacture Date |
| Not Returned to Manufacturer | (mm/yyyy) |
| | |
| | 5. Labeled for Single Use? |
| No (Attach page to explain why not) or provide code: | |
| | Yes No |
| Event Problem and Evaluation Codes (Refer t | lo coding manual) |
| Patient Patient | |
| Code | |
| Device Code | _ |
| Code | |
| Method - | - - |
| | |
| Results | |
| Conclusions - | |
| If Pomodial Action Initiated, Check Type | Is Heart of Davies |
| If Remedial Action Initiated, Check Type | 8. Usage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Relabeling Modification/ | If action reported to FDA under 21 USC 360i(f), list correction/ |
| Other: | removal reporting number: |
| | |
| - | |
| Additional Manufacturer Narrative | and / or 11. Corrected Data |
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CaseID: 10877680

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@ida.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

MPLAINT RECORD



| 1087 | 7680-01-00-03 | COMPLAINT #: | 2608 |
|---|---|--|--|
| | | _ DATE OF COMPLAINT: | 01/31/2015 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTET |
| SIZE: | N/A | LOT NO.: | N/A |
| REPORTER: | (b) (6) | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE: | |
| COUNTRY: | USA | ZIP CODE: | |
| PHONE #: | | | |
| E-MAIL: | CUSTOMER POSTED THE FOLLOWING MESSAGE O | (b) (6) | NOT DE MODERNA DE COMO |
| 2010, THE FDA SHOWN AND ISSUED A RECOME TRUE. SIDE I AUGUST 12 TH SHE I HAD NEVER HAD ON OVER AN HOUR! SHOWN AND HOUR! | AINT: REQUESTS TO CONTACT HYLAND'S: I STRONGLY S SAR PILLS. AMONG OTHER THINGS THEY CONTAIN BELLA DONNA (BAR PILLS. AMONG OTHER THINGS THEY CONTAIN BELLA DONNA (BALL. THE TABLETS HAD INCONSISTENT AMOUNTS OF IT. THEY SA EFFECTS OF B.D. ARE SEIZURES AMONG OTHER THINGS. ON AUGI HAD A SEIZURE LASTING 20 MIN. WE DID NOT MAKE A CONNECTION NE BEFORE AND THE TABLETS WERE THE ONLY VARIABLE. CONTIN HE HAD NOT HAD A SEIZURE SINCE STOPPING THE TABLETS, OVER SOV/PRESSANNOUNCEMENTS.UCM230761.HTM | A POISON) WHICH SUPPOS D WAY OF ENSURING LOW Y THEY HAVE CORRECTED UNITED TO A CONTROL N BETWEEN THE TABLETS ON NUED TAKING THEM. HAD | EDLY IS OK IN SMALL DOSES. IN LEVELS OF THE BELLA DONNA I THIS BUT WE DON'T FIND THAT R STARTED TAKING THESE. AND SEIZURE, ALTHOUGH SHE |
| | FOR ADDITIONAL SPACE PLEASE USE REVERSE OR A | ATTACH A SEPARATE SHE | ET |
| | | | |
| PRODUCT RECEIVE | ED FOR Y N PRODUC | CT BEING RETURNED FOR | INSPECTION: Y (N) (CIRCLE ONE) |
| | DATE | REQUESTED PRODUCT BE | RETURNED: |
| | | UPS CALL | TAG ISSUED: Y (CIRCLE ONE) |
| | | | |
| | | DATE PRODUC | T RECEIVED: |
| SECTION II: | INVESTIGATION | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| | | | |
| | | | |
| ADVERSE EVENT FO | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | 01/31/15 | |
| ADVERSE EVENT FO | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDYTA FI | RACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | | |
| | | | |
| | | | |
| | | | |
| CORRECTIVE ACTIO | ON(S) COMPLETED BY: | DATE: | |
| SECTION IV | ADVERSE EVENT REPORTS | ΔF #: | DSS |
| SECTION IV: | ADVERSE EVENT REPORTS | AL #. | FEB 2 5 2015 |
| ADVERSE EVENT SE | ERIOUS: (Y)/ N | | 2 5 2015 |
| ADVERSE EVENT RE | EPORTED ON: 01/31/15 | BY: EDYTA FRACKI | EWICZ |
| SECTION V: | Testill | | 07-12-15 |
| REVIEWED BY MANA | AGEMENT BY: | DATE: | 02.12 |
| BY: | Tull / Jalux | DATE: _ | 02-12-15 |

cc: QA / QC Packaging Production Shipping / Receiving

FEB 2.4.2015





Serious Adverse Event SAE-0007-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty eight (138) Adverse Events (AE) which also included forty four (44) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

ate

02-06-15

DSS FEB 2 5 2015

FEB 2 4 2015

CaseID: 10877680



SE EVENT DATA FORM



| AE #:1598 | B COMPLAINT #: | 2608 |
|---|--|---|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD | <u>1)</u> |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| | | |
| CITY: | STATE: | |
| COUNTRY: | USA ZIP CODE: | |
| PHONE #: | | |
| E-MAIL: | | |
| | | |
| SECTION II: | PACKAGING INFORMATION: | |
| AFFI | FIX PACKAGING LABEL HERE AFFIX COPY OF OUTER (INCLUDE DRUG FACTS AND PANELS | PRINCIPAL DISPLAY |
| Indications: Importing violence of sub- trigation of single sertimeness and sub- reliability due to change with friences and sub- reliability due to change with friences. All the change of the change of the change of the tongen it tower and due if you prefind in the large of those part due if you prefind in my large distribution would have for a death or the change of the change of the change of the subset. J called mouth factor before before the tongen distribution would have for a death or the tongen distribution would have for a death of the tongen distribution would have for a death of the tongen distribution would have for death of the tongen distribution would have been before the tongen distribution of the change of the change of the change of the change of the change of the PATE, MARIEL COMMANT AT PATES. IN ASSECTION OF ALL PATES. CALCARA IN ASSECTION OF ALL PATES. CALCARA IN ASSECTION OF ALL PATES. CALCARA IN ASSECTION OF ALL PATES. CALCARA IN ASSECTION OF ALL PATES. CALCARA IN ASSECTION OF ALL PATES. CALCARA IN ASSECTION OF ALL PATES. | AND A DESCRIPTION OF THE THEORY AND A DESCRIPTION OF A DE | Teething Tablets The Management of the Control of |
| SECTION III: | CORRECTIVE ACTION: | |
| | | DSS |
| 2 2 | | FEB 2 5 2015 |
| CORRECTIVE ACT | CTION(S) COMPLETED BY: DAT | E: |
| SECTION IV: REVIEWED BY MA | MANAGEMENT BY: QA/QC DIRECTOR DA | TE: <u>02-10-15 FEB 2.4</u> 2015 |



user-facilities, tors and manufact TORY reporting

| Cas | eID: 10901130 |
|----------------------|---|
| | MB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse. |
| Mfr Report # 54.00 | |
| UF/Importer Report # | |
| | |

PLEASE TYPE OR USE BLACK INK

| FORM FDA 350 | 0A (2/13) | | | | rag | e 1 |
|--|--|---------|-------------------------------------|-------------------------------------|-------------|-----|
| A. PATIENT INF | ORMATION | | | | | |
| 1. Patient Identifier (b) (6) | 2. Age at Time. of Event: | | | 3. Sex | 4. Weight | |
| (b) (0) | or Event: | 3 | Years | √ Female | | lbs |
| | Date | | | | or | |
| In confidence | of Birth: | 00110 | | Male | k | kgs |
| B. ADVERSE EV | VENT OR PR | ODUC | TPROBLE | VI | | |
| 1. Adverse Even | | | luct Problem (e. | g., defects/malf | unctions) | ╝ |
| Outcomes Attribut (Check all that apply | | vent | | | | - 1 |
| Death: | | | Disability o | r Permanent Dar | nage | ļ |
| Life-threatenin | (mm/dd/yyyy) 9 | | Congenital | Anomaly/Birth D | efect | |
| ☐ Hospitalization | - initial or prolong | ged | Other Serio | ous (Important M | edical Even | ts) |
| Required Inter | vention to Prevent | t Perma | nent Impairment | /Damage (Device | es) | |
| 3. Date of Event (mm | | T | 4. Date of This | Report (mm/dd | (УУУУ) | ٦ |
| 00/0 | 0/0000 | | | 02/09/2015 | | ╝ |
| 5. Describe Event or MESSAGE POSTEI | Problem ON (b) (6) | RF | PORTING TH | HAT CHILD | HAD A | |
| SEIZURE WHILE | | | | | in in | 1 |
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| 6. Relevant Tests/Lab | oratory Data, Inc | luding | Dates | | | ٦ |
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| Other Relevant Hist race, pregnancy, smo | ory, including Pi oking and alcohol | use, he | ng Medical Con patic/renal dysfu | ditions (e.g., all nction, etc.) | ergies, | 1 |
| UNKNOWN | | | | | | |
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| | | | (| Continue on | page 3) | 1 |

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

| and manufacturers RY reporting | UF/Importer R | eport # | | |
|-----------------------------------|------------------|--------------------------------|--|------------------|
| 5 | | | | |
| C. SUSPECT PROD | UCT(S) | | FDA U | se Only |
| 1. Name (Give labeled stren | | | | |
| #1 HYLAND'S BABY | TEETHING TA | ABLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & Rou | te Used | 3. Therapy D | ates (If unknown, give du | ration) |
| #1 UNKNOWN DOSAGE | | #1 | best estimate) | |
| #2 | Morn of the con- | #2 | nem pene | |
| 4. Diagnosis for Use (Indica | ation) | 5. I | Event Abated After Use | |
| #1 TEMP RELIEF TE | | | Stopped or Dose Reduce | d? Doesn't |
| #2 | MAF | 7 0 3 2 <u>0</u> 1! | <u></u> | Apply |
| 6. Lot# | 7. Exp. Date | #2 | | Doesn't Apply |
| #1 | #1 | | Event Reappeared After Reintroduction? | |
| #2 | #2 | | Tyes TNo 17 | oesn't |
| 9. NDC# or Unique ID | | | | pply oesn't |
| 54973-3127-1 | | #2 | ☐ res ☐ No ☐ A | pply |
| 0. Concomitant Medical P | roducts and The | apy Dates (Exc | clude treatment of event) | |
| | | | | |
| | | | , | |
| D. SUSPECT MEDIC Brand Name | AL DEVICE | | | |
| . Common Device Name | | | 2b. Procode | |
| . Manufacturer Name, City | and State | | | |
| . Model# | Lot# | | 5. Operator of Dev | ice |
| Catalog # | Expiration | Date (mm/dd/y) | Health Profes | sional |
| | | | Lay User/Patio | ent |
| Serial # | Unique Ider | ntifler (UDI)# | Other: | |
| . If Implanted, Give Date (r | nm/dd/yyyy) | 7. If Explanted | d, Give Date (mm/dd/yyyy |) |
| . Is this a Single-use Devic | e that was Repro | cessed and R | eused on a Patient? | |
| Yes No | | | | |
| If Yes to Item No. 8, Enter | Name and Addr | ess of Reproce | essor | |
| | | | DS | S |
| 0. Device Available for Eva | _ ` | , | MAR - 4 | 1 20 |
| Yes No | Returned to Ma | nufacturer on: | (mm/dd/yyyy) | يكا |
| 1. Concomitant Medical Pr | oducts and Thera | apy Dates (Exc | | |
| | | | (Continue on page | 21 |
| . INITIAL REPORTE | R | | (Continue on page | J) |
| Name and Address | | MAR - 3 | 2751 5 | 4 |
| | | | | |
| | | MAR - | 3 2015 | 9- |
| hone # | Email | MAR - | 3 2015 | |
| hone # Health Professional? 3. | | | 4. Initial Reporter Also Report to FDA | Sent |

| Individual cas | e perech webe | | | | OID: 40004400 |
|---|-------------------------------------|--|------------------------------------|-----------------------|---|
| | | | | | CaseID: 10901130 |
| | | | | | FDA USE ONLY |
| | | | 5 | 1 | |
| 109011 | 30-01-00-02 | | 2 of 5 | | |
| , | | | H. DEVICE MANUFAC | CTURERS ONLY | Y |
| 1. Check One | 2. UF/Importer I | Report Number | 1. Type of Reportable Event | | 2. If Follow-up, What Type? |
| User Facility import | ter | | Death | | Correction |
| 3. User Facility or Importer Name/A | Address | | Serious Injury | | Additional Information |
| | | | Malfunction | | Response to FDA Request |
| | | | | | Device Evaluation |
| | | | | | Device Evaluation |
| • | | | 3. Device Evaluated by Man | ufacturer? | Device Manufacture Date (mm/yyyy) |
| | | | Not Returned to Manu | ufacturer | (////////////////////////////////////// |
| 4. Contact Person | 5. Phone N | lumber | Yes Evaluation | n Summary Attached | |
| 6 Date Hear Engiller and 1 a | T | lo. p | No (Attach page to exprovide code: | explain why not) or | 5. Labeled for Single Use? |
| Importer Became | Type of Report | 8. Date of This Report (mm/dd/yyyy) | provide code. | | Yes No |
| Aware of Event (mm/dd/yyyy) | Initial | | | | _ _ |
| 1 | Follow-up # | | 6. Event Problem and Evalu | ation Codes (Refer to | coding manual) |
| 9. Approximate 10. Event Pr | oblem Codes (Refer to codi | ing manual) | Patient Code |]-[| - |
| Age of Device Patient | | | Device D | | |
| Code | | | Code | | - |
| Device | 1_ | | Mathod | | |
| Code | 40 | | Method | | _ |
| 11. Report Sent to FDA? | 12. Location Where Event | | Results | - | |
| Yes(mm/dd/yyyy) | Hospital | Outpatient Diagnostic Facility | | | |
| □ No (ITIITUGGYYYYY) | Home | Ambulatory | Conclusions | | |
| 13. Report Sent to Manufacturer? | Nursing Home | Surgical Facility | 7. If Remedial Action Initiate | ed, Check Type | 8. Usage of Device |
| Yes | Outpatient Treatment Facility | ıı | Recall N | lotification | Initial Use of Device |
| ☐ No (mm/dd/yyyy) | Other: | | | nspection | Reuse |
| Manufactures No 12 dd- | | (Specify) | | Patient Monitoring | Unknown |
| 14. Manufacturer Name/Address | | | Relabeling M | lodification/ | 9. If action reported to FDA under |
| | | | | djustment | 21 USC 360I(f), list correction/ removal reporting number: |
| | | | Other: | | • |
| | | | | | |
| | | | 10. Additional Manufactu | urer Narrative | and / or 11. Corrected Data |
| G. ALL MANUFACTURERS | | | | | |
| Contact Office (and Manufacturin | | 2. Phone Number | | | |
| Name | | 310-768-0700 | | | |
| DYTA FRACKIEWICZ | | 3. Report Source | | | |
| Address | | (Check all that apply) | | | |
| YLAND'S, INC. | | Foreign | | | |
| .54 W. 131ST STREET | | Study | | | |
| OS ANGELES, CA 90061 | | Literature | | | |
| Email Address | | ✓ Consumer | | | |
| TANDARD@HYLANDS.COM | | Health Professional | | | |
| . Date Received by | 5. | User Facility | | | |
| Manufacturer (mm/dd/yyyy) | (A)NDA # | Company Representative | 1 | | |
| 02/05/2015 | IND# | Distributor | | | |
| . If IND, Give Protocol# | | Other: | | | |
| | BLA # | ا | | | |
| . Type of Report | PMA/ 510(k) # | | | | |
| (Check all that apply) | Combination | | | | |
| 5-day 30-day | Product Yes | | | | |
| 7-day Periodic | Pre-1938 Yes | | ! | | _ |
| 10-day Initial | OTC Product 7 Yes | | | | D90 |
| 15-day Follow-up# | | | | | DSS Mar - 4 2015 |
| | 8. Adverse Event Term(s) SEIZURE | | 1 | | MAR - 4 2015 |
| 4973 AE # 1599 | SEIGURE | I | 1 | | - 2013 |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Individual case safety report

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Papervork Reduction Act (PRA) Staff information unless it dis
PRAStaff@tda.hhs.gov valid OMB control numb
Please DO NOT RETURN this form to the above PRA Staff email address.

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MPLAINT RECORD

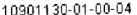


| 1090° | 1130:01-00:03 | COMPLAINT #: | 2609 |
|-------------------|--|--|-----------------------------------|
| | - | DATE OF COMPLAINT: | 02/05/15 |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | ВТЕТ |
| SIZE: | N/A (b) (6) | LOT NO.: | N/A |
| REPORTER: | | | |
| ADDRESS: | | | |
| | | | |
| CITY: | | STATE: | |
| COUNTRY: | USA | ZIP CODE: | |
| PHONE #: | | | |
| E-MAIL: | CUSTOMER POSTED THE FOLLOWING TW | O MESSAGES ON (b) (6) AND D | ID NOT RESPOND TO HYLAND'S |
| DAUGHTER DOC TO | LAINT: REQUEST TO CONTACT US: I USE THE TE DLD US TRY THEM BECAUSE SHE THREE AND JUSGOT ALL | ETHING TABLETS AND MY KID WENT . HER TEETH. | INTO SEIZUREW BUT MY |
| | | | |
| | FOR ADDITIONAL SPACE PLEASE USE REVE | RSE OR ATTACH A SEPARATE SHEE | ET . |
| | | | |
| PRODUCT RECEIVE | ED FOR Y N (CIRCLE ONE) | PRODUCT BEING RETURNED FOR II | NSPECTION: Y (N) (CIRCLE ONE) |
| | (0.1.012 0.112) | DATE REQUESTED PRODUCT BE | , |
| | | 5/112 (10000) ED (110000) EE | |
| | | UPS CALL T | AG ISSUED: (CIRCLE ONE) |
| | | | ,, |
| | | DATE PRODUCT | RECEIVED: |
| SECTION II: | INVESTIGATION | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| | | | |
| | | | |
| | | | |
| ADVEDCE EVENT EC | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION O | NI. 00/05/45 | |
| | ORWARDED TO PHARMACIST / NURSE FOR EVALUATION B | | ACKIEWICZ |
| SECTION III: | CORRECTIVE ACTION: | LUTTATE | ACNIEWICZ |
| <u>JEOTTOITM.</u> | SOURCE HE ACTION. | | |
| | | | |
| | | | |
| | | | |
| CORRECTIVE ACTIO | DN(S) COMPLETED BY: | DATE: | |
| | | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: _ | 1599 |
| ADVERSE EVENT SE | ERIOUS: Y N | | • |
| ADVERSE EVENT RE | EPORTED ON: 02/05/15 | BY: EDYTA FRACKIE | WICZ |
| SECTION V: | | | DSS |
| DEI/IBA-B | alert. | | 02-18 - MAR - 4 2015 |
| REVIEWED BY MANA | AGEMENT BY: | 7 DATE: _ | 02-18-15 MAR - 4 2015 02-17-15 |
| BY: | Vue Balle | DATE: | 02-17-15 |

cc: QA / QC Packaging

Production Shipping / Receiving







Serious Adverse Event SAE-0008-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty nine (139) Adverse Events (AE) which also included forty five (45) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ pm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

2/13/15

Date

DSS MAR - 4 2015

CaseID: 10901130



SE EVENT DATA FORM



| AE #: _ | 1599 | COMPLAINT #:2609 |
|--|--|--|
| SECTION I | <u>:</u> | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) |
| NAME: ADDRESS: | : | (b) (6) - |
| CITY: | | STATE: |
| COUNTRY: PHONE #: E-MAIL: | : | USA ZIP CODE: |
| SECTION II | <u>l:</u> | PACKAGING INFORMATION: |
| | AFFI | X PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| plant plant to go delight to any parties of a parties to parties of a parties to parties of a parties and to parties of a parties and to parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties of any parties of a parties a parties of a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a parties a partie | A PERSONALA DE RENORA COSTEA CO LEGARDOS CALOSES | the land is a series of the se |
| SECTION II | <u>ll:</u> | CORRECTIVE ACTION: |
| | | |
| CORRECTIV | VE ACT | TION(S) COMPLETED BY: DATE: |
| SECTION IN | | NAGEMENT BY: Aftert for DATE: 02-18-1MAR-420 QA/QC DIRECTOR DATE: 02-17-15 |

user-facilities, tors and manufacturers TORY reporting

Page 1 of 5

| CaseID: 10945484 | |
|--|--|
| Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 | |

| Mfr Report # | |
|--------------------|--------|
| UF/Importer Repeat | \sim |
| ()1 | |
| 100 | |

FURM FDA 3500A (2/13)

| | A. PATIENT IN | FORMATION | | | | |
|---|---|-----------------------------|--------|--------------------------|----------------------------------|-----------|
| | 1. Patient Identifier (b) (6) | 2. Age at Time of Event: | | | 3. Sex | 4. Weight |
| | (6) (6) | or | 3 | Months | Female | |
| | h | Date | | | ✓ Male | or |
| | In confidence B. ADVERSE E | of Birth: | DIL | T DDOD! F | | |
| | | | יטטו | TPROBLE | IVI | |
| | 1. Adverse Even | | | duct Problem (6 | .g., defects/malfe | inctions) |
| | 2. Outcomes Attribu (Check all that appli | | ent | | | |
| | Death: | (mm/dd/yyyy) | | Disability of | r Permanent Dar | mage |
| | Life-threatenin | | | Congenital | Anomaly/Birth D | efect |
| | | a - initial or prolonge | | | ous (Important M | |
| | | vention to Prevent | Perma | | | |
| | 3. Date of Event (mn | n/dd/yyyy) 25/2015 | | | Report (mm/dd | |
| | 5. Describe Event or | | | | 03/03/2015 | |
| | 3 MONTH OLD B AFTER RECEIVI HAS A HISTORY LATELY AFTER | NG ONE TABLE OF ASTHMA A | T O | F BABY TEE IRTH, THAT | THING TABLE HAS NOT RE | ETS. H |
| | 6. Relevant Tests/Lab | poratory Data, Incli | uding | Dates | (Continue on | page 3) |
| | | • | · | | | |
| | UNKNOWN | | | | | |
| I | | | | | | |
| | | | | | | |
| | | | | | | |
| ۱ | | | | | | |
| | | | | | (Oamline) | |
| ŀ | 7. Other Relevant Hist | tory, Including Pre | existi | ng Medical Con | (Continue on ditions (e.g., alle | |
| l | race, pregnancy, sm ASTHMA AT BIRT | oking and alcohol u | se, he | patic/renal dysfu | nction, etc.) | . g , |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
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| | | | | | | |

| | | | The state of the s | | | FDA Use Only |
|---|----------------|-----------------|--|-----------|-------------------------------|------------------|
| C. SUSPECT PR | | | | | | |
| 1. Name (Give labeled #1 HYLAND'S BA | - | | | | | |
| #2 | | | | | | |
| 2. Dose, Frequency & | Route Us | ed | 3. Therany | Dates (| If unknown | give duration) |
| | | | from/to/ | or best e | stimate) | jivo darakonj |
| #2 | | V | $\Xi D-$ | | | |
| 4. Diagnosis for Use | Indication) | | 15 | Event | Abated Afte | r Heo |
| #1 TEMP RELIEF | AR I | 8 :2015: | sx | Stopp | ed or Dose F | Reduced? |
| #2 | P 20 | A Num. | | #1 Y | es No | Doesn't Apply |
| 6. Lot# | 77 5 | Date | | 2 🗌 Y | es No | Doesn't Apply |
| #1A08815 | #1 | | 8 | . Event | Reappeared oduction? | After |
| #2 | #2 | | # | | es No | Doesn't |
| 9. NDC# or Unique ID | | | | | | Apply Doesn't |
| 54973-3127-1 | -I Dd | | 1 | | es No | L Apply |
| 10. Concomitant Medic | | us and The | rapy Dates (E | xclude : | reatment of e | event) |
| THORITA ADDOTOR | -1 | | | | | |
| | | | | | | |
| | | | | (C | ontinue on | page 3) |
| D. SUSPECT MEI | DICAL | DEVICE | | | | |
| 1. Brand Name | | | | | | |
| 2. Common Device Nar | me | | | 2b. P | rocode | |
| 3. Manufacturer Name, | City and | State | | | | |
| | | | | | | |
| 4. Model# | | Lot # | | | 5. Operator | of Device |
| | | | | | | Professional |
| Catalog # | | Expiration | Date (mm/dd/ | (УУУУ) | Lay Us | er/Patient |
| Serial # | | Unique Ide | ntifier (UDI) # | | Other: | |
| 6. If Implanted, Give Da | to (mm/di | ****** | 7 15 | لي | | |
| o. Il limpianteu, Give Da | ite (Illilivac | <i>₩ŶŶŶŶ</i> | 7. If Explan | tea, Giv | Date (mm/c | (a/yyyy) |
| 8. Is this a Single-use D | evice tha | t was Repr | ocessed and | Reused | on a Patien | 17 |
| 9. If Yes to Item No. 8, I | Inter Nam | hhA has a | ace of Dance | 200000 | | |
| 5. 1. 1 66 to italii 110. 0, i | -iner man | ie alia Addi | ess of Repro | rcessor | | I |
| | | | | | | |
| 40 B. d. A. W. H. L. | | | | | | |
| 10. Device Available for Yes No | _ | | send to FDA) anufacturer on | | | |
| | | | | | (mm/dd/yy) | |
| 11. Concomitant Medica | al Product | ts and Ther | apy Dates (E | xclude t | reatment of e | vent) |
| | | | | | | |
| E INITIAL BERGE | TED | | | (Co | ntinue on | page 3) |
| E. INITIAL REPOR | CIER | | | | | |
| (b) (6) | | | | De | 20 | |
| | | | | DS | 55 | |
| (b) USA | | | M | AR 1 | 9 2015 | |
| Phone # | | Email | Address | | | |
| b) (6) | | | | | | |
| 2. Health Professional? | | pation | | 4. In | itial Reporte eport to FDA | r Also Sent |
| ∐ Yes 📝 No | NA | | | | Yes N | o 🔽 Unk. |

MAR 1 8 2015



| | | | 2. UI | F/Importer F | Report | Number | |
|--|---|--|-----------------|----------------------------------|--|--|--|
| User Facility Importer | | | | | | | |
| 3. User Facility or Imp | 3. User Facility or Importer Name/Address | | | | | | |
| | | | | | | | |
| 4. Contact Person | | | | 5. Phone N | | | |
| 4. Contact Person | | | | o. Phone N | umbei | | |
| 6. Date User Facility of Importer Became | | 7. Type of R | eport | | 8. Da | te of This Report | |
| Aware of Event (mn | v/dd/yyyy) | Initial | | | ,,,, | | |
| 1 | | Follow- | ıp# | | | | |
| Approximate Age of Device | 10. Event | Problem Cod | les (F | Refer to codin | ng mai | nual) | |
| | Patient Code | | _ | | | _ | |
| , | Device [| | = | | | | |
| | Code | | | <u></u> | | | |
| 11. Report Sent to FDA | 17 | I | | ere Event (| Occur | - | |
| Yes(mm/dd | (1000) | | spital | | | Outpatient Diagnostic Facility | |
| ∐ No | |] = | me | | П | Ambulatory | |
| 13. Report Sent to Man | ufacturer? | 1 = | _ | Home nt Treatmen | , – | Surgical Facility | |
| Yes(mm/dd/ | hara) | | cility | Treatment | • | | |
| ∏ No (minute) | ,,,,, | OII | Other:(Specify) | | | | |
| 14. Manufacturer Name | Address | | | | ,-,-,- | , | |
| | | | | | | | |
| G. ALL MANUFA | CTURER | | | | | | |
| 1. Contact Office (and | .5 | | | | | | |
| | Manufactu | | Devic | es) | | one Number | |
| Name | | | Devic | es) | 310- | 768-0700 | |
| | | | Devic | es) | 310- | | |
| Name EDYTA FRACKIEWI Address | | | Devic | es) | 310- 3. Re (C | 768-0700 | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST | CZ | ring Site for I | Devic | es) | 310- 3. Re (C) | port Source heck all that apply) | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. | CZ | ring Site for I | Devic | es) | 310- 3. Re (C) F | 768-0700 port Source pock all that apply) oreign tudy terature | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST | CZ | ring Site for I | Devic | es) | 310- 3. Re (C) F S | -768-0700 port Source neck all that apply) oreign tudy terature onsumer | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND | CZ REET 90061 | ring Site for I | Devic | es) | 310- 3. Re (C) F S | port Source neck all that apply) oreign tudy terature onsumer ealth Professional | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address | CZ REET 90061 | ring Site for I | | es) | 310- 3. Rec (C) F S U | port Source neck all that apply) oreign tudy terature onsumer ealth Professional ser Facility | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by | CZ REET 90061 | 5. (A)NDA# | | | 310- 3. Re (C) 5 5 5 7 7 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/do | CZ REET 90061 S.COM | 5. (A)NDA# | | | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc) 22/25/20 | CZ REET 90061 S.COM | 5. (A)NDA# IND# BLA# | | | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc 02/25/20 6. If IND, Give Protocol | CZ REET 90061 S.COM | 5. (A)NDA# | | | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc 32/25/20 6. If IND, Give Protocol 7. Type of Report (Check all that apply) | CZ REET 90061 S.COM Vyyyy) 15 | 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination | | | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc 02/25/20 6. If IND, Give Protocol | CZ REET 90061 S.COM Vyyyy) 15 | 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination | | Yes | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc | CZ REET 90061 S.COM Vyyyy) 15 | 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination | on | ☐ Yes | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc | CZ REET 90061 S.COM Vyyyy) 15 | 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination | on | Yes | 310- 3. Re (C) S S U | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc | CZ REET 90061 S.COM Vyyyy) 15 # | 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Pre-1938 OTC Produ 8. Adverse | on Jet | ☐ Yes ☐ Yes ☐ Yes ☑ Yes | 310- 3. Re (C) | port Source neck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor ther: | |
| Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/dc | CZ REET 90061 S.COM Vyyyy) 15 # | 5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Pre-1938 OTC Produ 8. Adverse | on Jet | ☐ Yes ☐ Yes ☐ Yes ☑ Yes | 310- 3. Re (C) | port Source leck all that apply) oreign tudy terature onsumer ealth Professional ser Facility ompany epresentative istributor | |

This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

| CaseID: | 10945484 |
|---------|----------|
|---------|----------|

FOA USE ONLY

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|--|---|
| H. DEVICE MANUFACTURERS ONLY | |
| 1. Type of Reportable Event | 2. If Follow-up, What Type? |
| Death | Correction |
| Serious Injury | Additional Information |
| Malfunction | Response to FDA Request |
| | Device Evaluation |
| Device Evaluated by Manufacturer? | Device Manufacture Date (mm/yyyy) |
| Not Returned to Manufacturer | |
| Yes Evaluation Summary Attached | 5 I sheled for Single Hee? |
| No (Attach page to explain why not) or provide code: | 5. Labeled for Single Use? |
| | ∐ Yes ☐ No |
| 6. Event Problem and Evaluation Codes (Refer to coo | ling manual) |
| Patient Code - | |
| Device | |
| Code | |
| Method - | |
| Results - | |
| Tresults | |
| Conclusions | · |
| 7. If Remedial Action Initiated, Check Type 8. U | sage of Device |
| Recall Notification | Initial Use of Device |
| Repair Inspection | Reuse |
| Replace Patient Monitoring | Unknown |
| Adjustment 2 | action reported to FDA under I USC 360i(f), list correction/ emoval reporting number: |
| Other: | anovai reporting number: |
| | |
| 10. Additional Manufacturer Narrative and | or 11. Corrected Data |
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PRASlaff@fda.hhs.gov
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PLAINT RECORD



| 10945484-01-00-03 | COMPLAINT#: 2611 | |
|--|--|---|
| | DATE OF COMPLAINT: 02/25 | 5/15 |
| PRODUCT: HYLAND'S BABY TEETHING TABLETS | ITEM CODE: BTET | ГT135 |
| SIZE: 135 TABLETS | LOT NO.: _A088 | 15 |
| REPORTER: (b) (6) | | |
| ADDRESS: | | |
| | | |
| CITY: | STATE: (b) (6) | |
| COUNTRY: USA | ZIP CODE: | |
| (b) (6) PHONE #: | | |
| E-MAIL: | | |
| 3 MONTH OLD BABY DEVELOPED DIFFICULTY NATURE OF COMPLAINT: TEETHING TABLETS. HE HAS A HISTORY OF A TREATMENT WITH PROAIR ALBUTEROL. HIS SYMPTONS OCCURRED EARLY SHORTNESS OF BREATH, "NOT UNLIKE HIS ASTHMA SYMPTOMS". THE MOTHER I BREATHS IN ORDER TO FACILITATE BREATHING". HE WAS GIVEN PROAIR AT HO! FOR HIS ASTHMA. A DOCTOR WAS CALLED BUT NOT YET REACHED. I SUGGESTI BREATHING WORSENED. | ASTHMA AT BIRTH, THAT HAS NOT REC MORNING AT 4 AM WITH WHEEZING, (REPORTED THAT HE "NEEDED TO BE M ME. BUT IT DID NOT SEEM TO HELP HIN | CURRED LATELY AFTER CONGESTION AND MAKING NOISES IN BETWEEN MAS IT HAD PREVIOUSLY |
| FOR ADDITIONAL SPACE PLEASE USE REVERSE | OR ATTACH A SEPARATE SHEET | |
| , | | _ |
| PRODUCT RECEIVED FOR Y N PRODUCT RECEIVED FOR (CIRCLE ONE) | ODUCT BEING RETURNED FOR INSPEC | CTION: Y N (CIRCLE ONE) |
| r | ATE REQUESTED PRODUCT BE RETU | RNED: |
| • | UPS CALL TAG IS | SUED: (CIRCLE ONE) |
| | DATE PRODUCT REC | EIVED: |
| SECTION II: INVESTIGATION | | |
| INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT. | | |
| | | |
| 445 | | |
| THE PROPERTY OF THE PROPERTY O | 02/25/15 | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | | |
| ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | TUTTI GOULD | |
| SECTION III: CORRECTIVE ACTION: | | |
| | | |
| · · · · · · · · · · · · · · · · · · · | | |
| | | |
| CORRECTIVE ACTION(S) COMPLETED BY: | DATE: | |
| SECTION IV: ADVERSE EVENT REPORTS | AE #: 1601 | |
| ADVERSE EVENT SERIOUS: | | DSS |
| ADVERSE EVENT REPORTED ON: 02/25/15 | BY: TUTTI GOULD | MAR 1 9 2015 |
| SECTION V: | | MAR 1 8 2015 |
| REVIEWED BY MANAGEMENT BY: | DATE: | 3- 09 - 13 |
| BY: QA / QC DIRECTOR | DATE: | 3-03-15 |

cc: QA/QC Packaging Production Shipping / Receiving





CaseID: 10945484

Serious Adverse Event SAE-0010-2015

Product in Inventory:

Twenty (20) units of Hyland's Baby Teething Tablets (BTET), lot # A08815, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A08815 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A08815. The Baby Teething bulk lot # 124034 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

A visual inspection of the retention samples was conducted and no issues were noted with the packaging of the products. The inspection also included a visual inspection of the contents of the bottle and it was confirmed that it matched the specifications.

The inspection did not yield any results that may be related to this incident.

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # A08815. We will continue to monitor our reported incidents for potential trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # A08815.

Manufacture and processing occurred within established procedures to ensure product quality.

03-03-15

Date

DSS MAR 1 9 2015 MAR 1 8 2015



SE EVENT DATA FORM



| AE #:16 | 601 | COMPLAINT #: 2611 |
|--|--|--|
| SECTION I: | PATIENT INFORMATION (IF DIF | FERENT FROM REPORTER ON FORM VD1) |
| NAME: | (b) (6) | • |
| ADDRESS: | | |
| | | |
| CITY: | | STATE: (b) (6) |
| COUNTRY: | USA | ZIP CODE: |
| PHONE #: | (b) (6) | |
| E-MAIL: | | |
| SECTION II. | DACKACING INFORMATION. | |
| SECTION II: | PACKAGING INFORMATION: | |
| A | AFFIX PACKAGING LABEL HERE | AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) |
| the plan is to skill I she skill which I willow now have be | With the Mit such as the Committee of th | Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets |
| SECTION III: | CORRECTIVE ACTION: | And an answering Parties are all the state of the state o |
| | | |
| CORRECTIVE | ACTION(S) COMPLETED BY: | DATE: |
| SECTION IV: | | MAR 19 |
| | Y MANAGEMENT BY: Fuc 130 | NULA DATE: 03-04-15 |
| | Euc Bo | |

MAR 1 8 2015

QA / QC DIRECTOR

iser-facilities, ors and manufacturers ORY reporting

| Fo | rm Approved | OMB No. 0910-0291, Expires: 6/30/20 See OMB statement on revers |
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| ort# | 54973 | |

Mfr Report # 54973
UF/Importer Report #

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|--|---|----|---|
|--|---|----|---|

| | A. PATIENT INF | ORIVIATION | | | |
|--------|---|---|--------------------|--------------------|----------------|
| | Patient Identifier (b) (6) | Age at Time of Event; | | 3. Sex | 4. Weight |
| | (b) (b) | or | | ✓ Female | lbs |
| | | Date | | | or |
| | in confidence | of Birth: | | Male | kgs |
| | B. ADVERSE EV | VENT OR PRODU | CT PROBLE | VI | |
| | 1. Adverse Even | t and/or Pro | duct Problem (e | .g., defects/malfo | unctions) |
| | 2. Outcomes Attribut | | | | |
| | (Check all that appl) | у) | | | |
| | Death: | (mm/dd/yyyy) | _ [_] Disability o | r Permanent Dar | nage |
| | Life-threatenin | | Congenital | Anomaly/Birth D | efect |
| | Hospitalization | - initial or prolonged | Other Serio | ous (Important M | edical Events) |
| | Required Inter | vention to Prevent Perm | anent Impairment | /Damage (Device | es) |
| | 3. Date of Event (mm | n/dd/yyyy) | 4. Date of This | Report (mm/dd | /yyyy) |
| | 05/00/2014 | 4 PRESENT | | 03/12/2015 | ı |
| | 5. Describe Event or | Problem | ov (b) (6) | | |
| | | LLY HAD POSTED A SEVERE ALLERG | | THAT HER THEN O | |
| | | ENT AN UPDATE A | | | |
| | | D GIVEN HYLAND' | | | |
| | 1 | EVELOPED SEVERE | | | MOUTH |
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| ڗ | HER BUTTOCKS. | | | | PAIN AND |
| BLACK | | A MONTH FOR THE | | | CHILD |
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| rlease | | | | | |
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| | | | | (Continue on | page 3) |
| | 6. Relevant Tests/Lab | oratory Data, Including | Dates | | |
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| | 7 Other Relevant His | tory Including Pressist | | (Continue on | |
| | | tory, Including Preexist toking and alcohol use, h | | nction, etc.) | oi gios, |
| | | CTORS MULTIPLE AL DIET, STOOL | | מזמסדא חואה | v |
| | CHILD ON SPECI | AL DISI, STOOL | SOF I ENERS | WIND LITEVITY | · |
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| | | | | (Continue on | page 3) |
| ļ | submission of a re | port does not con | | ` | |
| r | ersonnel, user fac aused or contribu | cility, importer, dist | tributor, man | ufacturer or | product |
| v | auseu or contribu | ited to the event. | | | |

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|--------------------------------|-------------------------------|-----------------|-----------------------------------|------------------------|
|)T | | | 4 | FDA Use Only |
| C. SUSPECT PROD | | | | |
| 1. Name (Give labeled stre | - , | | | |
| #1 HYLAND'S BABY | TEETHING TA | BLETS | | |
| #2 | | | | |
| 2. Dose, Frequency & Ro | ute Used | 3. Therapy D | ates (If unknow best estimate) | rn, give duration) |
| #1 | P Branc M. W. Barra | | Desi esimiale) | |
| #2 REC |) LIVE | #2 | | |
| 4. Diagnosis for Use (Indi | ication) | | Event Abated | After Use |
| #1 TEMP RELIEA PI | €e 0 + 1 ×2045× | | Stopped or Do | se Reduced? |
| #2 | | #1 | Yes ✓ | No Doesn't Apply |
| 6. Lot # | 7. Exa. 287e | #2 | Yes 🗌 | No Doesn't |
| #1 | #1 | 8. 1 | Event Reappea | |
| | | | Reintroduction | ? |
| #2 9. NDC# or Unique ID | #2 | #1 | Yes _ | No 🔽 Doesn't Apply |
| 54973-3127-1 | | #2 | ☐ Yes ☐ | No Doesn't |
| 10. Concomitant Medical | Products and Ther | apy Dates /Ex | clude treatment | of event) |
| | | | | or orong |
| | | | | |
| | | | | |
| | | | (Continue | on page 3) |
| D. SUSPECT MEDIC | CAL DEVICE | | | , , , |
| 1. Brand Name | | | | |
| 2. Common Device Name | | | 2b. Procode | |
| | | | | |
| 3. Manufacturer Name, Ci | ty and State | | | |
| | | | | |
| 4. Model# | Lot# | | 5. Opera | ator of Device |
| Catalog # | Expiration (| Date (mm/dd/y | | alth Professional |
| outureg # | | ate (minoury) | '''' 🔲 Lay | / User/Patient |
| Serial# | Unique Ider | tifier (UDI)# | | ner: |
| | | | | |
| 6. If Implanted, Give Date | (mm/dd/yyyy) | 7. If Explante | d, Give Date (n | nm/dd/yyyy) |
| 8. Is this a Single-use Dev | rice that was Repro | cessed and R | leused on a Pa | tient? |
| Yes No | | | | n ₆ |
| 9. If Yes to Item No. 8, Ent | ter Name and Addr | ess of Reproc | essor | 4. |
| | | | | |
| | | | | nee |
| 10. Device Available for E | valuation? (Do not | send to FDA) | | D99 |
| Yes No | Returned to Ma | inufacturer on: | ΔDI | 201 |
| 11. Concomitant Medical I | Producte and Thor | any Dates /Ev | clude treatment | .,,,, |
| 11. Conconitant medicar | Froducts and river | apy Dates (Ex | cidde ireaimeni | or event) |
| | | | | : |
| | | | (Continue | on page 3) |
| E. INITIAL REPORT | ER | | | |
| 1. Name and Address (b) (6) | | | | |
| | -10 | Δ. | | |
| | | Al Al | PR - 1 2 | 015 |
| | "LLL" | 5 / | - • | |
| Phone # | Email | Address | | |
| | (b) (b) | | | |
| I. | 3. Occupation | | 4. Initial Rep Report to | orter Also Sent FDA |
| Yes No | NA | | Yes | No Unk. |



e 2 of 5

| CaseID: 10984052 | |
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| FDA USE ONLY | |
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APR - 2 2015

| | | | | | | H. DEVICE WA | NUF | 4C IUKER | S UNLY | | | |
|---|----------------|-----------------------|--------------------------|----------------------------|-----|--------------------|-----------|---|-------------|------------|------------------|--------------------------------|
| 1. Check One | _ | | 2. UF/Importer | Report Number | 1 1 | . Type of Reportab | ole Eve | nt | | 2. If Fo | ollow-up, Wh | at Type? |
| User Facility | Impo | orter | | | 11 | Death | | | | 1 - | Correction | |
| 3. User Facility or Imp | orter Name | /Address | | | 11 | Serious injur | ry | | | 1 7 | Additional l | nformation |
| | | | | | 11 | Malfunction | | | | | | to FDA Request |
| | | | | | 11 | · | | | | - | Device Eva | - |
| | | | | | ΙL | | | | | | I perice Eva | Juauon |
| | | | | | 3 | . Device Evaluated | by Ma | nufacturer? | | | ice Manufact | ure Date |
| | | | | | | Not Returned | d to Ma | anufacturer | | (""" | Vyyyy) | |
| 4. Contact Person | | | 5. Phone I | lumber | 1 | Yes E | Evaluati | on Summary | Attached | | | |
| | | | | | 11 | | | explain why | | 5. Labe | eled for Sing | le Use? |
| Date User Facility or Importer Became | r | 7. Type of Re | port | 8. Date of This Report | 1 | provide code | e: | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | , |] _ | 7. r | - |
| Aware of Event (mm | v/dd/yyyy) | Initial | | (mm/dd/yyyy) | | | | | | - | Yes | No |
| | | | - # | | 6 | Event Problem an | nd Eval | luation Code | s (Refer to | coding mai | nual) | |
| 0. A = = = = = = = = = = = = = = = = = = | 40.5 | Follow-up | | | 11 | Pati | _ | | | | ¬ ′ | |
| 9. Approximate Age of Device | 10. Event F | Problem Code | es (Refer to cod | ing manual) | | Cod | | | ∟ | | | |
| | Patient | , | 7-[|]_ | 11 | Dev | 1 | | | | 7_ [| |
| 1 | Code _ | | | | | Cod | ie [| | | | ┛┈┕── | |
| 1 | Device Code | | - | - | 11 | Meth | nod | - | | 7- | | |
| 11. Report Sent to FDA | | 12 Location | n Where Event | Occurred | | | - | | | ᅴ | | |
| 1 | •• | Hos | | Outpatient | | Resu | ults | 1- | - | - | - | |
| Yes(mm/dd/ | (www) | | | Diagnostic Facility | | | F | | | 7 = | <u> </u> | |
| □ No (IIII) | ,,,,, | Hon | | Ambulatory | | Conclusio | ons | | | J | | |
| 13. Report Sent to Man | ufacturer? | | sing Home | Surgical Facility | 7. | If Remedial Action | n Initial | ted, Check T | ype 8 | . Usage of | Device | |
| Yes | | Faci | patient Treatme ility | nt | | Recall | | Notification | | ☐ ini | itial Use of De | evice |
| No (mm/dd/ | <i>'YYYY)</i> | Othe | • | | | Repair | = | | | | euse | |
| | | | | (Specify) | | | | Inspection | | | nknown | |
| 14. Manufacturer Name | Address | | | | 11 | Replace | | Patient Monit | ~ F | | reported to F | EDA undos |
| | | | | | | Relabeling | | Modification/ Adjustment | ľ | 21 USC 3 | 360i(f), list co | orrection/ |
| | | | | | | Other: | | | - 1 | removai | reporting nu | mber: |
| | | | | | | | | | | | | |
| | | | | | l ⊢ | | | | | | | |
| | | | | | 10 | . Additional M | lanufac | turer Narrat | ive a | nd/or | 11. 🔲 C | orrected Data |
| G. ALL MANUFAC | CTURER | S | | | | | | | | | | |
| Contact Office (and I | Manufactur | ing Site for D | evices) | 2. Phone Number | | | | | | | | |
| Name | | | | 310-768-0700 | Ш | | | | | | | |
| EDYTA FRACKIEWI | CZ | | | 3. Report Source | | | | | | | | |
| Address | | | | (Check all that apply) | | | | | | | | |
| HYLAND'S, INC. | | | | Foreign | | | | | | | | |
| 154 W. 131ST ST | | | | Study | | | | | | | | |
| LOS ANGELES, CA | 90061 | | | Literature | | | | | | | | |
| Email Address | | | | . Consumer | | | | | | | | |
| STANDARD@HYLAND | S.COM | | | Health Professional | | | | | | | | |
| 4. Date Received by | | 5. | | User Facility | | | | | | | | |
| Manufacturer (mm/do | V YYYY) | (A)NDA# | | Company | | | | | | | | |
| 03/10/20 | 15 | | | Representative Distributor | | | | | | | | |
| 6. If IND, Give Protocol | # | IND# - | | Other: | | | | | | | | ン さ ら R -2 20 |
| | | BLA#_ | | L Cina. | | | | | | | A D | D - 6 20 |
| 7. Type of Report | | PMA | | | | | | | | | AF | n 2 20 |
| (Check all that apply) | | 510(k) # | | | | | | | | | | |
| 5-day 30-day | y | Combinatio Product | n Yes | | | | | | | | | |
| 7-day Period | | | | | | | | | | | | |
| ☐ 10-day ✓ Initial | | Pre-1938 | Yes | | | | | | | A D- | | |
| ✓ 15-day Follow | /-up# | OTC Produ | ct 🗸 Yes | | | | | | | APR | 7-12 | N4E |
| 9. Manufacturer Report | | 8. Adverse | Event Term(s) | L | | | | | | | . (| UIJ |
| | | 1 | | , GI BLISTERING, | | | | | | | | |
| 54973 AE # 160 | 2 | 1 | | EMORRHOIDS | | | | | | | • | |
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff

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PRAStaff@fda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.



OMPLAINT RECORD



| 1098 | 84052-01-00-03 | COMPLAINT #: | 2612 | | |
|--|---|---|--|--|------|
| | 4 | DATE OF COMPLAINT: | 03/10/2015 | | |
| PRODUCT: | HYLAND'S BABY TEETHING TABLETS | ITEM CODE: | BTET | | |
| SIZE: | UNKNOWN | LOT NO.: | _Na | | |
| REPORTER: | (b) (6) | | | | |
| ADDRESS: | | | | | |
| CITY: | | STATE: | | | |
| COUNTRY: | USA | ZIP CODE: | | | |
| PHONE #: | | | | | |
| E-MAIL: | (b) (6) | | | - | |
| PROVIDED CLAR AN SAE. CUSTOI PHILLIPS VIA(D) (6 YEAR AND WE AI BLISTERING FRO BLEEDING INSIDI HER DIAPER CHA FOR THE BLISTE REGULAR BASIS SINCE WE GAVE PLACED ON A SP BEEN ON MIRALA VERY TRAUMATIC AND ENEMAS IS | ER DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT US RIFICATION THAT THE PRODUCT IN QUESTION WAS BABY TEETI MER DID NOT RESPOND TO HYLAND'S REGARDING TO CONTAC | S. MY DAUGHTER HAD A SEVERE S. ON 3/10/15 CUSTOMER SENT TI- HING TABLETS AND THE ADVERSE CT COMPANY BY PHONE: HI, I WAS SHITER HAD TO YOUR PRODUCTS. GIVEN THE TEETHING TABLETS A LER ANUS. THE BLISTERING WAS LISTERS THAT POPPED ON HER BI ISED TO GO TO THE BATHROOM A NUS. SHE STILL REFUSES TO TAKEN HAS BEEN WORKING WITH US TO THE SHIPPED ON THE SHIPPED ON THE STILL REFUSES TO THE STILL REFUSES TO THE PAUMEROUS TIMES BECAUSE OF ESS PAINFUL FOR HER TO GO TO RHOIDS. THIS HAS BEEN HORRIBISULAR BASIS. THE PAIN OF HAVINGULAR BASIS. THE PAIN OF HAVINGULAR BASIS. THE PAIN OF HAVINGULAR BASIS. THE PAIN OF HAVINGULAR BASIS. | ALLERGIC RE. HE FOLLOWING E EVENT WAS IE S CONTACTED IT HAPPENED IND IT CAUSED SO SEVERE TH UTT SO SHE RI AT ALL. IT TOO (E A BOWL MO TO GET HER BA THE BATHROO THE BATHROO IN THE BATHROO | G E-MAIL WHICH DETERMINED TO BE BY CHRISTINE DIN MAY OF LAST O SEVERE HAT SHE WAS EFUSED TO HAVE OK OVER A MONTH VEMENT ON A ACK TO NORMAL ND HAS BEEN DM. SHE ALSO HAS ND FOR US. IT IS R SUPPOSITORIES | |
| | | | | | |
| | FOR ADDITIONAL SPACE PLEASE USE REVERS | SE OR ATTACH A SEPARATE SHE | ET | | |
| PRODUCT RECEI INSPECTION: | IVED FOR Y N PI | RODUCT BEING RETURNED FOR I | | Y (CIRCLE ONE) | |
| | | DATE REQUESTED PRODUCT BE | RETURNED: | | |
| | | UPS CALL T | TAG ISSUED: | Y (N) (CIRCLE ONE) | |
| | | DATE PRODUCT | Γ RECEIVED: | | |
| SECTION II: | INVESTIGATION | | - | | |
| INVESTIGATION: | PLEASE SEE ATTACHED INVESTIGATION REPORT. | | | | |
| ADVERSE EVENT | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: | 03/10/15 | | | |
| ADVERSE EVENT | FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: | EDYTA FR | RACKIEWICZ | Dee | |
| SECTION III: | CORRECTIVE ACTION: | | | 000 | |
| | | | | APR - 2 2015 | 304t |
| CORRECTIVE AC | TION(S) COMPLETED BY: | DATE: | | | 2015 |
| oonneonve no | | DATE. | | | |
| SECTION IV: | ADVERSE EVENT REPORTS | AE #: _ | 1602 | | |
| ADVERSE EVENT | SERIOUS: Y N | 4 | | APR - 1 201 | 5 |
| ADVERSE EVENT | REPORTED ON: 03/10/15 | BY: EDYTA FRACKIE | WICZ | | - |
| SECTION V: | DIA OF L | | 03-10 | 1-15 | |
| REVIEWED BY MA | ANAGEMENT BY: | Λ | | | |
| BY: | QA/QC DIRECTOR | DATE: | 03-16 | 75 | |

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 10984052

SAE-0011-2015

Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) but no lot number, location of purchase or date of purchase for the units involved.

Review of Records:

Without the lot number a review of the batch records is not possible.

Retention Samples:

No retention samples were inspected because without the lot number of the products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible. However a review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been one hundred thirty seven (137) Adverse Events (AE) which also included forty five (45) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). The reports were reviewed and there does not appear to be any trend. We will continue to monitor future reports for any possible trends.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

Due to the limited information provided by the reporter no further investigation is possible at this time of this incident. Standard Homeopathic Co. has established and maintains procedures to ensure product quality.

Prepared by

3/16/15

Date

APR - 2 2015

APR - 1 2015



EVENT DATA FORM



| AE #:1602 | 2 COMPLAINT #: _2612 | |
|--|--|--|
| SECTION I: | PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1) | |
| NAME: | (b) (6) | |
| ADDRESS: | | |
| CITY: | STATE: | |
| COUNTRY: PHONE #: | USA ZIP CODE: | |
| E-MAIL: | (b) (6) | |
| SECTION II: | PACKAGING INFORMATION: | |
| AFF | FIX PACKAGING LABEL HERE AFFIX COPY OF OUTER CARTON H (INCLUDE DRUG FACTS AND PRINCIPAL PANELS) | |
| Antifications: language of reference and our critishing data Schwarzer and our critishing data Schwarzer and our critishing data Schwarzer and our critishing data Schwarzer diges. All control of the schwarzer day of th | ACT TRALETS MADE TO THE TENNON AND T | and to the state of the state o |
| SECTION III: | CORRECTIVE ACTION: | |
| | | DSS |
| | | APR - 2 2015 |
| CORRECTIVE AC | TION(S) COMPLETED BY: DATE: | |
| SECTION IV: | 0.7 11 | |
| REVIEWED BY MA | ANAGEMENT BY: DATE: 03 | 19-15 APR - 1 2016 |
| BY: | QA/QC DIRECTOR DATE: 03 | -19-15 APR - 1 2015 -16-15 |

sumer Report

Case D. 10993411

Fin Aproved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

| FDA USE ONLY | | | | | | |
|---------------------------|--------|--|--|--|--|--|
| Triage unit sequence # | | | | | | |
| : | 590752 | | | | | |

ine FDA Safety Information and Adverse Event Reporting Program

| RY reporting of |
|--------------------|
| duct problems and |
| product use errors |

| A. PATIENT INFORMATION | 2. Dose or Amount | Frequency | Route |
|---|--|--|--|
| Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight | #1 | | |
| (6) Date of Birth: 10 Months Female Ib | | | |
| (b) (6) | #2 | | : |
| In confidence | | | |
| B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR | Dates of Use (If unknown of the control of the contro | own, give duration) from/to | 5. Event Abated After Use Stopped or Dose Reduced? |
| neck all that apply: | #1 occasionally for | or few months | #1 Yes No Doesn't |
| ✓ Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicin | #2 | | Apply |
| Outcomes Attributed to Adverse Event | 4. Diagnosis or Reason | for Use (Indication) | #2 Yes No Doesn't |
| (Check all that apply) | #1 Teething pain | | 8. Event Reappeared After Reintroduction? |
| Death: Disability or Permanent Damage | #2 | | #1 Tyes No Doesn't |
| (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect | 76 | | Apply |
| Hospitalization - initial or prolonged Cher Serious (Important Medical Events) | 6. Lot# | 7. Expiration Date | #2 Yes No Doesn' |
| Required Intervention to Prevent Permanent Impairment/Damage (Devices) | #1 | #1 | 9. NDC # or Unique ID |
| Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) | #2 | #2 | |
| 04/02/2015 04/03/2015 | E. SUSPECT MED | DICAL DEVICE | |
| Describe Event, Problem or Product Use Error | 1. Brand Name | | |
| | | | |
| | 2. Common Device Nam | 10 | |
| | | • | CTU |
| | - | | |
| ee additional page(s) for complete text. | 3. Manufacturer Name, | City and State | APR - 6 2015 |
| | | | 0 2015 |
| | | | The second secon |
| | 4. Model # | Lot# | 5. Operator of Device |
| | | | Health Professional |
| | Catalog # | Expiration Date (m | m/dd/yyyy) Lay User/Patient |
| | | | Other: |
| Relevant Tests/Laboratory Data, Including Dates | Serial # | Other# | |
| | | | |
| | 6. If Implanted, Give Da | te (mm/dd/sood) 7 If Fy | planted, Give Date (mm/dd/yyyy) |
| see additional page(s) for complete text. | | | Junited, 2110 2210 (11111 20))))) |
| | | evice that was Reprocess | ed and Reused on a Patient? |
| | Yes No | to the second Address of B | |
| | a, it tes to item No. 8, En | ter Name and Address of R | *processor |
| Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) | | | |
| amengios, rave, programoy, amounty and alcohol use, liver/richley problems, etc.) | E OTHER (CONC | OMITANT) MEDICAL | PRODUCTS |
| | | OMITANT) MEDICAL rapy dates (exclude treatm | |
| ee additional page(s) for complete text. | | | |
| | | nal page(s) fo | or complete text. |
| | | | |
| | | e confidentiality sect | |
| . PRODUCT AVAILABILITY | 1. Name and Address (b) (6) | | Dec |
| roduct Available for Evaluation? (Do not send product to FDA) | | | 200 |
| Yes Z No Returned to Manufacturer on: | | | DSS PR - 6 2 |
| (mm/dd/yyyy) | | | |
| . SUSPECT PRODUCT(S) | Phone # | E-mail | |
| Name, Strength, Manufacturer (from product label) Name: Oragel Nighttime Formula | (b) (6) | (b) (6) | |
| Strength: | | | |
| | | 3 Occupation | 4. Also Reported to: |
| Manufacturer: Oragel | 2. Health Professional? | o. Occupation | 4. Also Reported to: |
| Name: | 2. Health Professional? | o. Occupation | Manufacturer |
| Manufacturer: Oragel Name: Strength: Manufacturer: | Yes No 5. If you do NOT want you | | Manufacturer User Facility |



I applied maximum strength oragel to my ten month old baby boys gums for teething pain. He had been crying for quite awhile, maybe an hour, even while I was applying it. I put a small amount on my finger and while trying to rub it on his gums I lost it. I didn't know if he swallowed it or it fell off my finger into our lap and blanket, but I didn't find it. I proceeded to try another small amount and succeeded in applying this dose to his gums. All the while he was still crying. Maybe a minute or even less later he went silent. I looked at his face and he was still crying but no noise or breath was coming out. He looked panicked. Then he went from red in the face, to purple, then blue, and finally white as his eyes rolled back in his head and he went limp. I panicked and ran outside for help from a neighbor while trying to dial 911. He was unresponsive for approximately 30 seconds and no breathing during this period either. Then as I ran across our street he began coming to. By the time the paramedics arrived he was regaining color, breathing and alert. They said his oxygen level and blood pressure was in the okay range so it was up to me if he went to the hospital or not. We opted out of the hospital but called the pediatrician who advised us to stop use of the oragel and to keep a close eye on him. We were lucky enough for our baby boy to return to normal by the end of the night.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

The paramedics tested his oxygen levels, heart rate and blood pressure which all were in okay levels at the time.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Race: White

Medical Conditions:

Allergies:

Important Information:

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

RX Meds:

OTC Meds: Vitamin D supplements for baby by enfamil

DSS APR - 6 2015