FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

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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
**Case ID: 9681215**

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

**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:**

**Suspect Products:**

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<th>Product Name</th>
<th>Compounded Drug?</th>
<th>Dose/Frequency</th>
<th>Route</th>
<th>Dosage Text</th>
<th>Indications(s)</th>
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<th>End Date</th>
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Event Information:
Preferred Term (MedDRA® Version: 17.0)
Antipsychotic drug level above therapeutic
Drug interaction
Toxicity to various agents

Event/Problem Narrative:
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 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...
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 History:

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<tr>
<th>Disease/Surgical Procedure</th>
<th>Start Date</th>
<th>End Date</th>
<th>Continuing?</th>
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<tr>
<td>Medical History Product(s)</td>
<td>Start Date</td>
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<td>Indications</td>
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Relevant Laboratory Data:

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<th>Test Name</th>
<th>Result</th>
<th>Unit</th>
<th>Normal Low Range</th>
<th>Normal High Range</th>
<th>Info Avail</th>
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Concomitant Products:

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<thead>
<tr>
<th>#</th>
<th>Product Name</th>
<th>Dose/Frequency</th>
<th>Route</th>
<th>Dosage Text</th>
<th>Indications(s)</th>
<th>Start Date</th>
<th>End Date</th>
<th>Interval 1st Dose to Event</th>
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Reporter Source:

<table>
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<tr>
<th>Study Report?</th>
<th>Sender Organization</th>
<th>503B Compounding Outsourcing Facility?</th>
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<tr>
<td>No</td>
<td>ASTRazeneca</td>
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Case ID: 9681215

Literature Text:
**Case ID: 10511270**

**Case Information:**
- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **HP:**
- **Country:** USA
- **Event Date:**
- **Outcomes:** HO,
- **Application Type:** NDA

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

**Patient Information:**
- **Age:** 3 YR
- **Sex:** Male
- **Weight:**

**Suspect Products:**

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<th>Product Name</th>
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<th>Dose/Frequency</th>
<th>Route</th>
<th>Dosage Text</th>
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<td>Teething</td>
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<td>No</td>
<td></td>
<td>UNK</td>
<td></td>
<td>Teething</td>
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<td>3</td>
<td>BABY ORAJEL TEETHING PAIN MEDICINE</td>
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**Interval 1st Dose to Event:**

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**Event Information:**

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<td>Dyspnoea</td>
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<td>Eye movement disorder</td>
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<td>Moaning</td>
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FDA - Adverse Event Reporting System (FAERS)
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 09/10 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:

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<tr>
<th>Disease/Surgical Procedure</th>
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<th>Continuing?</th>
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<td>Incision site complication</td>
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Relevant Laboratory Data:

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<tr>
<th>Test Name</th>
<th>Result</th>
<th>Unit</th>
<th>Normal Low Range</th>
<th>Normal High Range</th>
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### Concomitant Products:

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### Reporter Source:

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

**Literature Text:**
Case ID: 10511962

Case Information:
- Case Type: EXPEDITED (15-DAY)
- Country: USA
- Event Date: 19-Sep-2014
- Outcomes: OT
- Application Type: NDA
- FDA Rcvd Date: 19-Feb-2015
- Mfr Rcvd Date: 09-Feb-2015
- Mfr Control #: US-PFIZER INC-2014274670
- Application #: 019833

Suspect Products:

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<tbody>
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<td>Eye movement disorder</td>
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<td>Hypoaesthesia</td>
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<td>Local swelling</td>
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<td>Musculoskeletal stiffness</td>
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Preferred Term (MedDRA® Version: 18.0)  ReC

Pyrexia                NA
Seizure                NA
Vomiting               NA

Event/Problem Narrative:
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
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:

<table>
<thead>
<tr>
<th>Disease/Surgical Procedure</th>
<th>Start Date</th>
<th>End Date</th>
<th>Continuing?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear infection</td>
<td>03-Sep-2014</td>
<td></td>
<td>UNKNOWN</td>
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<tr>
<td>Kawasaki’s disease</td>
<td>09-Sep-2014</td>
<td></td>
<td>UNKNOWN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical History Product(s)</th>
<th>Start Date</th>
<th>End Date</th>
<th>Indications</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMOXICILLIN</td>
<td>03-Sep-2014</td>
<td>09-Sep-2014</td>
<td>Ear infection</td>
<td>Yeast infection</td>
</tr>
</tbody>
</table>
### Relevant Laboratory Data:

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
<th>Unit</th>
<th>Normal Low Range</th>
<th>Normal High Range</th>
<th>Info Avail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body temperature</td>
<td>101.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body temperature</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT brain scan</td>
<td>scalp hematoma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body temperature</td>
<td>102.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body temperature</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Concomitant Products:

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

### Reporter Source:

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

**Literature Text:**

---

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

If a field is blank, there is no data for that field

Page 12 of 12
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.

Processed Case Id's for Images:
9275207 9305621 9314081 9316714 9325460 9325466 9341721 9341729
9341740 9341747 9342328 9342345 9342356 9342360 9410155 9412421
9412536 9412646 9412659 9412660 9412682 9412689 9412695 9424540
9461703 9471241 9486434 9570361 9570446 9622302 9627012 9630574
9661367 9747541 9767440 9790085 9820308 9998991 9999086
10023432 10024252 10027923 10040722 10149861 10162192 10162233 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
A. PATIENT INFORMATION

1. Patient Identifier
2. Age at Time of Event, or Date of Birth (b) (6) month(s) old
3. Sex
   - Female
   - Male
4. Weight
   - lb
   - kg
5. Date
   - 03/31/2013

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

1. Adverse Event
2. Product Use Error
3. Outcomes Attributed to Adverse Event
   - Death
   - Disability or Permanent Damage
   - Life-Threatening
   - Congenital Anomaly/Birth Defect
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
   - Required Intervention to Prevent Permanent Impairment (Devices)
4. Date of Event (mm/dd/yyyy)
   - 03/31/2013
5. Date of this Report (mm/dd/yyyy)
   - 04/30/2013
6. Describe Event, Problem or Product Use Error

After giving my son the 2 tablets per hour for 3 hours— the label says you can give up to 2 tablets for 6-hour periods, he became extremely lethargic, fast and remained open but he would not make eye contact and looked like he was in a daze. When I put him on my knees he began to slide off and involuntarily. He was not moving. I rushed him to the ER and his heart rate was low but after a few minutes improved. The doctor said it was possibly from the belladonna in this product. After getting home, I found out it has been recalled in the past for very similar reactions. My son is now okay, but...

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No
- Returned to Manufacturer on

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   - Ryland's baby
   - Feeding Tablets
2. Dose or Amount
   - 2 tablets/hr
3. Frequency
   - 3 hrs
4. Route
   - po
5. Dates of Use (if unknown, give duration from/to (or best estimate))
   - Case Day
   - 03/31/2013 - 03/31/2013

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
2. Phone
3. Email
4. Also Reported to:
   - Manufacturer
   - User Facility
   - Distributor/Importer

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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.
My son, who is now 13 months old, had some unexplained seizure activity for a span of about 3 months. The events started when he was 6 months old. Recently I came across information that there has been a link to seizure activity. I used Hyland Teething tablets during this time quite frequently. My son had a very rough time teething and these seemed to help. Unfortunately I am now concerned that in trying to help ease my son's pain that I inadvertently cause other medical issues. I still have the same bottle of tablets that I used in October.

3 day hospital stay with a 48 hour EEG on (b)(6) Follow up EEG in (b)(6) when more episodes occurred. Multiple other seizure episodes without hospital stay because the doctors said that unless they lasted greater than 15 minutes that we should just wait the episode out at home. One

Unexplained rash breakouts during this time as well. His whole body would break out in a hive.
episode happened at church where a pediatrician witnessed my son's demeanor and health directly after the episode.
Individual Case Safety Report

Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event, or
   Date of Birth: (b) (6)
3. Sex [ ] Female [ ] Male
4. Weight 23.6 lb or kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
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:
   [ ] Death: (mm/dd/yyyy)
   [ ] Disability or Permanent Damage
   [ ] 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) 07/26/2010
4. Date of this Report (mm/dd/yyyy) 05/23/2013

5. Describe Event, Problem or Product Use Error
   We have video of several episodes posted on (b) (5)
   They are private and you would need to contact me for access. We were using baby orajel and night time baby orajel when we ended up in the hospital for a week due to my daughter's eyes rolling in to the back of her head and turning blue around her lips. They couldn't figure out what was going on and determined that she was having seizures and thought that the blue around her mouth may have been caused by sucking on her binkie. They sent us home with an anti-seizure drug but could not figure out what could have caused a perfectly normal 16 month old to start having the issue she was

C. PRODUCT AVAILABILITY
Product Available for Evaluation? [ ] Yes [ ] No [ ] Returned to Manufacturer or
(6)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (if product label)
   - Baby Orajel
     - Benzonatene 7.5%
     - CHURCH & DWIGHT
   - Nighttime
     - Benzonatene 10%
     - CHURCH & DWIGHT
2. Dose or Amount
   - #1 oj size 4 x daily po
   - #2 oj size 4 x daily po
3. Dates of Use: (if unknown, give duration) from/to (or
   best estimate)
   - #1 07/10/2010 09/05/2010
   - #2 07/10/2010 09/05/2010
4. Diagnosis or Reason for Use (Indication)
   - #1 teething pain
   - #2 teething pain
5. Lot #
   - #1
   - #2
6. Expiration Date
   - #1
   - #2

E. SUSPECT MEDICAL DEVICE
1. Brand Name Orajel
2. Common Device Name
3. Manufacturer Name, City and State
   MAY 24, 2013
4. Model #
5. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] 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, Enter Name and Address of Reprocessor
   DSS
   MAY 24, 2013

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
   (b) (6)
2. Phone (b) (6)
3. E-mail (b) (6)
4. Also Reported to:
   [ ] Manufacturer
   [ ] User Facility
   [ ] Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please place an "X" in this box: [ ]

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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 (8) 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.
B7. Other relevant history, including preexisting medical conditions continued

knight or other issues.
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 agitated, 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 reoccurring 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 the floor with his body still shaking. His eyes were open but I
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, in fact, had a seizure. Two days later, I followed up with his pediatrician. His pediatrician referred us to a neurologist. We see the neurologist Friday May 31, 2013.
MY SON HYLANDS TEETHING TABLETS* - 19 1/2 months old-, my son had a seizure. Took him to the ER and they confirmed it. - May 1st, 2013 -19 1/2 months old-, my 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.
the shelves and because Hylands teething tablets have caused delays and seizures with my son, I am seeking legal action and will be talking with a lawyer/attorney and will be seeing further actions.
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.
OLUNTARY reporting of events, product problems and product use errors

A. PATIENT INFORMATION
1. Patient Identifier
   (b)(6)
   [In confidence]
2. Age at Time of Event, or Date of Birth:
   [In confidence]
3. Sex
   
   [ ] Female
   
   [ ] Male
4. Weight
   17
   [b] lbs
5. Months
   [ ]
6. Days
   [ ]

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
   [ ] 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)
   [ ]
5. Describe Event, Problem or Product Use Error
   After using teething gel, child had seizures and twitching

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 label(s))
   Hylan's Teething Gel
   [ ]
   [ ]
2. Dose or Amount
   [ ]
   [ ]
   [ ]
3. Dates of Use
   [ ] mm/dd/yyyy
   [ ]
   [ ]
4. Diagnosis or Reason for Use (Indication)
   [ ]
   [ ]
5. Event Abated After Use
   [ ] Yes
   [ ] No
   [ ]
6. Lot #
   [ ]
   [ ]
7. Expiration Date
   [ ]
   [ ]
8. Other Relevant History, Including Prescribing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, income/employment problems, etc.)
   No health concerns prior to death.
   [ ]
   [ ]
   [ ]

G. REPORTER (See confidentiality section on back)
1. Name and Address
   [ ]
   [ ]
2. Phone
   [ ]
   [ ]
   [ ]
3. Occupation
   [ ]
   [ ]
4. Also Reported to:
   [ ]
   [ ]
   [ ]

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
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
Have used Hyland teething tablets as needed and per instructions since my son started teething in June of 2011. He was completely unconscious on June 20, 2011, and taken by ambulance to the ER. He was unconscious and not moving or responding for four hours straight. The dr said he'd had a seizure.

CTU
MAY 31 2013

No previous health problems or medical history. Very healthy toddler.
FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier (b)(6)
   2. Age at Time of Event: 6 Months
   3. Sex: Male
   4. Weight: lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. 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
   - Life-threatening
   - Congenital Anomaly/Disorder
dect
   - Hospitalization - Initial or Prolonged
   - Other Serious (Important Medical Events)
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy): 06/02/2009
4. Date of This Report (mm/dd/yyyy): 05/22/2013

5. Describe Event or Problem

GRANDDAUGHTER HAD A BLOOD CLOT ON HER BRAIN WITH SEIZURES. TOOK HER TO BE TESTED. DOCTORS NOT SURE WHAT IT WAS DUE TO. LOST STAR TISSUE ON HER BRAIN. WAS USING TEETHING TABLETS AT THE TIME BUT NOT SURE HOW MANY OR HOW OFTEN WANTS TO KNOW IF TEETHING TABLETS CAUSED THE INJURY.

C. SUSPECT PRODUCT(S)

1. Name (Describe labeled strength & manufacturer): RYLAND'S TEETHING TABLETS
2. Dose, Frequency & Route Used
3. Date(s) (If unknown, give duration): (Unknown, give duration)
4. Diagnosis for Use (Indication)
   - TEETHING PAIN
5. Event Altered After Use Stopped or Does Reduced?
   - Yes
   - No
   - Doesn't Apply

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model Number
5. Lot Number
6. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Explanted, Give Date (mm/dd/yyyy)
9. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   - Yes
   - No
10. If Yes to Item No. 8, Enter Name and Address of Reprocessor

E. INITIAL REPORTER

1. Name and Address
2. Health Professional?
   - Yes
   - No
3. Occupation
4. Initial Reporter Also Sent 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.
**Individual Case Safety Report**

**CaseID:** 9341721

**Page 2 of 5**

### F. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction
   - [ ] Other: __________

2. **Device Evaluation by Manufacturer?**
   - [ ] Not Returned to Manufacturer
   - [ ] Yes
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not or provide code)

3. **Device Evaluation Date (mm/dd/yyyy)**

4. **Device Evaluation (mm/dd/yyyy)**

5. **Labeled for Single Use?**
   - [ ] Yes
   - [ ] No

6. **Evaluation Codes (Refer to coding manual)**
   - [ ] Method
   - [ ] Results
   - [ ] Conclusions

7. **Location Where Event Occurred**
   - [ ] Hospital
   - [ ] Home
   - [ ] Ambulatory Diagnostic Facility
   - [ ] Outpatient Treatment Facility
   - [ ] Surgery
   - [ ] Other: __________

8. **Usage of Device**
   - [ ] Initial Use of Device
   - [ ] Recycle
   - [ ] Repair
   - [ ] Return
   - [ ] Patient Monitoring
   - [ ] Reuse
   - [ ] Unknown
   - [ ] Other: __________

9. **If action reported to FDA under 21 USC 360(h). List correction/removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

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### G. ALL MANUFACTURERS

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

EDDY A. FRAKIEWICZ
HYLANDS', INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

**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:

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

35/22/2013

**5. NDA #**

**IND #**

**STN #**

**6. IF IND, Give Protocol #**

**7. Type of Report (Check all that apply)**

- [ ] 60-day
- [ ] 30-day
- [ ] 7-day
- [ ] 10-day
- [ ] 15-day Follow-up

**8. Manufacturer Report Number**

54973 RAE052213EF002

**9. Adverse Event Term(s)**

BLOOD CLOT, 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1500 Piccard Drive, Room 400
Rockville, MD 20850

OMB: "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

SECTION I: COMPLAINT

COMPLAINT #: RVD052213EF002
DATE OF COMPLAINT: 05/22/13

PRODUCT: TEETHING TABLETS
ITEM CODE: TEET

SIZE: (b) (6)
LOT NO.: DOESN'T HAVE ANYMORE

REPORTER: (b) (6)
ADDRESS: 

CITY: USA
STATE: 

COUNTRY: COUNTRY:
ZIP CODE: 

PHONE #: (b) (6)
E-MAIL: 

NATURE OF COMPLAINT: GRANDDAUGHTER HAD A BLOOD CLOT ON HER BRAIN WITH SEIZURES. TOOK HER TO BE TESTED. DOCTORS NOT SURE WHAT IT WAS DUE TO. LEFT SCAR TISSUE ON HER BRAIN. WAS USING TEETHING TABLETS AT THE TIME BUT NOT SURE HOW MANY OR HOW OFTEN. WANTS TO KNOW IF TEETHING TABLETS CAUSED THE INJURY. PATIENT CONTINUES TO HAVE SEIZURES. GRANDMOTHER DID NOT HAVE VERY DETAILED INFORMATION TO PROVIDE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICES RELATED CONCERN AND forwarded directly to the pharmacist and medical director for timely AE data capture and evaluation.

PRODUCT RECEIVED FOR INSPECTION: 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 III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N BY: EDYTA FRACKIEWICZ

ADVERSE EVENT REPORTED ON: 05/22/13

SECTION V:

REVIEWED BY MANAGEMENT BY: [Signature]
DATE: 05-28-13

BY: QA / QC DIRECTOR

cc: QA / QC Production Shipping / Receiving

Form # VD1

UN 072013
SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE052213EF002  COMPLAINT #: RVD052213EF001

SECTION I:  PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: ____________________________
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 PANELS)

SECTION III:  CORRECTIVE ACTION:

________________________________________________________________________
CORRECTIVE ACTION(S) COMPLETED BY: ____________________________ DATE: ____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ____________________________ DATE: 05-28-13

____________________________________  QA / QC DIRECTOR
BY: N/A  DATE: ____________

DISTRIBUTION: FDA  ADVERSE EVENT FILE  JUN 07 2013
OTC

CaseID: 9341729

Page 1 of 4

FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier
   (b)(5)

2. Age at Time of Event:
   1 Year

3. Sex
   Female

4. Weight
   lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event
   or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   ☐ Death: [mm/dd/yyyy]
   ☐ Disability or Permanent Damage
   ☐ Lifetime-threatening
   ☐ Congenital Anomaly/Birth Defect
   ☐ Hospitalization - initial or prolonged
   ☐ Other Serious (Important Medical Events)
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Device(s))

3. Date of Event (mm/dd/yyyy)
   06/09/2009

4. Date of This Report (mm/dd/yyyy)
   05/23/2013

5. Describe Event or Problem
   GAVE 1 TABLET AS NEEDED FOR TEETHING IN 2009. MOTHER DOES NOT KNOW IF THERE WAS A TIME CONNECTION BETWEEN GIVING TEETHING TABLETS AND SEIZURES. CHILD WAS DIAGNOSED WITH FEBRILE CONVULSIONS. CHILD DID HAVE FEVERS AT THE TIME OF SEIZURES. CHILD HAS NOT HAD A SEIZURE IN QUITE A WHILE.

6. Relevant Tests/Laboratory Data, Including Dates
   UNKNOWN TESTS CONDUCTED

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
   MOTHER HAS SEIZURES RESULTING FROM HEAD TRAUMA. PATIENT'S BROTHER HAS SEIZURES ALSO.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & method of delivery)
   #1 HYLAND'S TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 TABLET AS NEEDED

3. Therapy Dates (If known, give duration in days to best estimate)
   #1

4. Diagnosis for Use (Indication)
   #1 TEETHING PAIN

5. Event Altered After Use
   Stopped or Dose Reduced?
   ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   #1

7. Exp. Date
   #1

8. NDC# or Unique ID
   54573-7504-1

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ 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, 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)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   ☐ Yes ☐ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA
   ☐ Yes ☐ No ☐ Unk.
May 23, 2013

Dear [Redacted]

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
ER COMPLAINT RECORD

COMPLAINT #: RVD052213EF001
DATE OF COMPLAINT: 05/22/13

TAKE BY: EDYTA FRACKIEWICZ
PRODUCT: TEETHING TABLETS
SIZE: 
REPORTER: (b) (6)
ADDRESS: 
CITY: 
STATE: (b) (6)
COUNTRY: USA
ZIP CODE: 
PHONE #: (b) (6)
E-MAIL: 

GAVE 1 TABLET AS NEEDED FOR TEETHING IN 2009. SHE DOES NOT KNOW IF THERE WAS A TIME CONNECTION BETWEEN GIVING TEETHING TABLETS AND SEIZURES. CHILD WAS DIAGNOSED WITH FEBRILE CONVULSIONS. CHILD DID HAVE FEVERS AT THE TIME OF SEIZURES. CHILD HAS NOT HAD A SEIZURE IN QUITE A WHILE. MOTHER HAS SEIZURES AS A RESULT OF HEAD TRAUMA. MOTHER WANTS A REFUND FOR ONE BOTTLE. ALSO TOOK REPORT FOR CHILD'S BROTHER WHO HAS SEIZURES AND WHO USED BABY TEETHING TABLETS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE)
RECEIVED SEP 06 2013

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEETHING RECALL AS A SERVICE RELATED CONCERN AND forwarded DIRECTLY TO OUR PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

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

05/22/13: PREPARED REFUND REQUEST TOTALING $ 522. 06/12/13: MAILED REFUND CHECK # 508375 TOTALING $ 16.26 ON ARTICLE # 70081630 000486289877

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 06/23/13 & 06/11/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y (CIRCLE ONE)
ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

BY: N/A QA/QC DIRECTOR

cc: QA/QC Production Shipping / Receiving

SEP 09 2013

DSS SEP 06 2013
For use by healthcare facilities, state distributors and manufacturers for MANDATORY reporting.

Page 1 of 5

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier
   [O (6)]

2. Age at Time of Event:
   6 Months

3. Sex
   ☑ Female
   ☐ Male

4. Weight
   [ ] lbs
   [ ] kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defects/instabilities)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   ☐ Death: [mm/dd/yyyy]
   ☑ Life-threatening
   ☐ Dicability or Permanent Damage
   ☐ 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)
   [ ]

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. CONTINUE TO HAVE SEIZURES - DROP SEIZURES DAILY AND GRAND MAL ONCE A MONTH. TAKES KERRA FOR SEIZURES.

C. SUSPECT PRODUCT(S)

1. Name (GIVE Labeled strength & manufacturer)
   [ ] Hyland's Teething Tablets

2. Dose, Frequency & Route Used
   [ ]

3. Therapy Dates (if unknown give duration) [mm/dd/yyyy]
   [ ]

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Catalog #

5. Model #

6. Lot #

7. Serial #

D. SUSPECT MEDICAL DEVICE

E. INITIAL REPORTER

1. Name and Address
   [ ]

2. Health Professional? [ ] Yes [ ] No

3. Occupation
   [ ]

4. Initial Reporter Also Sent Report to FDA [ ] 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.
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.
**B.5. Describe Event or Problem (continued)**

- [Blank space for description]

**B.6. Relevant Tests/Laboratory Data, Including Dates (continued)**

- [Blank space for data]

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

- [Blank space for information]

**Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish)**

- [Blank space for dates]

**Other Remarks**

- [Blank space for remarks]

**DSS**

- [Signature]

**Date:**

- **Jun 07 2013**

- **Jun 06 2013**
CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: TEETHING TABLETS

SIZE: ( ) ( )

REPORTER: ( ) ( )

ADDRESS: 

CITY: 
COUNTRY: USA
PHONE #: ( ) ( )

E-MAIL: 

COMPLAINT #: RVD052213EF003

DATE OF COMPLAINT: 05/22/2013

ITEM CODE: TEET

LOT NO.: DOESN'T HAVE ANYMORE

Purchased product in 2003. Back in 2003 for the 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 the 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 Keppra for seizures. No fever at the time. Went to the doctor who conducted a spinal tap and other tests with inconclusive results. Told her that side effects due to homeopaths tend to be transient in nature.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: This complaint was taken during Teet recall as a Service Related Concern and forwarded directly to the pharmacist and medical director for timely AE data capture and evaluation.

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

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y [ ] N [ ]

ADVERSE EVENT REPORTED ON: 05/22/13

BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 

BY: N/A

QA / QC DIRECTOR

cc: QA / QC
Packaging

Production
Shipping / Receiving

DATE: 05-28-13

DATE: JUN 06 2013

Form # V01
SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE052213EF003
COMPLAINT #: RVD052213EF003

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V21)

NAME: (Redacted)
ADDRESS: (Redacted)
CITY: (Redacted)
STATE: (Redacted)
COUNTRY: USA
ZIP CODE: (Redacted)
PHONE #: (Redacted)
E-MAIL: (Redacted)

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9341740-01-00-05

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: ________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 05-28-12

BY: N/A QA/QC DIRECTOR DATE: JUN 6 2013

DSS

FORM SAE01

DISTRIBUTION: FDA ADVERSE EVENT FILE

CaseID: 9341740
FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) ____________

2. Age at Time of Event: 2 Years
   (mm/dd/yyyy) 12/23/2010
   Date of Birth: (b) (6) ____________

3. Sex [] Female  [] Male
4. Weight  lbs  kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [] Adverse Event  and/or  [] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   [] Death: (mm/dd/yyyy) ____________
   [] Disability or Permanent Damage
   [] 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) 12/23/2010
   Date of This Report (mm/dd/yyyy) 02/22/2013

5. Describe Event or Problem
   CHILD HAD JUST TURNED 2 YEARS OLD. DOES NOT KNOW HOW MUCH OR HOW OFTEN SHE WAS GIVING TEETHING TABLETS. CAN'T REMEMBER HOW OLD WHEN SHE STARTED USING. WENT TO THE ER; HOSPITALIZED OVERNIGHT. X-RAYS AND MRI A FEW WEEKS LATER. TESTS WERE NORMAL. HAD ANOTHER SEIZURE 2 MONTHS LATER BUT DOES NOT KNOW IF USING TEETHING TABLETS. DOCTOR DIAGNOSED FEVERISH SEIZURES. NO OTHER SEIZURES. WANTS A RUST UND. HAD A FEVER OF 101F AFTER THE SEIZURE AT THE HOSPITAL. NO ALLERGIES. FULL TERM BABY.

6. Relevant Tests/Laboratory Data, Including Dates
   X-RAYS AND MRI: TESTS WERE NORMAL.

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
   NO KNOWN ALLERGIES. FULL TERM BABY. HAD 101F AFTER THE SEIZURE AT THE HOSPITAL.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & package size) #1: HYLAND'S TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1: UNKNOWN

3. Therapy Dates (if unknown, give duration in years or best estimate)
   #1: 02/22/2013

4. Diagnosis for Use (Indication)
   #1: TEMP RELIEF TEETHING PAIN

5. Event Aborted After Use Stopped or Does Reduced?
   #1: Yes  No  Doesn't Apply

6. Let #
   #1: 02/22/2013

9. NDC# or Unique ID: 54973-7504-1

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #
5. Lot #

6. Operator of Device
   [] Health Professional
   [] Lay User/ Patient
   [] Other

7. Catalog 
8. Expiration Date (mm/dd/yyyy)
9. Serial 
10. Other #
11. If Implanted, Give Date (mm/dd/yyyy)
12. If Implanted, Give Date (mm/dd/yyyy)
13. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   Yes  No
14. If Yes to Item No. 13, 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)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?  Yes  No
3. Occupation

4. Initial Reporter Also Sent Report to FDA
   Yes  No  [ ] Unknown
### F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

<table>
<thead>
<tr>
<th>1. Check One</th>
<th>2. User Facility/Importer Report Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. User Facility or Importer Name/Address

<table>
<thead>
<tr>
<th>4. Contact Person</th>
<th>5. Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>7. Type of Report</th>
<th>8. Date of this Report (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Approximate Age of Device

<table>
<thead>
<tr>
<th>10. Event Problem Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code:</td>
</tr>
<tr>
<td>Device Code:</td>
</tr>
</tbody>
</table>

11. Report Sent to FDA?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>(mm/dd/yyyy)</td>
<td>(mm/dd/yyyy)</td>
</tr>
</tbody>
</table>

12. Location Where Event Occurred

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Outpatient Diagnostic Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home</td>
<td>Ambulatory Surgical Facility</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>Outpatient Treatment Facility</td>
</tr>
<tr>
<td>Other</td>
<td>(Specify)</td>
</tr>
</tbody>
</table>

13. Report Sent to Manufacturer?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>(mm/dd/yyyy)</td>
<td>(mm/dd/yyyy)</td>
</tr>
</tbody>
</table>

14. Manufacturer Name/Address

### G. ALL MANUFACTURERS

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

EDYTA FRACKIWICZ
HYLAND'S, INC.
154 W. 1315TH STREET
LOS ANGELES, CA 90061

2. Phone Number

310-768-0700

### H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event

<table>
<thead>
<tr>
<th>Death</th>
<th>Serious Injury</th>
<th>Malfunction</th>
<th>Other</th>
</tr>
</thead>
</table>

2. If Follow-up, What Type?

<table>
<thead>
<tr>
<th>Correction</th>
<th>Additional Information</th>
<th>Response to FDA Request</th>
<th>Device Evaluation</th>
</tr>
</thead>
</table>

3. Device Evaluated by Manufacturer?

| Not Returned to Manufacturer | Yes | Evaluation Summary Attached |

| No (Attach page to explain why not) or provide code: |

5. Labeled for Single Use?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. Evaluation Codes (Refer to coding manual)

| Method | Results | Conclusions |

|          |          |             |

7. If Removal Action Initiated, Check Type

<table>
<thead>
<tr>
<th>Recall</th>
<th>Notification</th>
<th>Repair</th>
<th>Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replace</td>
<td>Patient Monitoring</td>
<td>Relabeling</td>
<td>Modification/Adjustment</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Usage of Device

| Initial Use of Device | Reuse | Unknown |

9. If action reported to FDA under 21 USC 381K, list correction/removal reporting 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."

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.
May 28, 2013

Dear [Name],

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,

[Signature]

Dan Krombach
President

Enc: Refund Check - $6.22
COMPLAINT RECORD

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: HYLAND'S TEETHING TABLETS

SIZE: 

REPORTER: 

ADDRESS: 

CITY: 

COUNTRY: USA

PHONE #: (b) (6)

E-MAIL: 

DATE OF COMPLAINT: 05/24/13

ITEM CODE: TEET

LOT NO.: DOESN'T HAVE PURCHASED IN 2010

RECEIVED SEP 06 2013

NATURE OF COMPLAINT: CHILD HAD JUST TURNED 2 YEARS OLD. DOES NOT KNOW HOW MUCH OR HOW OFTEN SHE WAS TAKING TEETHING TABLETS. CAN'T REMEMBER HOW OLD WHEN SHE STARTED USING THEM. WENT TO THE ER, HOSPITALIZED OVERNIGHT, XRAYS AND MRI A FEW WEEKS LATER. TESTS WERE NORMAL. HAD ANOTHER SEIZURE IN 09/10 BUT DOES NOT KNOW IF USING TEETHING TABLETS. DOCTOR DIAGNOSED AS EPILEPSY. NO OTHER SEIZURES. WANTS A REFUND. HAS A FEVER OF 101°F AFTER THE SEIZURE AT THE HOSPITAL. NO ALLERGIES. FULL TERM BABY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION ON: 05/24/13

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

05/28/13: PREPARED REFUND REQUEST TOTALING $0.22. 06/12/13: MAILED REFUND CHECK # 505577 TOTALING $ 6.22 ON ARTICLE # 700818300004 86290863

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 05/28/13 & 06/12/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

DATE: SEP 09 2013

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: 

DATE: 08-27-13

BY: QA / QC DIRECTOR

cc: QA / QC Packaging Production Shipping / Receiving
**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & unit/measure)
   - HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   - 1 TABS 3 TIMES; 2 TABS PM

3. Therapy Dates (If known, give duration) (Note: if used most recently)
   - #1

4. Diagnosis for Use (Indication)
   - #1 TEMP RELIEF TEETHING PAIN

5. Event Abated After Use
   - #1 Yes #2 No

6. Lot #
   - #112723

7. Exp. Date
   - #1

8. Event Reappeared After
   - #1 Yes #2 No

9. NDC or Unique ID
   - 54973-3127-1

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

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

**E. INITIAL REPORTER**

1. Name and Address

2. Health Professional? Yes No

3. Occupation

4. Initial Reporter Also Sent Report to FDA Yes No
H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction
   - [ ] Other:

2. If Follow-up, What Type?
   - [ ] Correction
   - [ ] Additional Information
   - [ ] Response to FDA Request
   - [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
   - [ ] Not Returned to Manufacturer
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - [ ] Yes
   - [ ] No

6. Evaluation Codes (Refer to coding manual)
   - Method: [ ] [ ] [ ] [ ]
   - Results: [ ] [ ] [ ] [ ]
   - Conclusions: [ ] [ ] [ ] [ ]

7. If Remedial Action Initiated, Check Type
   - [ ] Recall
   - [ ] Notification
   - [ ] Repair
   - [ ] Inspection
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modification/Adjustment
   - [ ] Other:

8. Usage of Device
   - [ ] Initial Use of Device
   - [ ] Reuse
   - [ ] Unknow

9. If action reported to FDA under 21 USC 351(e), list correction/ removal reporting number:

10. Additional Manufacturer Narrative and/or 11. Corrected Data

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   - EDYTA FRACKIENICZ
   - HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061

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:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 35/29/2013

5. (ANDA # )
   - IND #
   - STN #

6. IF IND, Give Protocol #

7. Type of Report
   - (Check all that apply)
   - [ ] 5-day
   - [ ] 10-day
   - [ ] Periodic
   - [ ] Pre-1938
   - [ ] OTC Product
     - [ ] Yes

8. Manufacturer Report Number
   - 54973 AE # 1383

9. Adverse Event Term(s)
   - SEIZURES

The public reporting burden for this collection of information has been estimated to average 65 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 406
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.

DSS
AUG 23 2013

AUG 22 2013
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)

Other Remarks

DSS
AUG 23 2013

AUG 22 2013
May 29, 2013

Dear [Name],

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
COMPLAINT RECORD

COMPLAINT #: 2333
DATE OF COMPLAINT: 05/23/13

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS

REPORTER:
ADDRESS:
CITY:
COUNTRY: USA
PHONE #:
E-MAIL:

STATE:
ZIP CODE:

ON MAY 5, 2013, GAVE 2 TABLETS OF BABY TEETHING TABLETS IN AM, NOON, AFTERNOON. CUSTOMER CALLED ON 05/24/13, MAY 5, 2013 CHILD STARTED SHAKING AT APPROXIMATELY 6:45 PM. CHILD WAS ALERT, SHOOK FOR 30 SECONDS. FROM 05/04 - 05/07 HAD 3 MORE EPISODES. TOOK HIM TO THE DOCTOR AND SAID HE LOOKED FINE. 05/10/13, SAW A NEUROLOGIST WHO SAID CHILD WAS FINE. DID TEST MEASUREMENTS AND ALL WAS FINE. 05/10/13 PM MOTHER GAVE 2 TABLETS AND 30 MINUTES LATER CHILD HAD A SHAKING EPISODE. DOCTOR'S CALLED SHAKING EPISODES "SEIZURES". HAS NOT USED BABY TEETHING TABLETS SINCE 05/10/13. NO SHAKING EPISODES / SEIZURES SINCE 05/10/13, WANTS A REFUND FOR ONE BOTTLE OF BABY TEETHING TABLETS (135 COUNT). TOLD HER TO DISCUSS CAUSES FOR SYMPTOMS WITH DOCTORS. NO FEVER ON MAY 5. NOT ILL ON MAY 5. CHILD WAS FULL-TERM BABY. NO NEW FOODS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORD, MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURE TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/23/13
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION

05/29/13: PREPARED REFUND REQUEST TOTALING $10.04.

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON: 05/23/13

SECTION V: REVIEWED BY MANAGEMENT BY: 

DATE: 06-04-13

BY: 

QA/QC DIRECTOR

cc: QA/QC Production

AUG 22 2013
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1363
COMPLAINT #: 2333

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 

ADDRESS: 

CITY: 

COUNTRY: USA

PHONE #: 

E-MAIL: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: ____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 06-04-13

BY: ___________________________ DATE: ____________

QA / QC DIRECTOR
COMPLAINT RECORD

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/23/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T136

SIZE: 135 TABLETS

LOT NO.: 112123

CITY: 

COUNTRY: USA

STATE: 

ZIP CODE: 

PHONE #: 

E-MAIL: 

ON MAY 5, 2013, GAVE 2 TABLETS OF BABY TEETHING TABLETS IN AM, NOON, AFTERNOON. CUSTOMER CALLED ON 05/24/13. MAY 5, 2013, CHILD STARTED SHAKING AT APPROXIMATELY 6:45 PM. CHILD WAS ALERT, SHOOK FOR 30 SECONDS. FROM 05/06 - 05/07 HAD 3 MORE EPISODES. TOOK HIM TO THE DOCTOR AND SAID HE LOOKED FINE. 05/10/13, SAW A NEUROLOGIST WHO SAID CHILD WAS FINE. DID TEST MEASUREMENTS AND ALL WAS FINE. 05/11/13 PM MOTHER GAVE 2 TABLETS AND 30 MINUTES LATER CHILD HAD A SHAKING EPISODE. DOCTORS CALLED SHAKING EPISODES "SEIZURES". HAS NOT USED BABY TEETHING TABLETS SINCE 05/11/13. NO SHAKING EPISODES / SEIZURES SINCE 05/11/13. WANTS A REFUND FOR ONE BOTTLE OF BABY TEETHING TABLETS (135 COUNT). TOLD HER TO DISCUSS CAUSES FOR SYMPTOMS WITH DOCTORS. NO FEVER ON MAY 5. NOT ILL ON MAY 5, CHILD WAS FULL-TERM BABY. NO NEW FOODS.

FOR ADDITIONAL SPACE PLEASE USE 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: 

UPS CALL TAG ISSUED: Y (CIRCLE ONE)

DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

SECTION III: CORRECTIVE ACTION:

05/29/13: PREPARED REFUND REQUEST TOTALING $ 10.04. 06/12/13: MAILED REFUND CHECK # 509378 TOTALING $ 10.04 ON ARTICLE # 70081830

00488280848.

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 05/29/13 & 06/12/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 

DATE: 08-06-13

DATE: 08-05-13

DSS AUG 23 2013

AUG 2 2 2013

QA / QC DIRECTOR

cc: QA / QC Packaging

Production Shipping / Receiving

AUG 2 2 2013/UD1
Individual Case Safety Report

9342345-02-00-01

FORM FDA 3500A (6/10)

Page 1 of 2

A. PATIENT INFORMATION

1. Patient Identifier: [Redacted]
2. Age at Time of Event: [Redacted] Year
3. Sex: [Redacted]
4. Weight: [Redacted] lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (Check all that apply)
   - [ ] Death
   - [ ] Disability or Permanent Damage
   - [ ] Life-threatening
   - [ ] Congenital Anomaly/Birth Defect
   - [ ] Hospitalization - initial or prolonged
   - [ ] Other Serious (Important medical Event(s))
   - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Deviations)

2. Date of Event: 01/01/2012
3. Date of This Report: 05/23/2013

C. SUSPECT PRODUCT(S)

1. Name (Brand Name, strength & refill/quantity): [Redacted] TABLETS
2. Dose, Frequency & Route Used: 1 TABLET AS NEEDED

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   - [ ] Health Professional
   - [ ] Lab User/Patient
   - [ ] Other
   - [ ] Serial #
   - [ ] Expiration Date (mm/dd/yyyy)
   - [ ] Other
6. If Implantated, Give Date (mm/dd/yyyy)
7. If Implanted, 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
   - [ ] Other

D. SUSPECT MEDICAL DEVICE

10. Device Available for Evaluation? (Do not send to FDA)
    - [ ] Yes
    - [ ] No
    - [ ] Returned to Manufacturer on (mm/dd/yyyy)

E. INITIAL REPORTER

1. Name and Address
2. Health Professional?
   - [ ] Yes
   - [ ] No
3. Occupation
4. Initial Reporter Also Sent Report to FDA
   - [ ] Yes
   - [ ] No
   - [ ] Link

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.
### H. Device Manufacturers Only

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Correction</td>
</tr>
<tr>
<td>Serious Injury</td>
<td>Additional Information</td>
</tr>
<tr>
<td>Malfunction</td>
<td>Response to FDA Request</td>
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<tr>
<td>Other:</td>
<td>Device Evaluation</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
</tr>
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<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
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<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>Evaluation Summary Attached</td>
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<td>No/Attach page to explain why no</td>
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<tr>
<td>or provide code:</td>
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<tbody>
<tr>
<td>Yes</td>
<td>Method: ________________________________</td>
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<tr>
<td>No</td>
<td>Results: _________________________________</td>
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<tr>
<td></td>
<td>Conclusions: ______________________________</td>
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</tbody>
</table>

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<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td>Initial Use of Device</td>
</tr>
<tr>
<td>Notification</td>
<td>Reuse</td>
</tr>
<tr>
<td>Repair</td>
<td>Unknown</td>
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<tr>
<td>Inspection</td>
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<tr>
<td>Replacement</td>
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<tr>
<td>Patient Monitoring</td>
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<tr>
<td>Relabeling</td>
<td></td>
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<tr>
<td>Modification/Adjustment</td>
<td></td>
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<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

### G. All Manufacturers

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

EDYTA FRACKOWICZ  
HYLAND'S, INC.  
154 W. 131ST STREET  
LOS ANGELES, CA 90061  

**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:

**4. Data Received by Manufacturer (mm/dd/yyyy)**  
35/22/2013  

**5. (A)NDA #**  

**6. IND #**  

**7. STN #**  

**8. PMAW #**  

**9. 510(k) #**  

**10. Combination Product**  

**11. Pre-1938**  

**12. OTC Product**  

**13. Follow-up #**  

**14. Manufacturer Report Number**  
54973 AE # 1378  

**15. Adverse Event Term(s):**  
SEIZURES  

---

The public reporting burden for this collection of information has been estimated to average 60 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 OMB Collection of Information Office, Office of Chief Information Officer, 1550 Piccard Drive, Room 409, Rockville, MD 20850.

OMB Number: 0910-0192.

Please DO NOT RETURN this form to this address.

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**DSS**  
**AUG 23 2013**
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)

Other Remarks

DSS
AUG 23 2013

AUG 2 2 2013
COMPLAINT RECORD

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 06/22/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET---T135

SIZE: 135 TABLETS
LOT NO.: 113297

REPORTER:

ADDRESS:

CITY: USA
STATE: (b) (6)

COUNTRY: USA
ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

GAVE 1 TABLET 1 ½ YEARS AGO WHEN NEEDED. HAD A SEIZURE IN JANUARY 2012. HAD SEVERAL SEIZURES SINCE THEN. HAD AN ECG, 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 INSPECTION: 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: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13
ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

05/23/13 PREPARED REFUND REQUEST TOTALING $10.04

CORRECTIVE ACTION(S) COMPLETED BY: (b) (6) DATE: 06/23/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 06/22/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: AUG 23 2013

DATE: A0-04-13
DATE: 06-04-13

cc: QA / QC DIRECTOR

Production
Shipping / Receiving

AUG 2 2 2013

Form # VD1
COMPLAINT RECORD

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS
REPORTER: [Blank]
ADDRESS: [Blank]
CITY: [Blank]
COUNTRY: USA
PHONE #: [Blank]
E-MAIL: [Blank]

DATE OF COMPLAINT: 06/22/13
ITEM CODE: ST7—T136
LOT NO.: [Blank]

RECEIVED

AUG 2 2 2013

CDR

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

NATURE OF COMPLAINT: GAVE 1 TABLET 1 1/2 YEARS AGO WHEN NEEDED. HAD A SEIZURE IN JANUARY 2012. HAD SEVERAL SEIZURES SINCE THEN. HAD AN EEG. M.R.L. 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 SEIZURE CONVULSIONS.

SECTION II: INVESTIGATION
INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/22/13
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION
06/23/13: PREPARED REFUND REQUEST TOTALING $10.04. 06/12/13. MAILED REFUND CHECK #505676 TOTALING $16.26 ON ARTICLE #70081830 000486289677.

CORRECTIVE ACTION(S) COMPLETED BY: [Blank]
DATE: 06/23/13 & 06/12/13

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y
ADVERSE EVENT REPORTED ON: 06/22/13
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 08-06-13 AUG-23-2013

DSS

BY: [Signature]

DATE: 08-06-13 AUG-23-2013

cc: QA / QC Packaging
Production Shipping / Receiving
May 23, 2013

Dear [Name],

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,

[Signature]

Dan Krombach
President

Enc: Refund Check - $10.04
CaseID: 9342356

Page 1 of 5

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
   [In confidence]
2. Age at Time of Event: 4 Months
   Date of Birth:
   Male or Female
   Female
   Male
3. Sex
4. Weight
   lbs
   kgs
   lbs
   kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event
   Yes
   No
2. Outcomes Attributed to Adverse Event
   Death
   Disability or Permanent Damage
   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)
   04/06/2012 - PRESENT
4. Date of This Report (mm/dd/yyyy)
   05/24/2013
5. Describe Event or Problem
   05/24/13 INFORMATION OBTAINED FROM CUSTOMER: (b)(6)
   SON STARTED HAVING SEIZURES USING BABY TEETHING TABLETS FOR ONE MONTH PRIOR TO THIS. NO FEVER AT TIME OF SEIZURE. SEIZURE IN 2012 CAUSED HIM TO LOSE OXYGEN TO BRAIN. WENT TO HOSPITAL AND WAS HOSPITALIZED FOR 2 1/2 - 3 WEEKS. UNDERWENT GASTRIC TUBE SURGERY SECONDARY TO OXYGEN LOSS TO BRAIN. SEIZURE PRESENTED AS SHAKING AND DROOLING FOR 1 MINUTE.

C. SUSPECT PRODUCT(S)
1. Name (Trade labeled strength &/or lot/batch)
   HYLAND'S BABY TEETHING TABLETS
   #1
   #2
2. Date of Use
   1/2/2012
3. Therapy Data (In unknown, give duration from/to or best estimate)
   #1
   #2
4. Diagnosis for Use (Indication)
   TEETH RELIEF TEETHING PAIN
   #1
   #2
5. Event Altered After Use Stopped或 Does it Affect
   Yes
   No
   Doesn't Apply
6. Lot #
   #1
   #2
7. Exp. Date
   #1
   #2
8. Event Reappeared After Reintroduction
   Yes
   No
   Doesn't Apply
9. NDC# or Unique ID
   54973-3137-3
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
   Lot #
5. Operator of Device
   Health Professional
   Lay User/Patient
   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 that was Reprocessed and Reused on a Patient?
   Yes
   No
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)

E. INITIAL REPORTER
1. Name and Address
2. Health Professional
   Yes
   No
3. Occupation
   Phone #
4. Initial Reporter Also Sent Report to FDA
   Yes
   No
   Unk.
**H. DEVICE MANUFACTURERS ONLY**

1. **Type of Reportable Event**
   - ☐ Death
   - □ Serious Injury
   - ☐ Malfunction
   - ☐ Other:

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 ☐ No Evaluation Summary Attached
   - ☐ No (Attach separate page to explain why not) or provide code:

4. **Device Manufacturer Data (mm/dd/yyyy)**

5. **Labeled for Single Use?**
   - Yes ☐ No

6. **Evaluation Codes (Refer to coding manual)**
   - Method
   - Results
   - Conclusions

7. **If Remedial Action Initiated, Check Type**
   - ☐ 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 360(f), list correction/removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

**G. ALL MANUFACTURERS**

1. **Contact Office - Name/Address (and Manufacturing Site for Devices)**
   - MARK PHILLIPS
   - SDYTA FRANKOJULIC
   - HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061

2. **Phone Number**
   - 310-768-0070

3. **Report Source (Check all that apply)**
   - ☐ Foreign
   - ☐ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 05/22/2013

5. **FIND Give Protocol #**
   - 5
   - 30
   - Periodic
   - Initial
   - Follow-up #

6. **Type of Report (Check all that apply)**
   - Combination
     - Product
     - Pre-1938
     - OTC Product

7. **Adverse Event Term(s)**
   - 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:

**Department of Health and Human Services**
**Food and Drug Administration**
**Office of Clinical 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 07 2013**
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, hepatobiliary 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
JUN 07 2013

Other Remarks

DSS
JUN 07 2013
**CUSTOMER COMPLAINT RECORD**

**COMPLAINT #: 2335**

**DATE OF COMPLAINT: 05/22/13**

**PRODUCT: BABY TEETHING TABLETS**

**ITEM CODE: BTET-T135**

**SIZE: 135 TABLETS**

**LOT NO.: N/A**

**REPORTER: [Redacted]**

**ADDRESS: [Redacted]**

**CITY: [Redacted]**

**STATE: [Redacted]**

**COUNTRY: USA**

**PHONE #: [Redacted]**

**E-MAIL: [Redacted]**

**REPORTED READ ON INTERNET THAT TEETHING TABLETS CAUSE SEIZURES AND EPILEPSY IN INFANTS. REPORTER NOTED THE PRODUCT WAS TAKEN OFF THE SHELF AT WAL-MART A FEW DAYS AGO. REPORTER THEN STATED "MY SON IS NOW HAVING SEIZURES AND EPILEPTIC SEIZURES (SIC). 05/24/13 FOLLOW UP (EP): 05/26/13 SON STARTED HAVING SEIZURES USING BABY TEETHING TABLETS FOR ONE MONTH PRIOR. GIVING 1/2 TABLET BY MOUTH TWICE A DAY EVERY OTHER DAY FOR 1 MONTH. NO FEVER AT THE TIME OF SEIZURE. SEIZURE IN 2012 CAUSED HIM TO LOSE OXYGEN TO BRAIN. WAS SENT TO [Redacted] HOSPITAL AND WAS HOSPITALIZED FOR 2 1/2 TO 3 WEEKS. UNDERWENT GASTRIC TUBE SURGERY BECAUSE OF MEMORY LOSS 2 TO OXYGEN LOSS TO BRAIN. GOES TO OCCUPATIONAL THERAPY. DOCTOR IS NOT SURE WHY CHILD HAD SEIZURE. SEIZURE PRESENTED AS SHAKING AND DROCIAL FOR 1 MINUTE. TESTS IN HOSPITAL: MRI, X-RAY, SWALLOW STUDY, OBSERVATION AFTER EATING. DIAGNOSIS: FAILURE TO THRIVE, EPILEPSY, APNEA, GERD. MEDICATIONS: KEPLERAPAM EVERY MORNING 2.5ML EVERY PM; CYPROHEPTADINE 1 TEASPOON EVERY DAY, PEPCID. WILL GO BACK TO NEUROLOGIST IN 2 WEEKS AND WILL ASK ABOUT USE OF BABY TEETHING TABLETS. DOES NOT WANT A REFUND. CHILD BORN 6 WEEKS PREMATURE. NO OTHER MEDICATIONS AT THE TIME OF SEIZURE. NO INJURY OR ILLNESS AT THE TIME. ALLERGIC TO AMOXICILLIN AND LATEX.**

**FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET**

**PRODUCT RECEIVED FOR INSPECTION: [Y/N]**

**PRODUCT BEING RETURNED FOR INSPECTION: [Y/N]**

**DATE REQUESTED PRODUCT BE RETURNED: [ ]**

**RECEIVED: JUN 07 2013**

**CDR**

**INVESTIGATION: NO LOT NUMBER. PROCEDURES ARE IN PLACE TO ENSURE PRODUCT QUALITY.**

**Individual Case Safety Report**

**9342356-01-00-04**

**ADVERSE EVENT FORWARDER TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13**

**MARK PHILLIPS**

**SECTION III: CORRECTIVE ACTION:**

**SECTION IV: ADVERSE EVENT REPORTS**

**Y/N**

**ADVERSE EVENT REPORTED ON: 05/22/13**

**MARK PHILLIPS**

**SECTION V: REVIEWED BY MANAGEMENT: [Signature]**

**QA / QC DIRECTOR**
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1384
COMPLAINT #: 2335

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 PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

Individual Case Safety Report

9342356-01-00-05

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: _____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 06-03-13

BY: ___________________________ DATE: _____________

QA / QC DIRECTOR

DSS JUN 1 2013

DSS JUN 07 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SA8H1
GAVE TEETHING TABLETS AND SOMETIME AFTER THAT CHILD EXPERIENCED CONVULSIONS WITH EYES ROLLING BACK OF HEAD, STIFFENING UP, WHEN SHE CAME TO SHE WOULD CRY AND TAKE DEEP BREATHS. WAS HOSPITALIZED FOR ONE WEEKEND IN AUGUST. DOCTOR THOUGHT THAT ELECTROLYTES COULD BE OFF. CONVULSIONS OCCURRED IN HOSPITAL AND THEN NEVER HAPPENED AGAIN AND SHE NEVER USED PRODUCT AGAIN.
Individual Case Safety Report

CaseID: 9342360

Page 2 of 5

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<thead>
<tr>
<th>F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)</th>
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<tbody>
<tr>
<td>1. Check One:</td>
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<tr>
<td>User Facility</td>
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| 3. User Facility or Importer Name/Address |

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<th>4. Contact Person</th>
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<td>5. Phone Number</td>
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| 6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) |

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<tr>
<td>Initial</td>
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<tr>
<td>Follow-up #</td>
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| 8. Date of This Report (mm/dd/yyyy) |

| 9. Approximate Age of Device |

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<th>10. Event Problem Codes (Refer to coding manual)</th>
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<th>11. Report Sent to FDA?</th>
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<th>12. Location Where Event Occurred</th>
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<tr>
<td>Hospital</td>
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<td>Home</td>
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<td>Nursing Home</td>
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<td>Other Treatment Facility</td>
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<th>13. Report Sent to Manufacturer?</th>
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<td>Yes</td>
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| 14. Manufacturer Name/Address |

<table>
<thead>
<tr>
<th>G. ALL MANUFACTURERS</th>
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<tbody>
<tr>
<td>1. Contact Office - Name/Address (and Manufacturing Site for Devices)</td>
</tr>
<tr>
<td>EDYTA FRACKIEWICZ</td>
</tr>
<tr>
<td>HYLAND'S, INC.</td>
</tr>
<tr>
<td>154 W. 131ST STREET</td>
</tr>
<tr>
<td>LOS ANGELES, CA 90061</td>
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<th>2. Phone Number</th>
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<th>3. Report Source (Check all that apply)</th>
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<td>Foreign</td>
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<td>Health Professional</td>
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<tr>
<td>Company Representative</td>
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<td>Other:</td>
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<th>4. Date Received by Manufacturer (mm/dd/yyyy)</th>
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<th>5. (A)NDA #</th>
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<td>IND #</td>
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<tr>
<td>STN #</td>
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<th>6. If IND, GIVE Protocol #</th>
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<th>7. Type of Report (Check all that apply)</th>
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<tr>
<td>5-day</td>
</tr>
<tr>
<td>7-day</td>
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<tr>
<td>10-day</td>
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<tr>
<td>15-day</td>
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<th>8. Manufacturer Report Number</th>
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<td>54973 AE # 1380</td>
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<th>9. Adverse Event Term(s)</th>
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<tbody>
<tr>
<td>CONVULSIONS</td>
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<th>H. DEVICE MANUFACTURERS ONLY</th>
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<tbody>
<tr>
<td>1. Type of Reportable Event</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Serious Injury</td>
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<tr>
<td>Malfunction</td>
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<tr>
<td>Other:</td>
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<table>
<thead>
<tr>
<th>2. If Follow-up, What Type?</th>
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<tr>
<td>Correction</td>
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<tr>
<td>Additional Information</td>
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<td>Response to FDA Request</td>
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<tr>
<td>Device Evaluation</td>
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<th>3. Device Evaluated by Manufacturer?</th>
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<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No (Attach page to explain why not)</td>
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| 4. Device Manufacture Date (mm/dd/yyyy) |

<table>
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<tr>
<th>5. Labeled for Single Use?</th>
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<tbody>
<tr>
<td>Yes</td>
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<table>
<thead>
<tr>
<th>6. Evaluation Codes (Refer to coding manual)</th>
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<tbody>
<tr>
<td>Method</td>
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<th>7. If Remedial Action Initiated, Check Type</th>
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<tbody>
<tr>
<td>Recall</td>
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<tr>
<td>Notification</td>
</tr>
<tr>
<td>Repair</td>
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<tr>
<td>Inspection</td>
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<tr>
<td>Replace</td>
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<td>Patient Monitoring</td>
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<tr>
<td>Restoring</td>
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<td>Mod/Fixed/Adjustment</td>
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<th>8. Usage of Device</th>
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<tr>
<td>Initial Use of Device</td>
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<tr>
<td>Reuse</td>
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<td>Unknown</td>
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| 9. If action reported to FDA under 21 USC 380(f), List correction/ removal reporting number: |

<table>
<thead>
<tr>
<th>10. Additional Manufacturer Narrative</th>
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| 11. Corrected Data |

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 Picard 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

COMPLAINT #: 2329

DATE OF COMPLAINT: 09/23/13

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET—T135

SIZE: 135 TABLETS

LOT NO: 113965

RECEIVED

JUN 07 2013

PRODUCT RECEIVED FOR INSPECTION: Y

PRODUCT BEING RETURNED FOR INSPECTION: Y

DATE REQUESTED PRODUCT BE RETURNED: 06/23/13

UPS CALL TAG ISSUED: Y

DATE PRODUCT RECEIVED: 06/24/13

INVESTIGATION

REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/24/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CORRECTIVE ACTION:

06/24/13: PREPARED REFUND REQUEST TOTALING $ 9.10.

CORRECTIVE ACTION(S) COMPLETED BY: [Redacted]

ADVERSE EVENT REPORTS

ADVERSE EVENT REPORTED ON: 05/23/13

BY: EDYTA FRACKIEWICZ

REVIEWED BY MANAGEMENT BY: [Signature]

GA / QC DIRECTOR

cc: QA / QC
Production
Packaging
Shipping / Receiving

Form #: VD1
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1380
COMPLAINT #: 2329

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME:
ADDRESS:
CITY:
COUNTRY: USA
PHONE #:
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

Individual Case Safety Report

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY:

DATE:

BY:

QA/QC DIRECTOR

DATE:

DSS JUN 07 2013

DSS JUN 04 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAED1
A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event: 5 Years
3. Sex
   0 Female
   0 Male
4. Weight
   0 25 lbs
   0 or
   0 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/failures)
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   0 Death: 
     (mm/dd/yyyy)
   0 Disabling or Permanent Damage
   0 Life-threatening
   0 Congenital Anomaly/Birth Defect
   0 Hospitalization - Initial or Prolonged
   0 Other Serious (Non-Medical Events)
   0 Required Intervention to Prevent Permanent Impairment/Damage (Device)
3. Date of Event (mm/dd/yyyy)
   09/27/2010
4. Date of This Report (mm/dd/yyyy)
   11/02/2010

5. Describe Event or Problem
   TOOK 1/4 OF THE BOTTLE ON 9/25 AND THEN ON (b) (6) WENT TO
   ER WITH DIFFICULTY BREATHING. RASH ON ARMS THAT
   STARTED AROUND THE SAME TIME AND IS STILL CONTINUING.
   WENT TO ER. GIVEN STERiods TO HELP CHILD BREATHE;
   AQUAFOR FOR THE RASH. UNKNOWN ANTI-ITCH CREAM.
   ER PHYSICIAN'S DIAGNOSIS WAS CROUP, DOCTOR DIDN'T SEE
   THE RASH.

6. Relevant Tests/Laboratory Data, Including Dates

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

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & mfr/lababor)
   #1 HYLAND'S TEETHING TABLETS
   #2
2. Date, Frequency & Route Used
   #1 1/4 BOTTLE INGESTION
   #2
3. Therapy Dates (If unknown, give duration)
   #1
   #2

4. Diagnosis for Use (Indication)
   #1 IMPETIGO
   #2
5. Event Altered After Use
   #1 Yes  No  Doesn't Apply
   #2
6. Lot #
   #1
   #2
7. Exp. Date
   #1
   #2
8. NDC or Unique ID
   54973-7504-1

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   0 Health Professional
   0 Lay User/Patient
   0 Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   0 Yes  0 No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
    0 Yes  0 No  0 Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER
1. Name and Address (b) (6)
2. Phone #
3. Occupation  MOTHER
4. Initial Reporter Also Sent Report to FDA
   0 Yes  0 No  0 Unk.
### H. DEVICE MANUFACTURERS ONLY

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<thead>
<tr>
<th>Description</th>
<th>Yes</th>
<th>No</th>
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CASEID: 9410155

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS (PK OF 4 THROUGH AMAZON)
LOT NO.: THREW AWAY THE BOTTLE

REPORTER: (6) [Redacted]
ADDRESS: [Redacted]
CITY: [Redacted]
COUNTRY: USA
PHONE #: (6) [Redacted]
E-MAIL: [Redacted]

NATURE OF COMPLAINT: TOOK % OF THE BOTTLE ON 9/25 AND THEN ON [Redacted] WENT TO ER WITH DIFFICULTY BREATHING. RASH ON HIPS THAT STARTED AROUND THE SAME NIGHT AND IS STILL CONTINUING.

FOR ADDITIONAL SPACE PLEASE USE 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: [Redacted]
UPS CALL TAG ISSUED: Y [CIRCLE ONE]
DATE PRODUCT RECEIVED: [Redacted]

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/28/10
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: [Redacted] DATE: [Redacted]

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: N [CIRCLE ONE]
ADVERSE EVENT REPORTED ON: 10/28/19 BY: EDDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: [Signature] DATE: 4/7/10
BY: QA / QC DIRECTOR DATE: [Redacted]

CC: QA / QC Production Packaging Shipping / Receiving

APR 22 2013

APR 1 9 2013
Individual Case Safety Report

CaseID: 9410155

AE #: RAE102810EF-003
COMPLAINT #: RVD102810EF-003

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME:
ADDRESS:
CITY:
STATE:
COUNTRY: USA
ZIP CODE:
PHONE #: (b)(6)
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

IN郾SHONY

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ______________________________ DATE: ________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ______________________________ DATE: 11/23/10 APR 22 2013

BY: ______________________________ DATE: ________________ QA / QC DIRECTOR

DSS

APR 19 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE
MEDWATCH

FORM FDA 3500A (6/10)

Page 1 of 4

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
   or Date of Birth:
   In confidence

2. Age at Time of Event:
   6 Months

3. Sex
   □ Female
   □ Male

4. Weight
   4 lbs
   or 2 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. □ Adverse Event and/or Product Problem (e.g., defect/ malfunction)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ Life-threatening
   □ Congenital Anomaly/ Birth Defect
   □ Hospitalization - initial or prolonged
   □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Device)

3. Date of Event (mm/dd/yyyy)
   01/00/2013

4. Date of This Report (mm/dd/yyyy)
   08/03/2013

5. Describe Event or Problem
   SHE HEARD OF THE RECALL AND WANTED INFORMATION. CHILD
   HAS HAD 3 DOSES OF BABY TEETHING TABLETS 3 TIMES.
   SINCE 1 1/2 WEEKS MOTHER NOTICED CONSTIPATION, DRY
   SKIN. SHE THOUGHT IT MAY BE DUE TO INTRODUCTION OF SOLID
   FOOD (OATMEAL) SINCE 1 MONTH. CHILD HAD THIRD IMMUNIZION
   ON MAY 10, 2013, AND WAS GIVEN 3 GET. MOTHER GAVE LAST
   DOSE OF BABY TEETHING TABLETS 3 - 4 DAYS AGO. SHE
   NOTICED IN THE LAST 2 DAYS CHILD AT NIGHT IS "JITTERY",
   HEAD PULLS AWAY WHILE NURSING, WIDE EYED, LOOKING AROUND
   AS THOUGH SHE SEES SOMETHING (MOTHER CONSIDERED A GHOST).
   SHE THOUGHT MAYBE CAFFEINE WAS IN HER MILK ACCIDENTALLY
   AS HER SON LOOKED LIKE HE WAS ON CAFFEINE. MOTHER IS
   VERY SENSITIVE TO DRUGS AND HER ALLERGIES. SHE IS
   SEEING DOCTOR TODAY.

C. SUSPECT PRODUCT(S)
1. Name (Give Unlabeled Strength & ndb; ndb; ndb;
   HIBLAND'S BABY TEETHING TABLETS
   #2

2. Dose, Frequency & Route Used
   #1 2 - 3 TABS ONCE A DAY x 2WKS
   #2

3. Therapy Dates (If unknown, give duration)
   #1
   #2

4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN
   #2

5. Event Altered After Use Stopped or Dose Reduced?
   #1 No
   #2

6. Lot #
   #1 114193
   #2

7. Exp. Date
   #1
   #2

9. NDC# or Unique ID
   54973 - 3127- 1

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

D. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Implanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on Patient?
   □ Yes
   □ No

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

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

E. INITIAL REPORTER
1. Name and Address
   Phone # (b)(6)
   (b)(6)

2. Health Professional?
   □ Yes
   □ No

3. Occupation

4. Initial Reporter Also Sent 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.
**Individual Case Safety Report**

**Page 2 of 4**

**F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)**
1. Check One
   - User Facility
   - Importer
2. UFI/Importer Report Number
3. User Facility or Importer Name/Address

**4. Contact Person**
5. Phone Number

**6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)**
7. Type of Report
   - Initial
   - Follow-up #
8. Date of This Report (mm/dd/yyyy)

**9. Approximate Age of Device**
10. Event Problem Codes (Refer to coding manual)
    | Patient Code | Device Code |
    |--------------|-------------|
    |             |             |

**11. Report Sent to FDA?**
- Yes
  - (mm/dd/yyyy)
- No
  - (mm/dd/yyyy)

**12. Location Where Event Occurred**
- Hospital
- Outpatient Diagnostic Facility
- Home
- Ambulatory Surgical Facility
- Nursing Home
- Other:

**13. Report Sent to Manufacturer?**
- Yes
  - (mm/dd/yyyy)
- No
  - (mm/dd/yyyy)

**14. Manufacturer Name/Address**

**G. ALL MANUFACTURERS**
1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   - TUTTI GOULD
   - HYLAND'S, INC.
   - 154 W. 113ST STREET
   - LOS ANGELES, CA 90061
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:

**4. Date Received by Manufacturer (mm/dd/yyyy)**
   - 35/23/2013
5. (A)NDA #
   - IND #
   - STN #
   - PMRA 510(k) #

**7. Type of Report (Check all that apply)**
- 5-day
- 30-day
- 7-day
- Periodic
- 10-day
- Initial
- 15-day
- Follow-up #

**8. Manufacturer Report Number**
   - 54973 AE # 1386

**9. Adverse Event Term(s)**
   - CONSTIPATION, DRY SKIN

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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

**OMIS 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

SECTION I: COMPLAINT

COMPLAINT #: 2338

TAKEN BY: TUTTI GOULD
DATE OF COMPLAINT: 05/23/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET-T135

SIZE: 135 TABLETS
LOT NO.: 114193

REPORTER:

ADDRESS:

CITY:
STATE: (b) (6)

COUNTRY: USA
ZIP CODE:

PHONE #: (b) (6)

E-MAIL: 

NATURE OF COMPLAINT:
SHE HEARD OF THE RECALL AND WANTED INFORMATION. CHILD HAS HAD 3 DOSES OF BABY TEETHING TABLETS SINCE 3 WEEKS. SINCE 1½ WEEKS MOTHER NOTICED CONSTIPATION, DRY SKIN. SHE THOUGHT IT MAY BE DUE TO INTRODUCTION OF SOLID FOOD (OATMEAL) SINCE 1 MONTH. CHILD HAD THIRD IMMUNIZATION ON MAY 10, 2013 AND WAS GIVEN 3 O.S. MOTHER GAVE LAST DOSE OF BABY TEETHING TABLETS 3 – 4 DAYS AGO. SHE NOTICED IN THE LAST 2 DAYS CHILD AT NIGHT IS JITTERY, HEAD PULLS AWAY WHILE NURSING, WIDE EYED, LOOK UP AROUND AS THOUGH HE SEES SOMETHING (MOTHER CONSIDERED A GHOST). SHE THOUGHT MAYBE CAFFEINE WAS IN HER MILK ACCIDENTALLY AS HER SON LOOKED LIKE HE WAS ON CAFFEINE. MOTHER IS VERY SENSITIVE TO SOAPS AND HER ALLERGIES. SHE IS SEEING DOCTOR TODAY. CHILD HAS BEEN GIVEN 2 – 3 TABLETS, ONCE A DAY FOR 2 WEEKS. MOTHER TAKING PRENATAL VITAMINS AND .05 MG SYNTHROID AT TIME OF INCIDENT.

FOR ADDITIONAL SPACE PLEASE USE 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:

UPS CALL TAG ISSUED: Y (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

RECEIVED

JUN 07 2013

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
05/23/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:
TUTTI GOULD

DSS
JUN 01 2013

SECTION III: CORRECTIVE ACTION

Individual Case Safety Report

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 05/23/13 BY: TUTTI GOULD

REVIEWED BY MANAGEMENT BY: 

DATE: 06-09-13

DATE: 06-04-13

JUN 07 2013

Form # V01
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1388  COMPLAINT #: 2338

SECTION I:  PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VQ1)

NAME: (b)(6)

ADDRESS: ____________________________________________________________

CITY: ________________________________________________________________

COUNTRY: USA  STATE: (b) (6)

PHONE #: (b)(6)  ZIP CODE: ____________________________________________

E-MAIL: ______________________________________________________________

SECTION II:  PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Case Safety Report

9412421-01-00-04

SECTION III:  CORRECTIVE ACTION:

_______________________________________________________________

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________  DATE: __________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________  DATE: 06-05-13

BY: QA / QC DIRECTOR  DATE: __________

DISTRIBUTION: FDA  ADVERSE EVENT FILE
Individual Case Safety Report

9412536-01-00-01

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event: 7 Months
3. Sex
   □ Female
   or
   □ Male
4. Weight (lbs)
   or
   (kgs)
5. Date of Birth:
   In confidence

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. □ Adverse Event and/or □ Product Problem (e.g., defect/safety issues)
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death:
   (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ Life-threatening
   □ Congenital Anomaly/Birth Defect
   □ Hospitalization - Initial or prolonged
   □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Device)
3. Date of Event (mm/dd/yyyy)
   02/00/2013 - 03/31/2013
4. Date of This Report (mm/dd/yyyy)
   05/31/2013
5. Describe Event or Problem:

SPOKE WITH MOTHER ON 05/30/2013. IN FEBRUARY AND MARCH OF 2013 CHILD WAS Twitching AND JERKING IN EYES AND NECK THAT LOOKED LIKE SPASMS. DOCTOR THOUGHT IT WAS A "LITTLE SEIZURE" BUT DID NOT FEEL NEED TO DO TESTS. SYMPTOMS OCCURRED DURING THE DAY AND INCREASED IN FREQUENCY. SYMPTOMS STOPPED IN MARCH.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer)
   #1: HYLAND'S BABY TEETHING TABLETS
   #2
2. Dose, Frequency & Route Used
   #1: 3 TABS HS ONCE IN WHILE
   #2
3. Therapy Dates (If unknown, give duration)
   [start] [end] or (best estimate)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1: TEMP RELIEF TEETHING PAIN
   #2
5. Event Altered After Use
   Stopped or Dose Reduced?
   #1: Yes □ No □ Doesn't Apply
   #2: Yes □ No □ Doesn't Apply
6. Lot #
   #1: #115412
   #2
7. Exp. Date
   #1
   #2
8. NDC# or Unique ID
   54973-3127-2
9. Concomitant Medical Products and Therapy Dates
   (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

DSS
JUN 10 2013

4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:
   Catalog #
   Expiration Date (mm/dd/yyyy)
   Serial #
   Other #
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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 8, Enter Name and Address of Reprocessor

DSS
JUN 10 2013

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)

E. INITIAL REPORTER
1. Name and Address
2. Health Professional? □ Yes □ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA
   □ Yes □ No □ Unk.

USA
JUN 07 2013

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.
**H. DEVICE MANUFACTURERS ONLY**

1. **Type of Reportable Event**
   - Death
   - Serious Injury
   - Malfunction
   - Other:

2. **Follow-up, What Type?**
   - Correction
   - Additional Information
   - Response to FDA Request
   - Device Evaluation

3. **Device Evaluated by Manufacturer?**
   - Yes
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code:

4. **Device Manufacture Date (mm/dd/yyyy)**

5. **Labeled for Single Use?**
   - Yes
   - No

6. **Evaluation Codes (Refer to coding manual)**
   - Method
   - Results
   - Conclusions

7. **If Remodel Action Initiated, Check Type**
   - 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 386, list correction/ removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

**G. ALL MANUFACTURERS**

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

   EDYTA FRACKIEWICZ
   HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

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:

4. **Data Received by Manufacturer (mm/dd/yyyy)**
   05/24/2013

5. **AINDA #**
   IND #
   STN #
   PMA/510(k) #

6. **Type of Report**
   - 5-day
   - 7-day
   - 10-day Initial
   - 15-day Follow-up

7. **Manufacturer Report Number**
   54973 AS # 1398

8. **Adverse Event Term(s)**
   SEIZURES

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**DSS JUN 1 0 2013**
Individual Case Safety Report

PLAINT RECORD

COMPLAINT #: 2340
DATE OF COMPLAINT: 05/24/13
ITEM CODE: BTET-T250
LOT NO.: 115412

TAKEN BY: [Redacted] PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 250 TABLETS
REPORTER: [Redacted] ADDRESS: 

CITY: [Redacted] STATE: [Redacted]
COUNTRY: USA ZIP CODE: 
PHONE #: [Redacted] E-MAIL: 

NATURE OF COMPLAINT: CHILD WAS 7 MONTHS OLD AT THE TIME. TAKING AT NIGHT 3 TABLETS AT BEDTIME ONCE IN A WHILE. IN FEBRUARY / MARCH 2013 CHILD WAS TWITCHING AND JERKING IN EYES AND NECK; LOOKS LIKE SPASMS. WENT TO DOCTOR AND DOCTOR THOUGHT IT WAS A "LITTLE SEIZURE", BUT DID NOT FEEL A NEED TO DO TESTS. STOPPED USING PRODUCT IN MARCH 2013 AND REACTIONS STopped. REACTIONS WERE DURING THE DAY AND BECOMING MORE FREQUENT. NO FEVER OR ILLNESS AT THE TIME. DOES NOT WANT A REFUND. WANTS TO KNOW WHY BELLADONNA IS IN THE PRODUCT. WANTS BELLADONNA REMOVED FROM PRODUCT. T EXPLAINED THE INGREDIENTS IN PRODUCT TO HER IN DETAL. EXPLAINED THE RPUS AND THE FACT THAT HOMEOPATHY IS FDA REGULATED.

FOR ADDITIONAL SPACE PLEASE USE 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: 
UPS CALL TAG ISSUED: Y (CIRCLE ONE)
DATE PRODUCT RECEIVED: 

RECEIVED

JUN 07 2013

CDR

INVESTIGATION: REVIEWED BATCH RECORDS. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURE TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/24/13
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

ADVERSE EVENT SERIOUS: Y (CIRCLE ONE)
ADVERSE EVENT REPORTED ON: 05/24/13
BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: 
DATE: 06-04-13

cc: QA / QC Production
Packaging Shipping / Receiving

JUN 07 2013
EVENT DATA FORM

AE #: 1388
COMPLAINT #: 2340

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: __________________________
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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: __________________________ DATE: __________

SECTION IV: REVIEWED BY MANAGEMENT BY: ______________________ DATE: __________

BY: QA / QC DIRECTOR DATE: __________

DSS JUN 10 2013
DSS JUN 07 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAEDN
C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer)
   #1 HYLAND'S TEETHING GEL
   #2 TYLENOL
2. Dose, Frequency & Route Used
   #1 1-3 TIMES DAILY
3. Therapy Dates (if unknown, give duration)
   from/to (or best estimate)
   #1
   #2

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   ☐ Death: (mm/dd/yyyy)
   ☐ Eligibility or Permanent Damage
   ☐ Life-Threatening: Congenital Anomaly/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) 05/19/2013
4. Date of This Report (mm/dd/yyyy) 06/03/2013
5. Describe Event or Problem
   CHILD SEEMS TO HAVE A FEVER EVERY TIME SHE TAKES
   TEETHING GEL FOR TH LAST 6 DAYS. MOTHER STOPPED IT
   TODAY, 05/25/13. FEVER IS LESS BUT SHE IS PERSPIRING.
   HOSPITALIZED FOR 3 DAYS. FEVER GOES FROM 98F TO 104F.

E. INITIAL REPORTER
1. Name and Address
   # (b)(6)
2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☑ No ☐ Unk.

Please type or use black ink.
CUSTOMER COMPLAINT RECORD

SECTION: COMPLAINT

COMPLAINT #: 2339

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 05/25/13

PRODUCT: TEETHING GEL

ITEM CODE: TGEL-0.64Z

SIZE: 0.6 OUT (2 oz)

LOT NO.: 130135A

REPORTER: (b) (6)

ADDRESS:

CITY: USA

STATE: 

COUNTRY: 

ZIP CODE: 

PHONE #: (b) (6)

E-MAIL: 

RECEIVED JUN 17 2013

CDR

NATURE OF COMPLAINT: CHILD 'RUNS A TEMPERATURE' EACH TIME SHE GIVES IT TO HER FOR THE LAST 6 DAYS. STOPPED GIVING IT TO CHILD. TODAY SHE IS LESS FEVERISH (99.7) BUT IS PERESPIRING. STILL HAS FEVER. LAST DOSE SHE TAKES A PHRASE HOSPITAL AND DOCTORS. THEY THINK IT'S EVERY GEL. TAKING COMFIRM FOR FEVER. MOTHER PUTS A LITTLE GEL ON HER FINGER, SWABS ON GUM EVERY 1-2 X 1 DAY WHEN IRRTABLE. ADVISED MOTHER TO DISCONTINUE USING PRODUCT AND CONSULT YOUR DOCTOR.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/25/13

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

ADVERSE EVENT SERIOUS: Y/N

ADVERSE EVENT REPORTED ON: 05/25/13

BY: TUTTI GOULD

SECTION V: REVIEWED BY MANAGEMENT

REVIEWED BY MANAGEMENT BY: 

DATE: 06-04-13

DATE: 06-05-13

BY: 

FORM # 6D1

OC: QA/QC Packaging Production Shipping / Receiving

JUN 18 2013

DSS JUN 19 2013
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1387
COMPLAINT #: 2339

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: [Redacted]
ADDRESS: [Redacted]
CITY: [Redacted] STATE: [Redacted]
COUNTRY: USA ZIP CODE: [Redacted]
PHONE #: [Redacted] E-MAIL: [Redacted]

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: ____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: ____________

BY: ________________ DATE: ____________

DSS JUN 1 9 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE#1 JUN 1 8 2013
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 FINS AFTER. THEN 3 DAYS AGO, HE HAD A SEIZURE AND TRENORS 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.

SCHEDULED FOR A FUTURE EEG AND MRI.
**F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)**

1. Check One
   - [ ] User Facility
   - [ ] Importer

2. OF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

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

7. Type of Report
   - [ ] Initial
   - [ ] Follow-up

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
   - Patient Code
   - Device Code

11. Report Sent to FDA?
   - [ ] Yes (mm/dd/yyyy)
   - [ ] No (mm/dd/yyyy)

13. Report Sent to Manufacturer?
   - [ ] Yes (mm/dd/yyyy)
   - [ ] No (mm/dd/yyyy)

14. Manufacturer Name/Address

**G. ALL MANUFACTURERS**

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

   TUTTI GOULD
   HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

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:

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

   05/23/2013

5. (ANDA #)

   IND #

   STN #

   PMA/510(k) #

   Combination Product
   - [ ] Yes
   - [ ] No

   Pre-1998
   - [ ] Yes
   - [ ] No

   OTC Product
   - [ ] Yes
   - [ ] No

6. Type of Report (Check all that apply)
   - [ ] 6-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
     - [ ] Initial
   - [ ] 15-day
     - [ ] Follow-up

7. Manufacturer Report Number

   54973 AE # 1382

8. Adverse Event Term(s)

   SEIZURE, TREMORS, RASH

**H. DEVICE MANUFACTURERS ONLY**

1. Type of Reportable Event
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction
   - [ ] Other:

2. If Follow-up, What Type?
   - [ ] Correction
   - [ ] Additional Information
   - [ ] Response to FDA Request
   - [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
   - [ ] Yes
     - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - [ ] Yes
   - [ ] No

6. Evaluation Codes (Refer to coding manual)

   Method
   - [ ]
   - [ ]
   - [ ]

   Results
   - [ ]
   - [ ]
   - [ ]

   Conclusions
   - [ ]
   - [ ]
   - [ ]

7. If Remedial Action Initiated, Check Type

8. Usage of Device
   - [ ] Initial Use of Device
   - [ ] Reuse
   - [ ] Unknown

9. If action reported to FDA under 21 USC 380(a)(1), list corrective/remove reporting number:

10. Additional Manufacturer Narrative and/or

11. Corrected Data
B.6. 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)

Other Remarks

DSS

JUN 06 2013

JUN 05 2013
CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

COMPLAINT #: 2332

TAKEN BY: TUTTI GOULD
DATE OF COMPLAINT: 05/23/13

PRODUCT: BABY TEETHING TABLETS
ITEM CODE: BTET—T250

SIZE: 250 TABLETS
LOT NO.: 115032

REPORTER: [Redacted]
ADDRESS: [Redacted]

CITY: USA
STATE: [Redacted]
ZIP CODE: [Redacted]

PHONE #: [Redacted]

E-MAIL: [Redacted]

NATURE OF COMPLAINT:

17 MONTH OLD CHILD EXPERIENCED "JERKING EPILEPSY" 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 100.5 °F. 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.

HE HAS A HISTORY OF ASTHMA AND HAD AN ACUTE EPISODE AT THE END OF APRIL (APPROX 3 WEEKS AGO). HE WAS ON THE FOLLOWING MEDICATIONS: ALBUTEROL, FUMICORT, OMNICEF, AND GRAPFREED. HE ALSO HAD THROAT AND WAS TAKING NYSTATIN A FEW WEEKS AGO. HIS LAST IMMUNATIONS WERE ON DEC. 2012. JERKING LASTED 1 MINUTE, SEIZURE WAS DURING SLEEP, RASH — NOT KNOWN. JERKING AND RASH ON 05/16/13; SEIZURE ON 05/20/13; AND RASH ON 05/22/13.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION:

REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. PRODUCT WAS TESTED ACCORDING TO SPECIFICATIONS AND ALL RESULTS WERE WITHIN ACCEPTABLE LIMITS. INSPECTED RETAINED SAMPLES AND EVERYTHING LOOKS OKAY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13
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

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 05/23/13
BY: EDYTA FRACKIRWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

BY: [Redacted]
QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

DSS JUN 06 2013
Form # VD1

(Original Signature)

(Original Signature)

JUN 05 2013
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1382
COMPLAINT #: 2332

SECTION I:
PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME:
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 PANELS)

SECTION III:
CORRECTIVE ACTION:

Individual Case Safety Report

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV:
REVIEWED BY MANAGEMENT BY:

DATE: 05-30-13

BY:

DATE: 05-30-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUN 05 2013 FORM SA01
MY DAUGHTER HAS A SEIZURE, AND WE WERE ADMITTED TO THE HOSPITAL FOR A WEEK.
**F. FOR USE BY USER FACILITY IMPORTER (Devices Only)**

1. Check One
   - User Facility
   - Importer

3. User Facility or importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report
   - Initial
   - Follow-up

9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)
    - Patient Code
    - Device Code

11. Report Sent to FDA?
    - Yes
    - No

12. Location Where Event Occurred
    - Hospital
    - Home
    - Other:

13. Report Sent to Manufacturer?
    - Yes
    - No

14. Manufacturer Name/Address

---

**H. DEVICE MANUFACTURERS ONLY**

1. Type of Reportable Event
   - Death
   - Serious Injury
   - Malfunction
   - Other:

2. If Follow-up, What Type?
   - Correlation
   - Additional Information
   - Response to FDA Request
   - Device Evaluation

3. Device Evaluated by Manufacturer?
   - Not Returned to Manufacturer
   - Evaluation Summary Attached

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
   - Yes
   - No

6. Evaluation Codes (Refer to coding manual)
   - Method
   - Results
   - Conclusions

7. If Remedial Action Initiated, Check Type
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Restoring
   - Modification/Adjustment
   - Other:

9. If action reported to FDA under 21 USC 381(h), list correction/removal reporting number:

10. Additional Manufacturer Narrative

11. Corrected Data

---

**G. ALL MANUFACTURERS**

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   - EDYTA FRACKIEWICZ
   - RYLAND'S, INC.
   - 154 W. 1331ST STREET
   - LOS ANGELES, CA 90061

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:

4. Date Received by Manufacturer (mm/dd/yyyy)
5. (A)NDA #
6. IND #
7. STN #
8. PMA 510(k) #
9. Combination Product
10. Pre-1938
11. OTC Product

5. Manufacturer Report Number
   - 54973 RA00521238F004

6. Adverse Event Term(s)
   - SEIZURE

---

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
1500 P Street, N.W., 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

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ DATE OF Complaint: 05/24/13

PRODUCT: TEETHING TABLETS ITEM CODE: TEET

SIZE: 

REPORTER: (8) (6) 

ADDRESS: 

CITY: 
STATE: 
COUNTRY: USA 
ZIP CODE: 
PHONE #: (8) (6) 
E-MAIL: 

NATURE OF COMPLAINT: RECEIVED E-MAILED THAT DAUGHTER HAD A SEIZURE AND WAS ADMITTED TO (8) (6) FOR A WEEK

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

3 ATTEMPTS MADE TO REACH CUSTOMER ON 5/22, 5/23, AND 5/24 VIA E-MAIL. CUSTOMER DOES NOT RESPOND.

DATE REQUESTED PRODUCT BE RETURNED: 

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDING TO PHARMACIST / NURSE FOR EVALUATION ON: 05/22/13

ADVERSE EVENT FORWARDING TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION

Individual Case Safety Report

9412680-01-00-03

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON: 05/22/13 BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 

BY: N/A QA / QC DIRECTOR

DATE: 05-30-13

AE #: RAE052213EF004

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

JUN 05 2013
SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE052213EF004
COMPLAINT #: RVD052213EF004

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME:

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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 

SECTION IV:

REVIEWED BY MANAGEMENT BY: 

DATE: 05-30-13 

DATE: JUN 06 2013

BY: N/A 

QA / QC DIRECTOR 

DISTRIBUTION: FDA ADVERSE EVENT FILE
**A. PATIENT INFORMATION**

1. Patient Identifier (SSN)
2. Age at Time of Event: 10 Months
3. Sex: [ ] Female [ ] Male
4. Weight: [ ] lbs [ ] kg

---

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defects/instructions)
2. Outcomes Attributable to Adverse Event (Check all that apply)
   - [ ] Death: (mm/dd/yyyy)
   - [ ] Disability or Permanent Damage
   - [ ] 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)

---

5. Describe Event or Problem

WHEN CHILD WAS 6 MONTHS OLD, STARTED HAVING SHAKING AND STIFFENING EPISODES WHEN WOULD DURIE OUT FOR 5 - 10 SECONDS. HAPPENED 2 - 3 TIMES A WEEK FOR 2 MONTHS. RESOLVED AFTER TEETHING TABLETS WERE DISCONTINUED.

---

6. Relevant Tests/Laboratory Data, Including Dates

---

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

NO KNOWN ALLERGIES.
NO ILLNESSES.
FULL TERM BABY.
NO NEW FOODS AT THE TIME.

---

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & unit of measure)
   - [ NYLAND'S BABY TEETHING TABLETS ]

   - [ ]

2. Dose, Frequency & Route Used
   - [ ]

3. Therapy Dates (if unknown, give duration)
   - [ ]

4. Diagnosis for Use (Indication)
   - [ ]

5. Event Abated After Use
   - [ ] Yes [ ] No [ ] Doesn't Apply

---

6. Lot #
7. Exp. Date
8. Event Reappeared After Reinstitution?
9. NDC# or Unique ID
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

---

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] 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, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
   - [ ] Yes [ ] No [ ] Returned to Manufacturer on:

---

**E. INITIAL REPORTER**

1. Name and Address
2. Phone #
3. Occupation
4. Initial Reporter Also Sent Report to FDA

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**F. FDA Use Only**

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**PLEASE TYPE OR USE BLACK INK**

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**RECEIVED**

AUG 20 2013

CDR

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

1. Check One  
   - User Facility  
   - Importer  

2. User Facility or Importer Name/Address

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

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

7. Type of Report  
   - Initial  
   - Follow-up #

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)  
    - Patient Code
    - Device Code

11. Report Sent to FDA?  
    - Yes (mm/dd/yyyy)
    - No (mm/dd/yyyy)

12. Location Where Event Occurred  
    - Hospital
    - Home
    - Nursing Home
    - Outpatient Treatment Facility
    - Other (Specify)

13. Report Sent to Manufacturer?  
    - Yes (mm/dd/yyyy)
    - No (mm/dd/yyyy)

14. Manufacturer Name/Address

**G. ALL MANUFACTURERS**

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

   EDYTA FRACKIWICZ  
   HYLAND'S, INC.  
   154 W. 131ST STREET  
   LOS ANGELES, CA 90061

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:

4. Date Received by Manufacturer (mm/dd/yyyy)  
   36/07/2013

5. (ANDA #  
   IND #  
   STN #  
   PMA/  
   510(k) #

6. Type of Report (Check all that apply)  
   - 5-day
   - 10-day
   - 15-day (Follow-up #)

7. Type of Report (Check all that apply)  
   - Combination Product
   - OTC Product

8. Manufacturer Report Number  
   54973 AE # 1405

9. Adverse Event Term(s)  
   POSSIBLE SEIZURES

**H. DEVICE MANUFACTURERS ONLY**

1. Type of Reportable Event  
   - Death
   - Serious Injury
   - Malfunction
   - Other:

2. If Follow-up, What Type?  
   - Correction
   - Additional Information
   - Response to FDA Request
   - Device Evaluation

3. Device Evaluated by Manufacturer?  
   - Not Returned to Manufacturer
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?  
   - Yes
   - No

6. Evaluation Codes (Refer to coding manual)  
   - Method
   - Results
   - Conclusions

7. If Remedial Action Initiated, Check Type  
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modification/Adjustment
   - Other

8. Usage of Device  
   - Initial Use of Device
   - Revision
   - Unknown

9. If action reported to FDA under 21 USC 351(b)(2), list correction/ removal reporting number:

10. Additional Manufacturer Narrative

11. Corrected Data

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**DSS AUG 21 2013**

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The public reporting burden for this collection of information has been estimated to average 56 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](https://www.healthit.gov)  
[Food and Drug Administration](https://www.fda.gov)  
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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**OMD 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."
June 14, 2013

Dear [Name],

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,

[Signature]

Dan Krombach
President

Enc: Refund Check - $30.26

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) 520-0587
STOMER COMPLAINT RECORD

COMPLAINT #: 2375
DATE OF COMPLAINT: 06/12/13 (E-MAIL RECEIVED 07/19/13)
ITEM CODE: BTET—T130
LOT NO.: A27213 (1 BOTTLE); A02613 (2 BOTTLES)

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS
REPORTER:
ADDRESS:

CITY:
COUNTRY: USA
PHONE #:
E-MAIL:

STARTED USING BABY TEETHING TABLETS WHEN CHILD WAS 4 - 5 MONTHS OLD. USING 2 - 3 TABLETS EVERY 6 HOURS EVERY DAY FOR 4 MONTHS. WHEN CHILD WAS 6 MONTHS, STARTED HAVING SHAKING AND STIFFENING EPISODES, ZONED OUT FOR 5 - 10 SECONDS, HAPPENED 2 - 3 TIMES A WEEK FOR 2 MONTHS. STOPPED USING BABY TEETHING TABLETS AT 9 MONTHS (APPROXIMATELY 05/20/13). DOCTOR SUGGESTED TO STOP BABY TEETHING TABLETS AND SEE IF SYMPTOMS WENT AWAY AFTER DISCONTINUING PRODUCT. PEDIATRICIAN CALLED THEM EPISODES AND MOTHER CALLED THEM MINI SEIZURES. CUSTOMER WANTS A REFUND FOR 3 BOTTLES OF BABY TEETHING TABLETS. CUSTOMER ON VACATION AND UNABLE TO CALL EARLIER AND DID NOT HAVE BOTTLES AVAILABLE. NO KNOWN ALLERGIES. NO ILLNESSES. FULL-TIME BABY. NO NEW FOODS AT THE TIME.

FOR ADDITIONAL SPACE PLEASE USE 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:
UPS CALL TAG ISSUED: Y (CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: BULK LOT # 117126 (A27212), BULK LOT # 117318 (A02613). REVIEWED BATCH RECORDS FOR BOTH LOTS. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY.

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION ON: 06/12/13
ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION BY:

SECTION III: CORRECTIVE ACTION:

06/14/13. PREPARED REFUND REQUEST TOTALING $ 30.26. 07/26/13. MAILED REFUND CHECK # 509485 TOTALING $ 30.26 ON ARTICLE # 70361830 00489255442.

CORRECTIVE ACTION(S) COMPLETED BY: (Circle One)
DATE: 06/14/13 & 07/26/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 06/12/13
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 08-06-13

DATE: 08-05-13

DSS AUG 2 1 2013

AUG 2 0 2013

cc: QA / QC DIRECTOR

OAI / OL Director
Packaging
Shipping / Receiving
A. PATIENT INFORMATION

1. Patient Identifier (b)(6) [Blank]
2. Age at Time of Event
   Months
   4
3. Sex
   Female
   Male
4. Weight
   lbs
   0
   kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/infections)
2. Outcomes Attributed to Adverse Event
   Death (MM/dd/yyyy)
   Disability or Permanent Damage
   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)

5. Describe Event or Problem
   USD 1 TABLET ON (b)(6) [Blank] AND 20 MINUTES LATER CHILD BECAME "LOCKED UP" AND VOMITED. WENT TO HOSPITAL AND DOCTOR DIAGNOSED AS SEIZURE. RELEASED A FEW HOURS LATER AND NO SUBSEQUENT SEIZURES OBSERVED.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/lot/batch)
   #1: LYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1: TABLET ONCE

3. Therapy Dates (If known, give duration)
   #1

4. Diagnosis for Use (Indication)
   #1: TEMP RELIEF TEETHING PAIN

5. Event Aborted After Use
   #1: Yes
   #2: No

6. Lot #
   #1: 122713
   #2: [Blank]

7. Exp. Date
   #1: [Blank]
   #2: [Blank]

9. NDC# or Unique ID
   [Blank]

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model II
5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - 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, 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)

E. INITIAL REPORTER

1. Name and Address
2. Health Professional?
   - Yes
   - No
3. Occupation
   [Blank]
4. Initial Reporter Also Sent Report to FDA
   - Yes
   - No
   - Link

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.

DSS
AUG 2 1 2013

AUG 2 0 2013
### F. For Use by User Facility/Importer (Devices Only)

1. Check One
   - [ ] User Facility
   - [ ] Importer

2. UL Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
   - Initial
   - Follow-up:

7. Type of Report
   - [ ] Initial
   - [ ] Follow-up

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
    - Patient Code
    - Device Code

11. Report Sent to FDA?
    - [ ] Yes
    - [ ] No

12. Location Where Event Occurred
    - [ ] Hospital
    - [ ] Outpatient Diagnostic Facility
    - [ ] Home
    - [ ] Medical Facility
    - [ ] Nursing Home
    - [ ] Outpatient Treatment Facility
    - [ ] Other:

13. Report Sent to Manufacturer?
    - [ ] Yes
    - [ ] No

14. Manufacturer Name/Address

### G. All Manufacturers

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   - EDYTA FACKIERECEWICZ
   - HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061

2. Phone Number
   - (310)-768-0700

3. Report Source
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 06/05/2013

5. (A/NDA #)

6. If IND, Give Protocol #

7. Type of Report
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
   - [ ] Initial
   - [ ] 15-day

8. Manufacturer Report Number
   - 54973 AE # 1403

9. Adverse Event Term(s)
   - SEIZURES

### H. Device Manufacturers Only

1. Type of Reportable Event
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction
   - [ ] Other

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
   - [ ] No (Attach page to explain why not) and provide code

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - [ ] Yes
   - [ ] No

6. Evaluation Codes (Refer to coding manual)
   - [ ] Method
   - [ ] Results
   - [ ] Conclusions

7. If Remedial Action Initiated, Check Type
   - [ ] 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 360(f), list correction/removal reporting number:

10. Additional Manufacturer Narrative
    - and/or

11. Corrected Data

---

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
1255 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."
June 7, 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. 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
STOMER COMPLAINT RECORD

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: HYLAND'S BABY TEETHING TABLETS

SIZE: 125 TABLETS

REPORTER:

ADDRESS:

CITY: USA

COUNTRY: USA

PHONE #: (b) (b)

E-MAIL:

DATE OF COMPLAINT: 06/05/13

ITEM CODE: BTET-T135

LOT NO.: A22713

COMPLAINT #: 2575

STATE: (b) (b)

ZIP CODE:

SPOKE WITH CUSTOMER ON 06/06/13. USED 1 TABLET ON 06/05/13. 20 MINUTES LATER, CHILD BECAME "LOCKED UP," THREW UP. WENT TO HOSPITAL AND DOCTOR DIAGNOSED AS SEIZURE. CHILD RELEASED A FEW HOURS LATER. SAID TO KEEP AN EYE ON AND DISCONTINUE BABY TEETHING TABLETS. CHILD IS FINE NOW. WANTED A REFUND WHEN OFFERED FOR 1 BOTTLE OF BABY TEETHING TABLETS (135 COUNT). HE FOUND INFORMATION ON TEETHING TABLETS RECALL ON THE INTERNET, WHICH PROMPTED HIM TO CALL. THIS WAS THEIR FIRST TIME USING BABY TEETHING TABLETS. THEY ARE GOING BACK FOR A FOLLOW-UP APPOINTMENT TO DOCTOR. DO NOT KNOW IF HEADING A FEVER. MAY HAVE "CHILD NOT SICK. NOT PREMATURE. NO OTHER MEDICATIONS. NO FAMILY HISTORY OF SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE)

DATE PRODUCT RECEIVED:

RECEIVED

AUG 20 2013

CDR

INVESTIGATION: BULK LOT # 118887. REVIEWED BATCH RECORD. MANUFACTURING AND PACKAGING WERE DONE ACCORDING TO ESTABLISHED PROCEDURES TO ENSURE PRODUCT QUALITY. INSPECTED RETAINED SAMPLE AND EVERYTHING LOOKED OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/05/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

06/07/13: PREPARED REFUND REQUEST TOTALING $ 9.58. 07/26/13: MAILED REFUND CHECK # 099487 TOTALING $ 9.58 ON ARTICLE # 700818300004 06260426.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (b)

DATE: 06/07/13 & 07/26/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 06/05/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

BY: OA / QC DIRECTOR

DSS

AUG 21 2013

AUG 2 0 2013

cc: QA / QC Packaging Production Shipping / Receiving
**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>6 months</td>
<td>Female</td>
<td>lbs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>or kg</td>
</tr>
</tbody>
</table>

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. **Adverse Event** and/or **Product Problem** (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   - [ ] Death: (mm/dd/yyyy)
   - [ ] Disability or Permanent Damage
   - [ ] 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): 06/23/2013
4. Date of This Report (mm/dd/yyyy): 06/26/2013

5. **Describe Event or Problem**

CHILD STARTED SHAKING ON 06/23/2013. NOT CONCENTRATING AND A BLANK STARE. HAPPENED TWICE ON THAT DAY. WENT TO THE ER. DOCTOR DIAGNOSED AS SEIZURES AND REFFERED TO A NEUROLOGIST. NO SEIZURES SINCE THEN.

**C. SUSPECT PRODUCT(S)**

1. **Name** (Give labeled strength & manufactured by)
   - HVLAD'S BABY TEETHING GEL

2. **Dose, Frequency & Route Used**
   - [ ] Oral
   - [ ] Topical
   - [ ] Other: GUMS 2-3 X DAY

3. **Therapy Dates** (If unknown, give duration from (or best estimate))
   - [ ] Onset
   - [ ] Maximum
   - [ ] Improvement
   - [ ] Recovery

4. **Diagnosis for Use (Indication)**
   - [ ] TEMP RELIEF OF TEETHING PAIN

5. **Event Altered After Use**
   - [ ] Yes
   - [ ] No
   - [ ] Doesn't Apply

6. **Lot #**
   - #1
   - #2

7. **Exp. Date**
   - #1
   - #2

8. **NDC# or Unique ID**
   - 54973-7521-2

9. **Concomitant Medical Products and Therapy Dates** (Exclude treatment of event)

10. **Concomitant Medical Products and Therapy Dates** (Exclude treatment of event)

**D. SUSPECT MEDICAL DEVICE**

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. **Model #**

5. **Catalog #**

6. **Serial #**

7. **Expiration Date (mm/dd/yyyy)**

8. **Operator of Device**
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Laboratory
   - [ ] Other

9. **If Implanted, Give Date (mm/dd/yyyy)**

10. **If Explanted, Give Date (mm/dd/yyyy)**

11. **If this a Single-use Device that was Reprocessed and Reused on a Patient**
   - [ ] Yes
   - [ ] No

12. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

13. **Device Available for Evaluation? (Do not send to FDA)**
   - [ ] Yes
   - [ ] No
   - [ ] Returned to Manufacturer on (mm/dd/yyyy)

14. **Concomitant Medical Products and Therapy Dates** (Exclude treatment of event)

**E. INITIAL REPORTER**

1. **Name and Address**

2. **Health Professional?**
   - [ ] Yes
   - [ ] No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA**
   - [ ] Yes
   - [ ] No
   - [ ] Undetermined

**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.**
The public reporting burden for this collection of information has been estimated to average 60 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, 1990 Pickett Drive, Room 403, Rockville, MD 20850. Please DO NOT RETURN this form to this address.
June 26, 2013

Dear [Name],

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,

[Signature]

Dan Krombach
President

Enc: Refund Check - $8.43
CUSTOMER COMPLAINT RECORD

9412695-02-00-05

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: BABY TEETHING GEL
SIZE: 0.5 OUNCES
REPORTER: (b)(6)
ADDRESS: USA
CITY: (b)(6)
COUNTRY: USA
PHONE #: (b)(6)
E-MAIL: USING THE PRODUCT 2 – 3 TIMES A DAY FOR 3 – 4 DAYS (JUNE 18 – 22). ON (b)(6) CHILD STARTED SHAKING. NOT CONCENTRATING. BLANK STARE. LASTED ABOUT 20 MINUTES. HAD ABOUT 2 THAT DAY. WENT TO THE ER. HAD BLOOD TESTS. WERE NORMAL. REFERRED TO NEUROLOGIST. DOCTOR DIAGNOSED AS SEIZURES AND RECOMMENDED TO MONITOR. NO SEIZURES SINCE. OFFERED A REFUND AND SHE WANTS IT. TOLD HER NOT TO USE BABY TEETHING GEL AND TALK TO THE DOCTOR. NO FAMILY HISTORY OF SEIZURES. NO NEW FOODS / FORMULA FED. FULL TERM BABY. NO HEAD INJURY. HAD A FEVER MOTHER STATED THAT DOCTOR SAID FEVER WAS OKAY AND DUE TO TEETHING. FEVER BROKE ON FRIDAY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION
RECEIVED
AUG 20 2013

PRODUCT BEING RETURNED FOR INSPECTION

DATE REQUESTED PRODUCT BE RETURNED:

Y (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Y (CIRCLE ONE)

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:

06/25/13
EDYTA FRACKIEWICZ

06/26/13: PREPARED REFUND REQUEST TOTALING $ 8.43. 07/26/13 MAILED REFUND CHECK # 509489 TOTALING $ 8.43 ON ARTICLE # 700818300004 80285610.

CORRECTIVE ACTION(S) COMPLETED BY: (b)(6)

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS

ADVERSE EVENT REPORTED ON:

06/25/2013

Y / N

SECTION V:

REVIEWED BY MANAGEMENT BY:

BY: (Signature) QA / QC DIRECTOR

cc: QA / QC Packaging
Production Shipping / Receiving

DATE: 08-06-13 AUG 21 2013
DATE: 08-05-13

08-06-13 AUG 21 2013
A. PATIENT INFORMATION

1. Patient Identifier
   (b) (6) [Redacted]

2. Age at Time of Event: 8 Months
   or Date of Birth:

3. Sex: 
   □ Female
   □ Male

4. Weight: ___ lbs
   or ___ kg

IN CONFIDENCE

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [Redacted] Adverse Event and/or [Redacted] Product Problem (e.g., defects/malfunctions)

2. 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)
   - Required intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)
   11/06/2012

4. Date of This Report (mm/dd/yyyy)
   07/02/2013

5. Describe Event or Problem

   HAD 3 SEPARATE SEIZURES IN (b) (6) TO (b) (6) WHILE USING HYLANDS BABY TEETHING TABLETS. SEIZURES WERE ON THE LEFT SIDE OF THE BODY AND CHILD UNRESPONSIVE. HOSPITALIZED AFTER BITING, JERKING, FOAMING AT MOUTH, AND TURNED BLUE ON THIRD SEIZURE.

C. SUSPECT PRODUCT(S)

1. Name (Own institution strength & manufacturer)
   #1 HYLANDS BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 AS NEEDED FOR 3 MONTHS

3. Therapy Dates (If known, give duration)
   #1 [Redacted]

4. Diagnosis for Use (indications)
   #1 TEMP RELIEF TEETHING PAIN

5. Event Altered After Use
   #1 Yes
   #2 No

6. Lot #
   111465

7. Exp. Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 Yes
   #2 No

9. NDC# or Unique ID
   54973-3127-1

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Lot #

6. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other

7. If Implanted, Give Date (mm/dd/yyyy)

8. If Implanted, Give Date (mm/dd/yyyy)

9. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   □ Yes
   □ No

10. Device Available for Evaluation? (Do not send to FDA)
    □ Yes
    □ No
    □ Returned to Manufacturer etc.

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

DSS JUN 19 2013

E. INITIAL REPORTER

1. Name and Address
   (b) (6)

2. Health Professional?
   □ Yes
   □ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA
   □ Yes
   □ No
   □ Unk

JUL 2 5 2013

USA
### H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Death</td>
<td>[ ] Correction</td>
</tr>
<tr>
<td>[ ] Serious Injury</td>
<td>[ ] Additional Information</td>
</tr>
<tr>
<td>[ ] Malfunction</td>
<td>[ ] Response to FDA Request</td>
</tr>
<tr>
<td>[ ] Other</td>
<td>[ ] Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Not Returned to Manufacturer</td>
</tr>
<tr>
<td>[ ] Evaluation Summary Attached</td>
</tr>
</tbody>
</table>

| 4. Device Manufacturer Date (mm/yyyy) | [ ] No (Attach page to explain why not) or provide code. |

<table>
<thead>
<tr>
<th>5. Labeled for Single Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes</td>
</tr>
<tr>
<td>[ ] No</td>
</tr>
</tbody>
</table>

| 6. Evaluation Codes (Refer to coding manual) |

<table>
<thead>
<tr>
<th>Method</th>
<th>Results</th>
<th>Conclusions</th>
</tr>
</thead>
</table>

| 7. If Remedia Action Initiated, Check Type |

| [ ] Recall          | [ ] Notification |
| [ ] Repair          | [ ] Inspection   |
| [ ] Replace         | [ ] Patient Monitoring |
| [ ] Relabeling      | [ ] Modification/Adjustment |

<table>
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<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Initial Use of Device</td>
</tr>
<tr>
<td>[ ] Sale</td>
</tr>
<tr>
<td>[ ] Repair</td>
</tr>
<tr>
<td>[ ] Inspection</td>
</tr>
</tbody>
</table>

| 9. If action reported to FDA under 21 USC 351(f), list correction/removal reporting number: |

### G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   
   EDYTA FRACKIEWICZ  
   HYLAND'S, INC.  
   154 W. 131ST STREET  
   LOS ANGELES, CA  90061

2. Phone Number
   
   310-769-0700

3. Report Source  
   (Check all that apply)
   
   [ ] Foreign
   [ ] Study
   [ ] Literature
   [ ] Consumer
   [ ] Health Professional
   [ ] User Facility
   [ ] Company Representative
   [ ] Distributor
   [ ] Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
   
   37/01/2013

5. (ANDA #)
   
   IND #
   
   STN #
   
   PMA/ 510(k)#

6. If IND, Ghs Protocol #

7. Type of Report (Check all that apply)
   
   [ ] 5-day  
   [ ] 30-day  
   [ ] 7-day  
   [ ] Periodic  
   [ ] 10-day [ ] Initial  
   [ ] 15-day  
   [ ] Follow-up #

8. Manufacturer Report Number
   
   54973 AE # 1430

9. Adverse Event Term(s)
   
   SEIZURES, HOSPITALIZATION

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  
130 Piccard Drive, Room 400  
Rockville, MD 20850  
Please DO NOT RETURN this form to this address.
INDIVIDUAL CASE SAFETY REPORT

PRODUCT#: 2421
DATE OF COMPLAINT: 07/01/13
ITEM CODE: BTET-T135
LOT NO.: 114465

REPORTER: (b)(6)
ADDRESS: 

CITY: 
COUNTRY: USA
PHONE #: (b)(6)
E-MAIL: 

RECEIVED JUL 25 2013

CDR

NATURE OF COMPLAINT:
STARTED TEETHING 6 MONTHS AGO AND PURCHASED TABLETS AT WAL-MART. STARTED GIVING TABLETS AND 3 DAYS LATER IN (b)(6) HAD A SEIZURE DESCRIBED AS BECOMING UNRESPONSIVE. TWITCHING, JERKING LEFT HAND OF BODY, AMBULANCE PICKED HIM UP AND WENT TO (b)(6). AN EKG AND TESTING SHOWED NOTHING. SAID IT WAS ODD THAT ONLY HALF HIS BODY SEIZED, STAYED IN HOSPITAL FOR 8 HOURS, THEY CONTINUED USING TEETHING TABLETS. SECOND SEIZURE HAPPENED END OF (b)(6) ONLY LEFT SIDED. HAD A THIRD SEIZURE IN (b)(6) GOT A TABLET BEFORE BED THAT DAY PRIOR TO SEIZURE. DID NOT GIVE ANY TEETHING TABLETS AFTER THAT. THIRD SEIZURE WORSE BECAUSE HE STOPPED BREATHING, TURNED BLUE, FOAM OUT OF MOUTH, TWITCHING ON ONE SIDE, WENT TO ER AND STAYED OVERNIGHT. DOCTORS NOT SURE OF THE CAUSE. HAS BEEN TO NEUROLOGIST AND ALL TESTS ARE NORMAL. STOPPED BABY TEETHING TABLETS IN (b)(6) AFTER THIRD SEIZURE AND HAS HAD NO OTHER SEIZURES. HAS HAD MEDICAL EXPENSES AND WANTS A SETTLEMENT. OFFERED A REFUND FOR THE BOTTLE BUT DECLINED GAVE HIM OUR MAILING ADDRESS BECAUSE HE WANTED TO KNOW HOW HE COULD CONTACT OUR LEGAL DEPARTMENT. HE HAD MEDICAL INSURANCE BUT HAS EXPENSES RELATED TO CO-PAYS AND TRAVEL AS A RESULT OF CHILD'S SEIZURES.

FOR ADDITIONAL SPACE PLEASE USE 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: 
UPS CALL TAG ISSUED: Y (CIRCLE ONE)
DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMacist / NURSE FOR EVALUATION ON: 
ADVERSE EVENT FORWARDED TO PHARMacist / NURSE FOR EVALUATION BY: EDET FRACKIEWICZ 07/01/13

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N 
ADVERSE EVENT REPORTED ON: 07/01/13 BY: EDET FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 
BY: 

DATE: 07-10-13

DSS JUL 26 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 of 4 units, has been distributed.

Review of Records:

The BTET lot #114465 was manufactured using lot # (4). The associated manufacturing and packaging records were reviewed and did not reveal any issues.

Atropine and Scopolamine testing was conducted on the final container product BTET # 114465, and it was within specification, with results of ppm.

The final product lot #114465 was submitted for microbiological testing 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 coli, 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 4 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.
AE #: 1430
COMPLAINT #: 2421

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 
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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ 
DATE: ___________________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ 
DATE: 07-11-13 
DSS JUL 26 2013

DATE: 07-10-13

BY: ___________________________ 
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE 

CaseID: 9424540
A. PATIENT INFORMATION
1. Patient Identification
   (b)(6)
2. Age at time of Event or Date of Birth:
   (b)(6)
   1.5 Months
   3. Sex
   □ Female
   □ Male
   4. Weight
   [in kg]
   5. Height
   [in cm]

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. [x] 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: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ 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)
   04/24/2013
4. Date of this Report (mm/dd/yyyy)
   06/14/2013
5. Describe Event, Problem or Product Use Error
   My son born [Date] was taking Hyland's teething tablets since he was a month in a half old. So since
   [Date], He was hospitalized numerous times for Unknown reasons of high fever, constipation, agitation, respiratory problems, skin
   problems, emergency sinus 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.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, kidney problems, etc.)
   Race: White
   Medical Conditions: Allergies: Important
   Information: RX Meds: OTC Meds: gummy vitamins

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's teething tablets
   Strength:
   Manufacturer: Hyland's
   2. [ ] Name:
   Strength:
   Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name
   CTU
   AUG 1 5 2013
2. Common Device Name
   AUG 1 5 2013
3. Manufacturer Name, City and State

4. Model #
   Lot #
   5. Operator of Device
      □ Health Professional
      □ Lay User/Patient
      □ Other:
      Catalog #
      Expiration Date (mm/dd/yyyy)
      Serial #
      Other #
   6. If Implanted, Give Date (mm/dd/yyyy)
   7. If Explanted, Give Date (mm/dd/yyyy)

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
   (b)(6)
   PHONE #:
   E-mail (b)(6)
   2. Health Professional?  3. Occupation
      □ Yes  □ No  4. Also Reported to:
      □ Manufacturer
      □ User Facility
      □ Distributor/Importer
   5. If you do NOT want your identity disclosed to the manufacturer: place an "X" in this box: □
For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier (b) (9)

2. Age at Time of Event:
   - 0 Months

3. Sex
   - Female
   - Male

4. Weight
   - lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   - Death
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Other Serious (Important Medical Events)
   - Required Intervention to Prevent Permanent Impairment/Damage

3. Date of Event (mm/dd/yyyy)
   - 04/06/2010 TO PRESENT

4. Date of This Report (mm/dd/yyyy)
   - 08/01/2013

5. Describe Event or Problem

   SPRING OF 2010 CHILD BEGAN EXPERIENCING NON-CONVULSANT SEIZURES WITH SYMPTOMS OF BLUE LIPS, FINGERS, AND TOES, EYES BLANK AND DIABETIC, MOUTH HANG OPEN AND DROOLING, SHALLOW BREATHING. SEIZURES OCCURRED EVERY OTHER WEEK UNTIL HE WAS 15 MONTHS OF AGE AND THEN STOPPED AND WERE FOLLOWED BY SEVERAL FARGER SEIZURE EPISODES. CHILD HAS DIFFICULTY REACHING MILESTONES AND IS DIAGNOSED WITH AUTISM DISORDER.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mf/labeler)
   - HYLAND'S TEETHING TABS

2. Dose, Frequency & Route Used
   - mg/kg

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

4. Diagnosis for Use (indication)
   - #1 TEMP RELIEF TEETHING PAIN

5. Event Abated After Use
   - #1 Yes

6. Lot #
   - #1

7. Exp. Date
   - #1

8. Event Appeared After Reintroduction?
   - #1 Yes

9. NDC# or Unique ID
   - 54973-7504-1

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

D. SUSPECT MEDICAL DEVICE

4. Model #

5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other

6. Catalog #

7. Expiration Date (mm/dd/yyyy)

8. If Implanted, Give Date (mm/dd/yyyy)

9. If Explanted, Give Date (mm/dd/yyyy)

10. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
    - Yes
    - No

11. If Yes to Item No. 8, Enter Name and Address of Reprocessor

12. Device Available for Evaluation? (Do not send to FDA)
    - Yes
    - No

13. Returned to Manufacturer on
    - (mm/dd/yyyy)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   - Yes
   - No

3. Occupation
   - #1

4. Initial Reporter Also Sent Report to FDA
   - Yes
   - No

DSS

AUG 19 2013
**F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)**

1. Check One
   - [ ] User Facility
   - [ ] Importer

2. OI/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
   - [ ] Initial
   - [ ] Follow-up

7. Type of Report
   - [ ] Initial
   - [ ] Follow-up

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
    - Patient
    - Code
    - Device

11. Report Sent to FDA?
    - [ ] Yes
    - [ ] No

12. Location Where Event Occurred
    - [ ] Hospital
    - [ ] Outpatient Diagnostic Facility
    - [ ] Outpatient Treatment Facility
    - [ ] Other

13. Report Sent to Manufacturer?
    - [ ] Yes
    - [ ] No

14. Manufacturer Name/Address

**G. ALL MANUFACTURERS**

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   - EDITA FRACKELTON
   - HYLAND'S, INC.
   - 154 N. 131ST STREET
   - LOS ANGELES, CA 90061

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

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 07/25/2003

5. (ANDA #)

6. IND #

7. STN #

8. PMA/510(k) #

9. Type of Report (Check all that apply)
   - [ ] 6-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
   - [ ] Initial
   - [ ] Pre-1938
   - [ ] OTC Product

10. Manufacturer Report Number
    - 54973 AR #1484

11. Adverse Event Term(s)
    - NON-COVID-19 SEIZURES

**H. DEVICE MANUFACTURERS ONLY**

1. Type of Reportable Event
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Disfigurement
   - [ ] Other

2. If Follow-up, What Type?
   - [ ] Correction
   - [ ] Additional Information
   - [ ] Response to FDA Request
   - [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
   - [ ] Yes
   - [ ] No (Attach page to explain why not) or provide code

4. Device/Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - [ ] Yes
   - [ ] No

6. Evaluation Codes (Refer to coding manual)
   - Method
   - Results
   - Conclusions

7. If Remedial Action Initiated, Check Type
   - [ ] Recall
   - [ ] Notification
   - [ ] Repair
   - [ ] Inspections
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modifications/Adjustment
   - [ ] Other

8. Initial Use of Device
   - [ ] Initial Use of Device
   - [ ] Reuse
   - [ ] Unknown

9. If action reported to FDA under 21 USC 369(f), list correction/ removal reporting number:

**G. ALL MANUFACTURERS**

10. Additional Manufacturer Narrative
    - and/or

11. Corrected Data

**DSS**

AUG 16 2013

AUG 19 2013

The public reporting burden for this collection of information has been estimated to average 86 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 the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer
1350 Piccard Drive, Room 409
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

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: TEETHING TABLETS

SIZE: 125 TABLETS

REPORTER: [Redacted]

ADDRESS: [Redacted]

CITY: [Redacted]

COUNTRY: USA

PHONE #: [Redacted]

E-MAIL: [Redacted]

COMPLAINT #: 2590

DATE OF COMPLAINT: 07/25/13

ITEM CODE: TEET---1125

LOT NO.: NOT AVAILABLE

NATURE OF COMPLAINT:

SPRING OF 2010 CHILD BEGAN EXPERIENCING NON-CONVULSANT SEIZURES WITH SYMPTOMS OF BLUES IN EYES, FINGERS, AND TOES, EYES BLANK AND OILATED, MOUTH HUNG OPEN AND DROOLING, SHALLOW BREATHING. SEIZURES OCCURRED EVERY OTHER WEEK UNTIL HE WAS 15 MONTHS OF AGE AND THEN STOPPED AND WERE FOLLOWED BY SEVERAL LONGER SEIZURE EPISODES. CHILD HAS DIFFICULTY REACHING MILESTONES AND IS DIAGNOSED WITH AUTISM DISORDER. CHILD WAS BORN FULL TERM FROM UNCOMPLICATED VAGINAL DELIVERY. CHILD RECEIVED TREATMENT AT THE NEUROLOGY CLINIC AT [HOSPITAL NAME] AND WAS FOCUSED ON A DOTS TREATMENT. CHILD HAS HAD AN EEG, EKG, AND MRI. CHILD HAS ALSO UNDERGONE DEVELOPMENTAL TESTING BECAUSE OF DIFFICULTY REACHING MILESTONES. CHILD CAN SEE, CAN HEAR, CAN TALK, CAN WALK, BUT HAS PROBLEMS WITH APPLYING LEARNING TO REAL LIFE SITUATIONS. CHILD WENT TO LOCAL MEDICAL CENTER, RESULTS OF EKG, EEG, AND MRI WERE NORMAL. THERE WAS NO PRENATAL EXPOSURE TO CIGARETTES, ALCOHOL, OR TOXIC SUBSTANCES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION [Y] [N] (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION [Y] [N] (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED: [Y] [N] (CIRCLE ONE)

DATE PRODUCT RECEIVED: [Y] [N] (CIRCLE ONE)

RECEIVED AUG 16 2013

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

SECTION III: CORRECTIVE ACTION

Individual Case Safety Report

9471241-01-00-03

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: [REDACTED]

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: [Y] [N]

ADVERSE EVENT REPORTED ON: 07/25/13

BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

BY: [REDACTED] QA/QC DIRECTOR

DATE: 08-05-13

cc: QA/QC Packaging, Production, Shipping/Receiving

DSS AUG 19 2013

DATE: 08-06-13
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.

Date

08/02/13

Prepared by

Individual Case Safety Report

9471241-01-00-04
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1484  COMPLAINT #: 2490

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: [Redacted]
ADDRESS: ________________________________
CITY: ________________________________ STATE: ________________________________
COUNTRY: USA ZIP CODE: ________________________________
PHONE #: ________________________________ E-MAIL: ________________________________

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

AFFIX COPY OF OUTER CARTON HERE

SECTION III: CORRECTIVE ACTION:

________________________________________________________________________

CORRECTIVE ACTION(S) COMPLETED BY: ________________________________ DATE: ____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ________________________________ DATE: 08-06-13

BY: QA / QC DIRECTOR DATE: 08-05-13

DSS AUG 16 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM 8AED
### A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at time of Event or Date of Birth</th>
<th>3. Sex</th>
<th>4. Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)(6)</td>
<td>8 Months</td>
<td>Female</td>
<td>16 lb</td>
</tr>
</tbody>
</table>

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

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**
   - Death: [ ]
   - Disability or Permanent Damage [ ]
   - 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**
   - 06/18/2013

4. **Date of this Report**
   - 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, but I started giving them to her. In (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 heard from a friend that there was a recall.

### C. PRODUCT AVAILABILITY

<table>
<thead>
<tr>
<th>1. Product Available for Evaluation?</th>
<th>(Do not send product to FDA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ]</td>
<td>No [ ]</td>
</tr>
</tbody>
</table>

### D. SUSPECT PRODUCT(S)

<table>
<thead>
<tr>
<th>1. Name, Strength, Manufacturer (from product label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Name: hyland teething tablet Strength: Manufacturer:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Name, Strength, Manufacturer (from product label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#2 Name:</td>
</tr>
<tr>
<td>Strength:</td>
</tr>
<tr>
<td>Manufacturer:</td>
</tr>
</tbody>
</table>

### E. SUSPECT MEDICAL DEVICE

<table>
<thead>
<tr>
<th>1. Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Common Device Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUG 27 2013</td>
</tr>
</tbody>
</table>

| 3. Manufacturer Name, City and State |

<table>
<thead>
<tr>
<th>4. Model #</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5. Operator of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Professional [ ]</td>
</tr>
<tr>
<td>Lay User/Patient [ ]</td>
</tr>
<tr>
<td>Other: [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. If Implanted, Give Date (mm/dd/yyyy)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>7. If Explanted, Give Date (mm/dd/yyyy)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>8. Is this a single-use device that was Reprocessed and Reused on a Patient?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ] No [ ]</td>
</tr>
</tbody>
</table>

| 9. If yes to Item 8, Enter Name and Address of Reprocessor |

### F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

| Product names and therapy dates (exclude treatment of event) |

### G. REPORTER

<table>
<thead>
<tr>
<th>1. Name and Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: [ ] Address: [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Health Professional?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ] No [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Occupation</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>4. Also Reported to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer [ ]</td>
</tr>
<tr>
<td>User Facility [ ]</td>
</tr>
<tr>
<td>Distributor/Importer [ ]</td>
</tr>
</tbody>
</table>

**DSS AUG 27 2013**

**CaseID: 9486434**

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
RECEIVED

SEP 26 2012

CDR

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD AND URINE TESTS. BLOOD TEST RESULTS NORMAL; URINE TEST RESULTS PENDING.

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

HISTORY OF A MILD SEIZURE 1 MONTH AGO (SHAKING AND JERKING LASTING ONE MINUTE)

AT HOSPITAL, CHILD GIVEN TYLENOL FOR THE RESIDUAL MUSCLE PAIN AND STIFFNESS.

IMMUNIZATION SHOTS RECEIVED ON AUGUST 20TH.

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: 9570361**

---

### H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Death</td>
</tr>
<tr>
<td>□ Serious Injury</td>
</tr>
<tr>
<td>□ Misfunction</td>
</tr>
<tr>
<td>□ Other</td>
</tr>
<tr>
<td>2. If Follow-up, What Type?</td>
</tr>
<tr>
<td>□ Correction</td>
</tr>
<tr>
<td>□ Additional Information</td>
</tr>
<tr>
<td>□ Response to FDA Request</td>
</tr>
<tr>
<td>□ Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Not Returned to Manufacturer</td>
</tr>
<tr>
<td>□ Yes</td>
</tr>
<tr>
<td>□ Evaluation Summary Attached</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5. Labelled for Single Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Evaluation Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Recall</td>
</tr>
<tr>
<td>□ Notification</td>
</tr>
<tr>
<td>□ Repair</td>
</tr>
<tr>
<td>□ Inspection</td>
</tr>
<tr>
<td>□ Replace</td>
</tr>
<tr>
<td>□ Patient Monitoring</td>
</tr>
<tr>
<td>□ Relabeling</td>
</tr>
<tr>
<td>□ Modification/Adjustment</td>
</tr>
<tr>
<td>□ Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Initial Use of Device</td>
</tr>
<tr>
<td>□ Reuse</td>
</tr>
<tr>
<td>□ Unknown</td>
</tr>
</tbody>
</table>

| 9. If action reported to FDA under 21 USC 381(f), list correction/ removal/reporting number: |

<table>
<thead>
<tr>
<th>10. Additional Manufacturer Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>and/or</td>
</tr>
</tbody>
</table>

| 11. Corrected Data |

---

### G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   - TUTTI GOULD
   - HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061

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:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 09/08/2013

5. (AMDA #
   - IND #
   - STN #
   - PMN/510(k) #

6. Type of Report (Check all that apply)
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
   - [ ] Initial
   - [ ] 15-day

7. Manufacturer Report Number
   - 54973 AE # 1506

8. Adverse Event Term(s)
   - SEIZURE

---

**The public reporting burden for this collection of information has been estimated to average 65 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
1203 Piccard Drive, Room 403
Rockville, MD 20850

Please DO NOT RETURN this form to this address.
CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

COMPLAINT #: 2515

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 09/08/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET--T49

SIZE: 40 TABLETS

LOT NO.: A40313

A70913

REPORTER: (b)(6)

ADDRESS: 

CITY: 

STATE: (b)(6)

COUNTRY: USA

PHONE #: (b)(6)

ZIP CODE: 

E-MAIL: 

MOTHER SAID SHE CALLED YESTERDAY TO INQUIRE ABOUT THE TEETHING TABLETS. SHE WAS IN THE HOSPITAL FOR 8 HOURS WITH HER DAUGHTER FOR A SEIZURE THAT LASTED 6 MINUTES. STARTING AT 7 AM, HER DAUGHTER WOKE UP SCREAMING, SHE TOOK HER 1 TABLET OF BABY TEETHING TABLETS, THEN SHE FELL ASLEEP. 20 MINUTES LATER WHEN SHE WOKE UP SCREAMING, SHE PICKED HER UP AND SHE HAD A SEIZURE. HER EYES ROLLED BACK INTO HER HEAD SHE WAS STIFF AND BARELY BREATHING. CHILD COULD NOT MOVE HER ARMS OR LEGS AFTER THE SEIZURE, BUT REGAINED HER LEG MOVEMENT BY THE TIME THEY REACHED THE HOSPITAL, AND 1 1/2 HOURS LATER HER ARMS MOVEMENT RETURNED. SHE HAS BEEN GIVING HER DAUGHTER BABY TEETHING TABLETS FOR THE PAST 2 MONTHS AS NEEDED. MOTHER SAID SHE HAD ALSO BEEN GIVING TYLENOL. THE DOCTORS SAYS "THEY DON'T KNOW WHAT IT IS." MOTHER MENTIONED THAT A MONTH AGO, HER DAUGHTER HAD A BRIEF EPISODE OF JERKING AND SHAKING LASTING ONE MINUTE. AUGUST 22, 19 DAYS AGO SHE RECEIVED HER IMMUNIZATION "SHOTS." BLOOD AND URINE TESTS CONDUCTED ON 09/08/13. BLOOD TESTS NORMAL, URINE TEST RESULTS PENDING.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y  N

INDIVIDUAL CASE SAFETY REPORT

PRODUCT BEING RETURNED FOR INSPECTION: Y  N

DATE REQUESTED PRODUCT BE RETURNED: 

UPS CALL TAG ISSUED: Y  N

DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: SEP 27 2013

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y  N

ADVERSE EVENT REPORTED ON: 09/08/13

BY: TUTTI GOULD

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 09-17-13

DATE: 09-16-13

CC: QA/QC Packaging Production Shipping/Receiving Form # VD1
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, 6(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, 6(4) 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 ≤0.1 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 within established procedures to ensure product quality.
A. PATIENT INFORMATION
1. Patient Identifier: [Identification number]
2. Age at Time of Event: 7 Months
   - Sex: Male
   - Weight: 15 lbs
   - Date of Birth: [Date]

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event or Product Problem:
   - Outcomes Attributed to Adverse Event:
     - Death
     - Hospitalization
     - Other Serious

2. Date of Event (mm/dd/yyyy): 09/00/2013
3. Date of This Report (mm/dd/yyyy): 09/05/2013
4. Describe Event or Problem:
   - CHILD SUFFERED MILD SEIZURES LAST WEEK AFTER TAKING BABY TEETHING TABLETS. HAD 5 MINI SEIZURES IN 10 MINUTES.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & mfg/labeler):
   - MYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used:
   - #1 UNKNOWN DOSAGE
   - #2
3. Therapy Dates (if unknown, give duration):
   - #1
   - #2
4. Diagnosis for Use (Indication):
   - #1 TEMP RELIEF TEETHING PAIN
5. Event Altered After Use:
   - Stopped or Dose Reduced?
     - #1 Yes
     - #2
6. Lot #:
   - #1
   - #2
7. Exp. Date:
   - #1
   - #2
8. Event Reappeared After Reintroduction?
   - #1 Yes
   - #2
9. NDC or Unique ID:
   - 54973-3127-1
10. Concomitant Medical Products and Therapy Dates:

D. SUSPECT MEDICAL DEVICE
1. Brand Name:
2. Common Device Name:
3. Manufacturer Name, City and State:
4. Model #: [Model number]
   - Lot #: [Lot number]
5. Operator of Device:
   - #1 Health Professional
   - #2 Lay User/Patient
   - #3 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?
   - #1 Yes
   - #2 No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor:
   - [Reprocessor's name and address]
10. Device Available for Evaluation? (Do not send to FDA):
   - #1 Yes
   - #2 No
11. Concomitant Medical Products and Therapy Dates:

E. INITIAL REPORTER
1. Name and Address:
2. Phone #:
3. Occupation:
4. Initial Reporter Also Sent Report to FDA:
   - #1 Yes
   - #2 No
   - #3 Unknown

USA SEP 26 2013

DSS SEP 27 2013

RECEIVED SEP 26 2012

CDR
CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

COMPLAINT #: 2514
TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 09/04/13
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET
SIZE: NOT PROVIDED
LOT NO.: NOT PROVIDED
REPORTER:

ADDRESS:

CITY:
STATE: (6)
COUNTRY: USA
ZIP CODE:
PHONE #:
E-MAIL:

NATURE OF COMPLAINT: PER INTERNET POST: 7 MONTH GRANDSON SUFFERED MILD SEIZURES PAST WEEK AFTER TAKING TABLETS. HAD 5 MINI ONES IN 10 MINUTES. NO CONTACT INFORMATION PROVIDED FOR THIS CUSTOMER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED:
UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
09/04/13
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:
EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 09/04/13
BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWS BY MANAGEMENT BY: DSS
DATE: SEP 27 2013

BY: REGNAR D. WATT
QA / QC DIRECTOR
DATE: 09-19-13

DATE: 09-17-13

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

Date 9/10/13

DSS
SEP 27, 2013

SEP 26, 2013

AE # 1505
Complaint # 2514
CC-0656-2013
AE-0344-2013
SAE-0040-2013
AE #: 1505

COMPLAINT #: 2514

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (Redacted)

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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 

SECTION IV:

REVIEWED BY MANAGEMENT BY: 

DATE: 09-19-13

BY: 

DATE: 09-17-13

Distribution: FDA Adverse Event File

FORM SAEH

CaseID: 9570446

Hyland's
A. PATIENT INFORMATION
1. Patient Identifier
   (b)(6)
2. Age at Time of Event: 31 Years
3. Sex
   □ Female
   □ Male
4. Weight
   lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. □ Adverse Event  □ Product Problem (e.g. defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ 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) 05/19/2013
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 SWOLLEN. 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.

C. SUSPECT PRODUCT(S)
1. Name (Give actual strength & milliliter)
   HYLAND'S TEETHING GEL
   #1

2. Dose, Frequency & Route Used
   □ ONE APPLICATION TO GUMS
   #1
   #2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
   #1
   #2

4. Diagnosis for Use (Indication)
   TEMP RELIEF TEETHING PAIN
   #1
   #2

5. Event Aborted After Use
   Stopped or Dose Reduced?
   □ Yes
   □ No
   □ Doesn't Apply
   #1
   #2

6. Lot #
   #1
   #2

7. Exp. Date
   #1
   #2

8. NDC# or Unique ID
   54973-1521-2

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

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City, and State

4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:

6. Catalog #
7. Expiration Date (mm/dd/yyyy)

8. If Implanted, Give Date (mm/dd/yyyy)
9. If Explanted, Give Date (mm/dd/yyyy)

10. Device Available for Evaluation? (Do not send to FDA)
    □ Yes
    □ No
    □ Returned to Manufacturer on:

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

E. INITIAL REPORTER
1. Name and Address
   Phone # (b)(6)

2. Health Professional? □ Yes □ No
3. Occupation
   NA
4. Initial Reporter Also Sent Report to FDA
   □ 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.
**Individual Case Safety Report**

1. **Check One**
   - [ ] User Facility
   - [ ] Importer

2. **UDI/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

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

7. **Type of Report**
   - [ ] Initial
   - [ ] Follow-up #

8. **Date of This Report (mm/dd/yyyy)**

9. **Approximate Age of Device**

10. **Event Problem Codes (Refer to coding manual)**
    - [ ] Patient Code
    - [ ] Device Code

11. **Report Sent to FDA?**
    - [ ] Yes
    - [ ] No

12. **Location Where Event Occurred**
    - [ ] Hospital
    - [ ] Outpatient Diagnostic Facility
    - [ ] Home
    - [ ] Ambulatory Surgical Facility
    - [ ] Nursing Home
    - [ ] Outpatient Treatment Facility
    - [ ] Other:

13. **Report Sent to Manufacturer?**
    - [ ] Yes
    - [ ] No

14. **Manufacturer Name/Address**

---

**G. ALL MANUFACTURERS**

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

   EDYTA FRACKIESWICZ
   HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

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

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

   09/23/2013

5. **STN #**

6. **If IND, Give Protocol #**

7. **Type of Report (Check all that apply)**
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
   - [ ] Initial
   - [ ] 15-day
   - [ ] Follow-up

8. **Manufacturer Report Number**

   54973 AE # 1510

9. **Adverse Event Term(s)**

   ALLERGIC REACTION

---

**H. DEVICE MANUFACTURERS ONLY**

1. **Type of Reportable Event**
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction
   - [ ] Other:

2. **If Follow-up, What Type?**
   - [ ] Correction
   - [ ] Additional Information
   - [ ] Response to FDA Request
   - [ ] Device Evaluation

3. **Device Evaluated by Manufacturer?**
   - [ ] Not Returned to Manufacturer
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code:

4. **Device Manufacture Date (mm/dd/yyyy)**

5. **Labeled for Single Use?**
   - [ ] Yes
   - [ ] No

6. **Evaluation Codes (Refer to coding manual)**

   Method
   Results
   Conclusions

7. **If Remedial Action Initiated, Check Type**
   - [ ] 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 380(f), list correction/removal reporting number:**

10. **Additional Manufacturer Narrative**
    and/or

11. **Corrected Data**

**DSS**

**OCT 1 1 2013**

**OCT 1 0 2013**

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The public reporting burden for this collection of information has been estimated to average 86 minutes per responses, 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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Individual Case Safety Report

PLAINT RECORD

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: HYLAND'S TEETHING GEL

SIZE: 0.5 OZ.

REPORTER: (b) (6)

ADDRESS: 

CITY: 

COUNTRY: USA

PHONE #: (b) (6)

E-MAIL: 

COMPLAINT #: 2519

DATE OF COMPLAINT: 09/20/13

ITEM CODE: TGEI--U0.5Z

LOT NO.: 119022

NATURE OF COMPLAINT: MOTHER APPLIED TEETHING GEL TO HER OWN GUMS TO SEE WHAT WOULD HAPPEN. SHE GOT HIVES, ITCHING ALL OVER BODY, AND HER THROAT SWELLED. HAS ONLY HAD THIS TYPE OF REACTION WITH MANGOES BECAUSE SHE IS ALLERGIC TO THEM. 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 HAD TAKEN BENADRYL SO THEY TOOK A "WAIT AND SEE" APPROACH IN THE ER. SHE WAS RELEASED FROM ER AND NOT ADMITTED. DIAGNOSED IN ER AS "ALLERGIC REACTION."

FOR ADDITIONAL SPACE PLEASE USE 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: 

UPS CALL TAG ISSUED: Y [CIRCLE ONE]

DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/23/13

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

ADVERSE EVENT SERIOUS: Y [CIRCLE ONE]

ADVERSE EVENT REPORTED ON: 09/23/13

BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 

DATE: 10-01-13

DATE: 10-01-13

cc: QA / QC

Production

QA / QC DIRECTOR

Form # VD1
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, 80,000 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 240 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.

Prepared by

Date

10/11/13

Individual Case Safety Report

DSS

OCT 1 1 2013

9622302-01-00-04
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1510
COMPLAINT #: 2519

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (Redacted)
ADDRESS: (Redacted)
CITY: (Redacted)
COUNTRY: USA
PHONE #: (Redacted)
E-MAIL: (Redacted)

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE
AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

DSS
OCT-11-2013

CORRECTIVE ACTION(S) COMPLETED BY: ________________________ DATE: ____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: __________________________ DATE: ____________

BY: ___________________________ DATE: ____________

DISTRIBUTION: FDA ADVERSE EVENT FILE
FORM SAE01
An approximately 30 minutes after the child was administered Baby Orajel™, he became "white as a ghost" with blue fingernails and lips. He was admitted to the hospital and diagnosed with methemoglobinemia.
Baby Orajel® oral pain reliever for teething labels are attached.

Hospital Report is attached.

This report was escalated through litigation without first coming through consumer relations, therefore, the event was not reported within the required 15 day period for serious adverse events of this nature. This gap has since been closed with a procedure to review SAERS that come in through litigation in consumer relations and ensure that reports are forwarded to FDA within the required 15 days after date of awareness.

This report and the information submitted under this report do not constitute an admission that the drug or Church & Dwight Co., Inc. or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight actually occurred.

The public reporting burden for this collection of information has been estimated to average 86 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 (HFA-710)
5610 Fishers Lane
Rockville, MD 20857

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."
No print area

Cap

1/32" Quiet Area

Print Height 2-5/8

Tube Length 3-3/8

Any ink deck location can change provided the color order is maintained

DSS

OCT 15 2013

OCT 11 2013
### Admission Information - Hospital Account/Patient Record

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<th>None</th>
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<td>Admit Date/Time:</td>
<td>(b) (6) 5:26</td>
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<tr>
<td>IP Adm. Date/Time:</td>
<td>(b) (6) 5:26</td>
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<tr>
<td>Admission Type:</td>
<td>Urgent</td>
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<td>Admission Source:</td>
<td>Transfer From A Hospital (Different Facility)</td>
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<td>Secondary Service:</td>
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<td>Transfer Source:</td>
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### Final Diagnoses

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<th>CC</th>
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<th>Affects</th>
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<tr>
<td>289.7</td>
<td>METHEMOGLOBINEMIA</td>
<td>Yes</td>
<td>CC</td>
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<td>518.81</td>
<td>ACUTE RESPIRATORY FAILURE</td>
<td>Yes</td>
<td>MCC</td>
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<td>802.36</td>
<td>OPEN FRACTURE OF SYMPHYSIS OF BODY OF MANDIBLE</td>
<td>Yes</td>
<td>CC</td>
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<td>No</td>
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### Discharge Information - Hospital Account/Patient Record

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<td>Home Patient Family Member Other</td>
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<td>Discharge Destination:</td>
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<td>Discharge Provider:</td>
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<td>Unit:</td>
<td>(b) (6)</td>
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### Events

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<th>Event</th>
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<th>Room/Bed</th>
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<td>PED INTENSIVE CARE</td>
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<td>E.N.T.</td>
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<td>PED INTENSIVE CARE</td>
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<td>Transfer In</td>
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<td></td>
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<td>PED INTENSIVE CARE</td>
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<td>PED INTENSIVE CARE</td>
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<td>Inpatient</td>
<td></td>
<td></td>
<td>PED INTENSIVE CARE</td>
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<td></td>
<td></td>
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<td>Inpatient</td>
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<td>Pediatrics</td>
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</table>

### Allergies as of

| Date Reviewed: | |

Printed on 9/12/2011 9:50 AM
H&P Summary Notes (continued)

HPI:

(b)(6) 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 where his jaw was wired shut. He was discharged home 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 to the hospital because he was blue. Aside from being blue, was able to walk, talk, and scream.

Upon arrival to 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

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 20 mEq infusion
vancomycin 5 mg/mL in D5W IV PEDS
DILUTION 100 mg
piperacillin/tazobactam 100 mg/mL (of piperacillin) in D5W injection: 800 mg
heparin 1 Unit/mL in NS 60 mL premix PEDS line flush
fentanyl (SUBLIMAZE) 50 mcg/mL injection
fentanyl (SUBLIMAZE) 50 mcg/mL PEDS

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<td>acetaminophen</td>
<td>60 mg</td>
<td>Rectal</td>
<td>Q4H PRN</td>
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<tr>
<td>vancomycin</td>
<td>10 mg/kg</td>
<td>Intravenous</td>
<td>Q6H</td>
</tr>
<tr>
<td>piperacillin</td>
<td>240 mg/kg/ day</td>
<td>Intravenous</td>
<td>Q8H</td>
</tr>
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</table>
| fentanyl            | 1 mcg/kg  | Intravenous | Continuous |}

Printed on 9/12/2011 9:50 AM
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. was present for the entire case.

Resident Department of Otolaryngology

Electronically signed by MD at 1904

Discharge Summary Notes

Discharge Summary

PATIENT NAME: 
MRN: 
DOB: 

ADMISSION DATE: 
DISCHARGE DATE: 
ATTENDING PHYSICIAN: 
PRIMARY CARE PHYSICIAN: 

ADMISSION DIAGNOSIS: Methemoglobinemia
DISCHARGE DIAGNOSIS: Methemoglobinemia
Hospital Problems
Methemoglobinemia
Date Noted:

Respiratory failure
Date Noted:

Resolved Hospital Problems
No resolved problems to display.

Printed on 9/12/2011 9:50 AM
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

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

cloxacillin (CLOXIN) 75 mg/5 mL SolR
   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

DISCHARGE INSTRUCTIONS:
No discharge procedures on file.

REASON FOR HOSPITALIZATION AND HOSPITAL COURSE: This is a 2 y.o., male with history of recent mandible fracture after fall from 10ft retaining wall on (b)(6) who presented to (b)(6) Hospital with respiratory failure. He underwent maxillomandibular fixation on (b)(6) where his jaw was wired shut. He was discharged home on (b)(6) on clindamycin, tylanol #3, and motrin.

OCT 15 2013
Discharge Summary Notes (continued)

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 (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) to the hospital because he was blue. Aside from being blue, (b)(6) was able to walk, talk, and scream.

Upon arrival to (b)(6), (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, (b)(6) 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 7.38/38/153/99. 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:
(b)(6)

cc: Referring Physician:
(b)(6)

MD

Electronically signed by MD at 1015

Printed on 9/12/2011 9:50 AM
Patient Education (continued)

Title: Patient Information Guide (Resolved) (continued)

Point: Speak Up Handout (Resolved)

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<th>Learning Progress Summary</th>
<th>Comment</th>
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<th>Status</th>
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<tbody>
<tr>
<td>Family</td>
<td>Acceptance</td>
<td>E</td>
<td>VU</td>
<td>Mom at bedside for rounds. See IPOC for plan of care. MOm stated understanding and denies any additional questions at this time.</td>
<td>1224</td>
<td>Done</td>
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User Key

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Ancillary Notes

Ancillary Notes signed by MD at 1358

Author: MD
Service: Emergency
Author Type: Resident
Filed: 1358
Note Time: 1346
Cosign Required: Yes

Code Status: Full

No Known Allergies

Filed Vitals:

<p>| | | | | |</p>
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<td>36.4 °C (97.5 °F)</td>
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<td>SpO2</td>
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<td>98%</td>
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HPI and Hospital Course:

In brief, patient is a 2 y.o. male who presented to an outside facility with increase in duskeness 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 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

Printed on 9/12/2011 6:50 AM
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 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 dusksiness
Neurologically intact and appropriate

Pertinent Imaging/Lab results:
Methemoglobin 0.0

Pending Studies:
none

Consults:
ENT

Plan:
Resp: monitor. No need for continued ABG. Do not give oralgel.
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.
Individual Case Safety Report

The FDA Safety Information and
Adverse Event Reporting Program

Page 1 of 2

A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event or Date of Birth: 13. Sex 4. Weight
4 Months (b) (6) □ Female 15 lb
In confidentiality
□ Male or
kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
2. Outcomes Attributed to Adverse Event
□ Death: (mm/dd/yyyy) □ Disability or Permanent Damage
□ Life-threatening □ Congenital Anomaly/Birth Defect
□ Hospitalization - initial or prolonged □ Other Serious (Important Medical Events)
□ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
□ Yes □ No □ Returned to Manufacturer:
(mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
#1 Name: Hyland's Teething Tablets
Strength:
Manufacturer:

Please type or use black ink.

PLEASE TYPE OR USE BLACK INK

5. Describe Event, Problem or Product Use Error
when my son was four months old, I began giving him
Hyland's Teething Tablets. I gave him the recommended
dose. As time progressed I noticed he would never put
things in this mouth to teeth, didn't like spoons in
his mouth and wasn't really babbling like most infants
his age. I did continue giving him the Hylands
Teething Tablets all the way through his 1-2 years. At
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
avoidance, not saying ...

CUT

Please type or use black ink.

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
□ Health Professional
□ Lay User/Patient
□ Other:
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
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, Enter Name and Address of Reprocessor

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 (b) (6)
2. Phone # (b) (6)
3. E-mail
(b) (6)

4. Also Reported to:
□ Consumer □ Manufacturer
□ User Facility □ Distributor/Importer
5. If you DO NOT want your identity disclosed to the manufacturer, place an "X" in this box:

DSS
OCT 16 2013

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.
B.5. Describe Event or Problem (continued)
... 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 occurring 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 neurologic issues, but his inability to speak.

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/hemal 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)
A. PATIENT INFORMATION

1. Patient Identifier
   (b)(6)

2. Age at Time of Event:
   8 Months
   or
   Date of Birth:

3. Sex
   Female
   or
   Male

4. Weight
   lbs
   or
   7.6 lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event
   and/or
   ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   ☑ Death: (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)
   08/06/2012

4. Date of This Report: (mm/dd/yyyy)
   10/29/2013

5. Describe Event or Problem
   The patient experienced a desaturation event to the high 80s after his mother gave Orajel 15-20 times throughout the day. The methy hemoglobin level was elevated at >20% leading to the diagnosis of methemoglobinemia.

6. Relevant Test/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, nephrotoxic dysfunction, etc.)
   Event occurred FOB(2) after exploratory laparotomy and manual reduction of iliacolic intussusception.

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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mf) of
   Orajel Instant Relief for Teething Pain

2. (continued) 7.5% benzocaine

3. Therapy Dates (if unknown, give duration)
   #1 unk, 15-20 times, oral
   #2 unk, 15-20 times, oral
   #3 unk, 15-20 times, oral

4. Diagnosis for Use (Indication)
   #1 unk, 15-20 times, oral
   #2 unk, 15-20 times, oral

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   ☑ Health Professional
   ☑ Lay User/Patient
   ☑ 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, 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)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   ☑ Yes
   ☑ No

3. Occupation
   ☑ M.D.
   ☑ Pharmacist

4. Initial Reporter Also Sent Report to PDA
   ☑ Yes
   ☑ No
   ☑ Unk.

CDR Oct 3 02013

DSS OCT 3 1 2013

OCT 3 0 2013
The pertinent pages of the hospital report are attached. (pages 3, 4)

This report and information submitted under this report do not constitute an admission that the drug or Church & Dwight Co., Inc., or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight Co., Inc actually occurred.

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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, Room 400, 1350 Piccard Drive, Rockville, MD 20850.

Please DO NOT return this form to this address.
PICU Consultation Note


Admitting Service: General Surgery
Admitting Attending: [Redacted]
Date of Admission: [Redacted]
Date of Consultation: [Redacted]
Place of Consultation: [Redacted]
Requesting Service: Peds Hospitalist
Requesting Physician: Dr. [Redacted]
Reason for Consultation: Hypoxia/methemoglobinemia

Identification / Chief Complaint: 8 month old with intussusception s/p open reduction without resection

History of Present Illness:

[Redacted] is an 8 month old male from exploratory laparotomy and manual reduction of ileocolic intussusception. He has had an uncomplicated recovery until the afternoon of [Redacted] 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 oximeter probe was changed and his monitors were also changed but his hypoxia persisted with sats in low 90’s. 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 benzocaine toxicity leading to methemoglobinemia, a methh level was checked and was elevated at >20%.

I was called to consult on this patient given the diagnosis of methemoglobinemia, persistent 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  Report Request ID: [Redacted]
Inpatient Consultation

Other: 
[ ] 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 ileoceleal 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

DEVELOPMENT: 

HOME MEDICATIONS:
No Home Medication/Prescription Orders

ACTIVE MEDICATION ORDERS (as of 04:04):
Scheduled
acetaminophen 76 mg IV q4hr
PRN
acetaminophen 115 mg rectal q8hrPRN(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(cathelet 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.

MEASUREMENTS:
Measured Weight: 7.6 kg (04:20)
Print Date/Time: 12/11/2012 14:26 PST
Approx. Percentiles
Weight: 4 %ile

Report Request ID: 
Inpatient Consultation

Height: 72.5 cm (b) (0) (0) 04:20
BMI: 14.459 kg/m2 (b) (0) (0) 04:20

VITAL SIGNS OVER LAST 24 HOURS:
Temp 36.7 (36.1 - 36.7) 04:00
HR 106 (94 - 143) 04:02
Cuff BP 117/61 (86-118/49-72) 04:02
RR 21 (18 - 32) 04:02
SPO2 100 (88 - 100) 04:02

INTAKE & OUTPUT (Calculations based on current dose calc weight of 7.6 kg on (b) (0) (0) ):
Previous 0600 - 0559
Intake 1099.3 mL 144.6 mL/kg/24hrs 946.9 mL 124.6 mL/kg/22hrs
953.8 mL Infusions 845.4 mL Infusions
101 ml Meds 41 mL Meds
45 mL Oral 60 mL Oral
Output 828 mL 3.8 mL/kg/hr UOP 579 mL 3.2 mL/kg/hr UOP
700 mL Urine 538 mL Urine
100 mL Gastric 41 mL Stool
28 mL Stool 1 Stool Count
1 Stool Count
Balance 271.3 mL 367.9 mL

PHYSICAL EXAM: (Time of Exam: 0345)
General: [x ] crying but easily consoleable
Head: [x ] NC/AT [x ] AFOSS 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: _
GU: [x ] NL external genitalia Other: _
Extremities: [x ] warm [x ] no edema Capillary refill time: 2-3 sec Other: _
Neurologic: [ _ ] non focal/grossly intact Other: _
Skin: [x ] no rashes/lesions Other: _
Other: _

RADIOLOGY STUDIES (Completed):
XR Chest 1 View

Print Date/Time: 12/11/2012 14:26 PST
Report Request ID: (b) (5) 02:20 _

DSS OCT 3 1 2013

OCT 3 0 2013
Inpatient Consultation

LABS:
CHEM 23 (within 36 hours):

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<th>Value</th>
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<tbody>
<tr>
<td>AST</td>
<td>8.7</td>
</tr>
<tr>
<td>ALT</td>
<td></td>
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<tr>
<td>ALKP</td>
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<td>ALB</td>
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<tr>
<td>AST</td>
<td>8.7</td>
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<td>ALT</td>
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<tr>
<td>ALKP</td>
<td></td>
</tr>
<tr>
<td>ALB</td>
<td></td>
</tr>
</tbody>
</table>

Chem: 01:50
TBili: 01:50
DBili: 01:50

CBC w/Diff (within 36 hours):

<table>
<thead>
<tr>
<th>Item</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMN</td>
<td>11.2</td>
</tr>
<tr>
<td>Bands</td>
<td>646</td>
</tr>
<tr>
<td>Lymph</td>
<td>33.5</td>
</tr>
</tbody>
</table>

Last CBC: 01:50
CRP: 01:50

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 toxicity. 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 O2 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 pediatric from his bottle. His chest xray was concerning for possible LLL atelectasis 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%
4) given his rapid improvement, he will be safe to monitor in this time. we will check in again with the 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.

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

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: (b)(6)
Inpatient Consultation

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

Report prepared by: [Redacted] 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, management and recommendations discussed with fellow as described above. On re-evaluation at bedside pt had received methy/ene blue with return to saturation of 100% and resolution of cyanosis. Re-check level and treat if indicated. Would not hesitate to transfer to PICU for evidence of further decline.

Entered by [Redacted] MD on [Redacted] 23:35

DSS
OCT 3 1 2013

OCT 3 0 2013

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

Report Request ID: [Redacted]
Inpatient Consultation

SIGN ED BY: (b) (6) 03:56 PDT; L (b) (6) 03:23 PDT; (b) (6) 02:10 PDT

Addendum by (b) (6) MD on (b) (6) 03:56 PDT

Elevated methemoglobin percent indicative of methemoglobinemia.

Called Poison Control and spoke with (b) (6) - 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 04 levels with mom, and given the parental anxiety this evening I will still check a level in 4 hours (at around 0630) and 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 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

Entered by MD on (b) (6) 03:54

Addendum by (b) (6) on (b) (6) 03:23 PDT

GASES (within 1 day(s)):

Venous 01:50 7.38 / 48.3 / 20.2 / 28.0 / 3.3 Methemoglobin % 20.2

Print Date/Time: 12/11/2012 14:28 PST

Report Request ID: (b) (6)
CHEM 10 (within 36 hours):

<table>
<thead>
<tr>
<th>136</th>
<th>104</th>
<th>&lt;5</th>
<th>L</th>
<th>8.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.6</td>
<td>28</td>
<td>0.4</td>
<td>H</td>
<td>1</td>
</tr>
</tbody>
</table>

Chem: (b)(6) 01:50 (b)(6) 01:50

CBC w/Diff (within 36 hours):

<table>
<thead>
<tr>
<th>11.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>646 H</td>
</tr>
<tr>
<td>33.5</td>
</tr>
</tbody>
</table>

PMN: Bands: Lymph: Mono: Eos:

Last CBC: (b)(6) 01:50

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

GENERAL PEDIATRICS CONSULT 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 Admission: (b)(6)
Date of Consultation: (b)(6) 0110
Place of Consultation: (b)(6)
Requesting Service: Pediatric Surgery
Requesting Physician: Dr. (b)(6)

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

HISTORY OF PRESENT ILLNESS: (b)(6) is an 8 month old boy with a history of possible milk allergy and GERD who is 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 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 and 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 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 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 Oragen occasionally at home for a couple days prior to admission, but notes that she used it much more frequently (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 I was contacted at around 0030 this morning by the Oncology resident because of concern for methemoglobinemia.

REVIEW OF SYSTEMS:

Print Date/Time: 12/11/2012 14:25 PST

Report Request ID: (b)(6)
Constitutional: See HPI.
Eyes: No eye discharge. See HPI. + "Poking" at eyes.
ENT/Mouth: See HPI.
Respiratory: See HPI.
Cardiovascular: No concerns
GI/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 Allimentum, 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: Allimentum (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
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
diphensyramidINE 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: NKDA

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

Report Request ID:
**Inpatient Consultation**

**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.

**MEASUREMENTS:**
- Measured Weight: 7.6 kg (04:20)
- Height: 72.6 cm (04:20)
- BMI: 14.459 kg/m² (04:20)

**Approx. Percentiles**
- Weight: 4 %ile
- Height: 71 %ile
- Wt for Length: 1 %ile

**VITAL SIGNS OVER LAST 24 HOURS:**
- Temp: 36.1 (36.1 - 38.7) 23:45
- HR: 114 (94 - 143) 23:50
- Cuff BP: 95/68 (88-107/41-57) 23:50
- RR: 29 (15 - 32) 23:50
- SPO2: 91 (88 - 99) 23:50

**INTAKE & OUTPUT (Calculations based on current dose calc weight of 7.8 kg on):**

<table>
<thead>
<tr>
<th>Intake</th>
<th>144.6 mL/kg/24hrs</th>
<th>Since 0600</th>
<th>106.7 mL/kg/12hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous 0600-0559</td>
<td>1099.3 mL</td>
<td>810.9 mL</td>
<td>725.4 mL Infusions</td>
</tr>
<tr>
<td>Intake Infusions</td>
<td>953.6 mL</td>
<td>25 mL</td>
<td>60 mL Oral</td>
</tr>
<tr>
<td>Intake Meds</td>
<td>45 mL Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Output</td>
<td>3.8 mL/kg/hr UOP</td>
<td>579 mL</td>
<td>3.7 mL/kg/hr UOP</td>
</tr>
<tr>
<td>Output Urine</td>
<td>700 mL Urine</td>
<td>538 mL</td>
<td></td>
</tr>
<tr>
<td>Output Gastric</td>
<td>100 mL Gastric</td>
<td>41 mL Stool</td>
<td></td>
</tr>
<tr>
<td>Output Stool</td>
<td>28 mL Stool</td>
<td>1 Stool Count</td>
<td></td>
</tr>
<tr>
<td>Balance</td>
<td>271.3 mL</td>
<td>231.9 mL</td>
<td></td>
</tr>
</tbody>
</table>

**PHYSICAL EXAM:**

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

**Head:** NCAT, AFOSF

**Eyes:** Bilateral eyelids a little dusky, no conjunctival 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/o r, no stertor/striker

**Cardiac:** RRR, + 1/6 soft systolic murmur at LUSB, brachial and femoral pulses +2

**GI/Abdomen:** Normactive 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

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

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

**Report Request ID:**
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):
\[
\begin{array}{ccc}
139 & 106 & <5 \text{ L} / \\
5.2 & 27 & 0.3 \\
\end{array}
\]

Chem: (b)(6) 06:40 (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 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 3 1 2013

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

SIGNED BY: (b) 17:14 PDT; (b) 09:51 PDT

PEDiatric SURGERY DISCHARGE SUMMARY

PATIENT: (b) MRN: (b) FIN: (b) DOB: (b) LOC: (b)

Admitting Service: General Surgery
PCP: (b)
Admitting Attending: (b)

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

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 . He was transferred here and intussusception was confirmed on repeat US at . Reduction with barium enema was attempted four times unsuccessfully 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 , 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 methemoglobin 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 04:20

Discharge Vital Signs:
Temp: 37.4 04:00
HR: 145 04:00

Print Date/Time: 12/11/2012 14:25 PST

Report Request ID: (b)
Discharge Summary

Cuff BP 100/55 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: _
GI/Abdomen: [x] soft, non-tender, non-distended  [ _] no masses Other: _
GU: [ _] NL external genitalia Other: _
Extremities: [x] warm  [ _] no edema Capillary refill time: _ Other: _
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 General Surgery clinic in 1 month

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 family will be contacted by the clinic to schedule.
[ _] PMD/Other services: _
Other: _
Please call the Pediatric General Surgery Office at (b)(6) with any questions.

External CC:
CONTACT INFORMATION:

Print Date/Time:  12/11/2012 14:26 PST  
Report Request ID:  (b)(6)
Discharge Summary

SIGNED BY: (b)(6) [b](5) 01:56 PDT)
Discharge Summary

Referring MD: 

Primary Care Provider: 

Other: 

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.

Entered by MD or 17:14

Print Date/Time: 12/11/2012 14:29 PST

Report Request ID:
Discharge Summary

SIGNED BY: [Redacted] 09:51 PDT

Discharge Record Form Entered On: [Redacted] 09:56 PDT
Performed On: [Redacted] 09:51 PDT by [Redacted]

DC Record Form
Discharge Date: [Redacted] PDT
Attending MD on Day of Discharge: [Redacted]
Admission Date: [Redacted] PDT
Admitting Diagnosis: Intussusception
Principal Diagnosis: Intussusception

Principal Operations/Procedures: operative reduction of intussusception
Brief Hospital Course Summary: Admitted on [Redacted] with intussusception on abdominal ultrasound. Attempted to reduce with barium enema 4 times unsuccessfully. Taken to OR for operative reduction of intussusception. Desat to high 80s on [Redacted] found to have methemoglobinemia with methemoglobin level 20.2. Given metylene blue with return to normal oxygen saturations on room air. Discharged [Redacted] 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 [Redacted] 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: [Redacted]
Catalog Code: acetaminophen
Order Dt/Tm: [Redacted] 20:50; Comment: *** Do not 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
Status: Ordered
Ordered As Mnemonic: Tylenol oral; Simple Display Line: 80 mg, 2.5 mL, PO, q4hr, PRN: fever/chills; Ordering Provider: [Redacted]

Print Date/Time: 12/11/2012 14:26 PST
Report Request ID: [Redacted]
Discharge Summary

Catalog Code: acetaminophen ; Order Di/Tm: 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
Status: Ordered ; Order As Mnemonic: Benadryl pediatrics ; Simple Display Line: 7.6 mg, 0.15 mL, IV, q6hr, PRN: dry eyes ; Ordering Provider: Catalog Code: diphenhydramine ; Order Di/Tm: 16:56

Acetaminophen 10 mg/mL inj
Status: Discontinued ; Order As Mnemonic: acetaminophen IV ; Simple Display Line: 76 mg, 7.6 mL, IV, q4hr ; Ordering Provider: Catalog Code: acetaminophen ; Order Di/Tm: 11:01 ; Comment: *** Do not administer any acetaminophen containing products within 4 hours of each other. ***

Acetaminophen 325 mg suppository
Status: Ordered ; Order As Mnemonic: acetaminophen rectal ; Simple Display Line: 115 mg, 0.35 supp, rectal, q6hr, PRN: discomfort/fever ; Ordering Provider: Catalog Code: acetaminophen ; Order Di/Tm: 09:30 ; Comment: *** 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
Status: Ordered ; Order As Mnemonic: lidocaine 4% topical cream ; Simple Display Line: 1 application, topically, as needed, PRN: procedure ; Ordering Provider: Catalog Code: lidocaine topical ; Order Di/Tm: 09:30

medline solution
Status: Ordered ; Order As Mnemonic: medline solution ; Simple Display Line: 1 bag, IV, as needed, PRN: protocol ; Ordering Provider: Catalog Code: medline solution ; Order Di/Tm: 09:30 ; 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.

Print Date/Time: 12/11/2012 14:26 PST
Report Request ID:
Morphine 2 mg/mL inj prefilled syringe : 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: [redacted] ; Catalog Code: morphine ; Order Dt/Tm: [redacted] 

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: [redacted] ; Catalog Code: sodium chloride ; Order Dt/Tm: [redacted] ; Comment: *** Use to lock PIV catheter after use and at least every 8 hours *** *** Refer to [redacted] Vascular access chart for additional information *** 

Dextrose 5%-NAACL 0.45%-KCL 20mEq/L 1,000 mL : Dextrose 5%-NAACL 0.45%-KCL 20mEq/L 1,000 mL ; Status: Discontinued ; Ordered As Mnemonic: D5 1/2 NS + KCl 20mEq/L 1,000 mL ; Simple Display Line: 40 mL/hr, IV, Stop: 9:28:00 PDT ; Ordering Provider: [redacted] ; Catalog Code: Dextrose 5% with 0.45% NaCl and KCl 20 m ; Order Dt/Tm: [redacted] 

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: [redacted] ; Catalog Code: acetaminophen ; Order Dt/Tm: [redacted] 

Print Date/Time: 12/11/2012 14:26 PST
Outpatient/Clinic Documents

HISTORY OF PRESENT ILLNESS: (b)(6) returns to the Pediatric Surgery Clinic at Children's Hospital for a follow-up visit after his recent operative reduction of his nonreducible intussusception performed on (b)(6). His postoperative course was complicated in the hospital by methemoglobinemia due to Orajel 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 (b)(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.

D: (b)(6) 02:04 P
T: (b)(6) 11:57 P
Print Date/Time: 12/11/2012 14:26 PST
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 on (b)(6) 06:22
Electronically signed on (b)(6) 12:44

(b)(6), BS Medical Student

Electronically signed on (b)(6) 06:22

(b)(6)
Individual Case Safety Report

A. PATIENT INFORMATION
1. Patient Identifier (blank)
2. Age at Time of Event: 6 Months
   - Female
   - Male
3. Date of Birth:

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. 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
   - 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)

5. Describe Event or Problem

ON 11/10/13, CHILD EXPERIENCED LOSS OF APPETITE, LETHARGY AND WEAKNESS AND WAS DIAGNOSED WITH AN EAR INFECTION. CHILD BECAME UNRESPONSIVE AND TOOK TO HOSPITAL AND PUT IN ICU. CHILD IS LETHARGIC AND SLEEPING CONTINUOUSLY. CHILD PLACED ON FEEDING TUBE. CHILD HAD CHOKING EPISODE AND STOPPED BREATHING AND PUT ON BREATHING TUBE. POSSIBLE BELLADONNA POISONING PER DOCTORS BUT RUNNING TESTS TO DETERMINE OTHER POSSIBLE CAUSES OF SYMPTOMS.

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.

7. 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, importor, disributor, manufacturer or product caused or contributed to the event.
H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   - Death
   - Serious injury
   - Malfunction
   - Other: 

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
   - No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - Yes
   - No

6. Evaluation Codes (Refer to coding manual)
   - Method
   - Results
   - Conclusions

7. If Remedial Action Initiated, Check Type
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modification/Adjustment

8. Usage of Device
   - Initial Use of Device
   - Reuse
   - Unknown

9. If action reported to FDA under 21 USC 3800(f), list correction/removal reporting number:

10. Additional Manufacturer Narrative and/or

11. Corrected Data

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   EDYTA FRACKIEWICZ
   HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

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:

4. Date Received by Manufacturer (mm/dd/yyyy)
   11/14/2013

5. If IND, Give Protocol #

6. Type of Report
   (Check all that apply)
   - Combination
   - Product
   - Yes
   - Pre-1938
   - Yes
   - OTC Product
   - Yes

7. Manufacturer Report Number
   54973 AE # 1517

8. Adverse Event Term(s)
   EXTREME LETHARGY, WEAKNESS, CHOKING, HOSPITALIZATION

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.
CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: BABY TEETHING TABLETS / TEETHING TABLETS
SIZE: UNKNOWN
REPORTER: (0) (0)
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: 
E-MAIL: 

NATURE OF COMPLAINT: CUSTOMER POSTED ON (0) (0) THAT ON NOV. 10 CHILD EXPERIENCED LOSS OF APPETITE, LETHARGY AND WEAKNESS. 11/10/13: CHILD DIAGNOSED WITH AN EAR INFECTION AND PRESCRIBED ANTIBIOTICS. (0) (0) CHILD BECAME UNRESPONSIVE AND TAKEN TO HOSPITAL AND PUT IN ICU. CHILD IS EXTREMELY LETHARGIC AND SLEEPING CONTINUOUSLY. (0) (0) CHILD PLACED ON FEEDING TUBE. (0) (0) CHILD HAD CHOKE EPISODE AND STOPPED BREATHING AND PUT ON BREATHING TUBE. POSSIBLE BELLADONNA POISONING PER DOCTORS, BUT RUNNING TESTS TO DETERMINE CAUSE OF SYMPTOMS. SEE ATTACHED POSTINGS.

TESTS: RENAL URINE. X-RAY CHEST, SPINAL TAP, CT SCAN, EEG, AND MRI WHICH WAS NORMAL. WAITING FOR RESULTS OF TESTS. URL ADDRESS: 

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION:

Individual Case Safety Report

9747541-01-00-03

DATE: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 11/14/13

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 

REVIEWED BY MANAGEMENT BY: 

DATE: 

QA / QC DIRECTOR

Form # VD1
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 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

[Signature]

Date

11/26/13

Individual Case Safety Report

9747541-01-00-04
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1517

COMPLAINT #: 2527

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME:

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 PANELS)

Individual Case Safety Report

9747541-01-00-05

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: __________________________ DATE: __________________________

SECTION IV: REVIEWED BY MANAGEMENT BY: __________________________ DATE: 11-27-13

BY: __________________________ DATE: 11-27-13

QA/QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1517

COMPLAINT #: 2527

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME: [redacted]
ADDRESS: [redacted]
CITY: [redacted]
STATE: [redacted]
COUNTRY: USA
ZIP CODE: [redacted]
PHONE #: [redacted]
E-MAIL: [redacted]

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: [redacted] DATE: [redacted]

SECTION IV:

REVIEWED BY MANAGEMENT BY: [redacted] DATE: 11-27-13

BY: [redacted] QA / QC DIRECTOR
A. PATIENT INFORMATION

1. Patient Identifier (b)(6)
   
2. Age at Time of Event:
   8 Months

3. Sex
   Female

4. Weight
   8 lbs or kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
   - Adverse Event
   - Product Problem

2. Outcomes Attributed to Adverse Event (Check all that apply)
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - 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) 10/09/2013
4. Date of This Report (mm/dd/yyyy) 10/16/2013

5. Describe Event or Problem
   HAD 8 SMALL "SEIZURES" LASTING A COUPLE OF SECONDS. EYES ROLLED BACK INTO HEAD, WAS DRACKLING, AND HEAD JERRED LEFT AND RIGHT. CHILD HAS NEVER EXPERIENCED THESE TYPES OF SYMPTOMS.

C. SUSPECT PRODUCT(S)

1. Name (Give listed strength and niffler)
   - HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   - 2 TABS UNDER TONGUE

3. Therapy Dates (if unknown, give duration from/to or best estimate)

4. Diagnosis for Use (indication)
   - TEMP RELIEF SX IRRITABILITY

5. Event Abated After Use Stopped or Dose Reduced?
   - Yes

6. Lot #
   - #1B006813

7. Exp. Date
   - #1

8. Event Reappeared After Reintroduction?
   - Yes

9. NDC# or Unique ID
   - 54973-3127-1

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   - Health Profession
   - Lay User/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

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
    - Yes

11. Concomitant Medical Products and Therapy Dates (Excluding treatment of event)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   - Yes

3. Occupation
   - NA

4. Initial Reporter Also Sent Report to FDA
   - 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.
<table>
<thead>
<tr>
<th><strong>H. DEVICE MANUFACTURERS ONLY</strong></th>
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<tbody>
<tr>
<td><strong>1. Type of Reportable Event</strong></td>
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<tr>
<td>□ Death</td>
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<tr>
<td>□ Serious Injury</td>
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<td>□ Malfunction</td>
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<td>□ Other:</td>
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<th><strong>2. If Follow-up, What Type?</strong></th>
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<tr>
<td>□ Correction</td>
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<tr>
<td>□ Additional Information</td>
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<td>□ Response to FDA Request</td>
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<tr>
<td>□ Device Evaluation</td>
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<th><strong>3. Device Evaluated by Manufacturer?</strong></th>
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<tr>
<td>□ Not Returned to Manufacturer</td>
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<tr>
<td>□ Yes</td>
</tr>
<tr>
<td>□ Evaluation Summary Attached</td>
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<tr>
<td>No (Attach page to explain why and provide code:</td>
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<th><strong>4. Device Manufacture Date</strong> (mm/dd/yyyy)</th>
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<th><strong>5. Labeled for Single Use?</strong></th>
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<td>□ Yes</td>
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<td>□ No</td>
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<th><strong>6. Evaluation Codes (Refer to coding manual)</strong></th>
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<tr>
<td>Method</td>
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<td>Results</td>
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<tr>
<td>Conclusions</td>
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<th><strong>7. If Remodel Action Initiated, Check Type</strong></th>
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<td>□ Recall</td>
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<tr>
<td>□ Notification</td>
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<tr>
<td>□ Repair</td>
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<tr>
<td>□ Inspection</td>
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<tr>
<td>□ Replace</td>
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<tr>
<td>□ Patient Monitoring</td>
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<tr>
<td>□ Relabeling</td>
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<tr>
<td>□ Modification/Adjustment</td>
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<td>□ Other:</td>
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<th><strong>8. Usage of Device</strong></th>
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<tr>
<td>□ Initial Use of Device</td>
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<tr>
<td>□ Reuse</td>
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<tr>
<td>□ Unknown</td>
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<th><strong>9. If action reported to FDA under 21 USC 360(i), list correction/removal reporting number:</strong></th>
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<th><strong>G. ALL MANUFACTURERS</strong></th>
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<tr>
<td><strong>1. Contact Office - Name/Address (and Manufacturing Site for Devices)</strong></td>
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<tr>
<td>EDYTA FRACKIEWICZ</td>
</tr>
<tr>
<td>HYLAND'S, INC.</td>
</tr>
<tr>
<td>154 W. 131ST STREET</td>
</tr>
<tr>
<td>LOS ANGELES, CA 90061</td>
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<tr>
<th><strong>2. Phone Number</strong></th>
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<tr>
<td>310-768-0700</td>
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<th><strong>3. Report Source</strong> (Check all that apply)</th>
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<tr>
<td>□ Foreign</td>
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<tr>
<td>□ Study</td>
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<td>□ Literature</td>
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<td>□ Other:</td>
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<tr>
<th><strong>4. Date Received by Manufacturer (mm/dd/yyyy)</strong></th>
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<tr>
<td>10/09/2013</td>
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<th><strong>5. (A)NDA #</strong></th>
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<th><strong>STN #</strong></th>
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<th><strong>PMMA/310(k) #</strong></th>
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<tr>
<th><strong>Combination Product</strong></th>
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<tr>
<td>□ Yes</td>
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<td>□ No</td>
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<tr>
<th><strong>Pro-1038</strong></th>
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<tr>
<td>□ Yes</td>
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<td>□ No</td>
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<tr>
<th><strong>OTC Product</strong></th>
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<tr>
<td>□ Yes</td>
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<td>□ No</td>
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<tr>
<th><strong>6. If IND, Give Protocol #</strong></th>
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<tr>
<th><strong>7. Type of Report</strong> (Check all that apply)</th>
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<tbody>
<tr>
<td>□ 5-day</td>
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<tr>
<td>□ 7-day</td>
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<tr>
<td>□ 10-day</td>
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<tr>
<td>□ 15-day</td>
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<tr>
<th><strong>8. Manufacturer Report Number</strong></th>
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<tr>
<td>54973 AE # 1513</td>
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<tr>
<th><strong>9. Adverse Event Term(s)</strong></th>
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<tr>
<td>SEIZURES</td>
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</table>

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**

**SECTION I: COMPLAINT**

**TAKEN BY:** EDYTA FRACKIEWICZ  
**DATE OF COMPLAINT:** 10/10/13  
**PRODUCT:** BABY TEETHING TABLETS  
**ITEM CODE:** BTET---T135  
**SIZE:** 135 TABLETS  
**LOT NO.:** 890513  
**RECEIVED**  
**NOV 05-2013**  
**CDR**

**PRODUCT RECEIVED FOR INSPECTION:** [ ] (CIRCLE ONE)  
**PRODUCT BEING RETURNED FOR INSPECTION:** [ ] (CIRCLE ONE)  
**DATE REQUESTED PRODUCT BE RETURNED:**  
**UPS CALL TAG ISSUED:** [ ] (CIRCLE ONE)  
**DATE PRODUCT RECEIVED:**  

**SECTION II: INVESTIGATION**

**INVESTIGATION:** PLEASE SEE ATTACHED INSPECTION REPORT.

**SECTION III: CORRECTIVE ACTION**

**CORRECTIVE ACTION(S) COMPLETED BY:**  
**DATE:**  

**SECTION IV: ADVERSE EVENT REPORTS**

**ADVERSE EVENT SERIOUS:** [ ]  
**ADVERSE EVENT REPORTED ON:** 10/10/13  
**BY:** EDYTA FRACKIEWICZ  

**SECTION V: REVIEWED BY MANAGEMENT BY:**  
**DATE:**  

**EX: QA/ QC DIRECTOR**  
**DATE:**  

**CO: QA/ QC Production Packaging Shipping / Receiving**
3E EVENT DATA FORM

AE #: 1513  COMPLAINT #: 2522

SECTION I:  PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME: 

ADDRESS: 

CITY: 

COUNTRY: USA

PHONE #: 

E-MAIL: 

STATE: 

ZIP CODE: 

SECTION II:  PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III:  CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 

SECTION IV:

REVIEWS BY MANAGEMENT BY: 

DATE: 10-25-13

BY: 

DATE: 10-22-13

DISTRIBUTION: FDA  ADVERSE EVENT FILE

FORM 3EAE01

NOV 0 6 2013

NOV 0 5 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 89(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 within specification of ≤ 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 # 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.

Prepared by

Date

10/22/13
Patient Information

1. Patient Identifier
   (b)(6)

2. Age at Time of Event
   or Date of Birth:
   DOB:
   (b)(6)

3. Sex
   □ Female
   ☑ Male

4. Weight
   23.0000 lb
   or
   kg

Adverse Event, Product Problem or Error

1. ☑ Adverse Event
2. ☑ Product Problem (e.g., defects/malfunctions)
3. ☑ Product Use Error

Outcomes Attributed to Adverse Event

4. ☑ Disability or Permanent Damage
5. ☑ Congenital Anomaly/Birth Defect
6. ☑ Other Serious (Important Medical Events)
7. ☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

Date of Event

7/30/13
12/11/13

Describe Event, Problem or Product Use Error

Parents gave 2 teething tablets and put
him down for nap. Abnormal breathing noted
during nap - grunting, squirming, wouldn't
wake for 10 min. Eval in ED concerning for
seizure.

Relevant Tests/Laboratory Data, Including Dates

Influenza (neg)
RSV (neg)

CTU
DEC 30 2013

Other Relevant History, Including Preexisting Medical Conditions (e.g.,
allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Did have fever for 1-2 days
prior to event. Diagnosed with ear
infection that day

Product Availability

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☑ No

Suspect Product(S)

1. Name, Strength, Manufacturer (from product label)
   #1 Name: Hyland's Teething Tablets
   Strength:
   Manufacturer:

   #2 Name:
   Strength:
   Manufacturer:

E. Suspect Medical Device

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Lot #

6. Catalog #

7. Expiration Date (mm/dd/yyyy)

F. Other (Concomitant) Medical Products

1. Name and Address(b)(6)
   Name:
   Address:
   City:
   Phone #

2. Health Professional?

3. Occupation

4. Also Reported to:
   ☑ Manufacturer
   ☑ User/Facility
   ☑ Distributor/Importer

G. Reporter (See confidentiality section on back)

1. Name and Address(b)(6)
   Name:
   Address:
   City:
   Phone #

2. Health Professional?

3. Occupation

4. Also Reported to:
   ☑ Manufacturer
   ☑ User/Facility
   ☑ Distributor/Importer

Submit a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
**Adverse Event Reporting Program**

### A. PATIENT INFORMATION
- **Patient Identifier:** (b)(6)
- **2. Age at Time of Event or Date of Birth:**
  - 5 Months *(b)(6)*
- **3. Sex:**
  - **Female**
  - **Male**
- **4. Weight:** 12 lbs

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
- **Event:** Adverse Event
- **Product Use Error:** Problem with Manufacturer of Same Medicine
- **2. Outcomes Attributed to Adverse Event:**
  - **Death:**
  - **Disability or Permanent Damage:**
  - **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:** 12/02/2013
- **4. Date of this Report:** 01/10/2014

### C. PRODUCT AVAILABILITY
- **5. Relevant Tests/Laboratory Data, Including Dates:**
  - Autopsy is pending

### D. SUSPECT PRODUCT(S)
- **1. Name, Strength, Manufacturer (from product label):**
  - **Name:** Hyland Teething Tablets
  - **Strength:**
  - **Manufacturer:**
- **2. Name:**
  - **Strength:**
  - **Manufacturer:**

### E. SUSPECT MEDICAL DEVICE
- **1. Brand Name:** CTU
- **2. Common Device Name:**
- **3. Manufacturer Name, City and State:**
- **4. Model #:**
- **Lot #:**
- **Serial #:** Other
- **5. Operator of Device:**
  - **Health Professional**
  - **Lay User/Patient**
  - **Other:**
- **6. If Implanted, Give Date:**
- **7. If Explanted, Give Date:**

### 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:**
- **2. Phone #:**
- **E-mail:**
- **3. Health Professional?**
- **4. Also Reported to:**
  - **Manufacturer**
  - **User Facility**
  - **Distributor/Importer**
- **5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:**
Individual Case Safety Report

Health Professional Report

OLUNTARY reporting of events, product problems and product use errors

A. PATIENT INFORMATION

1. Patient identifier: (b)(6)
2. Age at time of Event or Date of Birth:
   (b)(6)
   4 Months
3. Sex: Female
4. Weight: 7.2 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

Outcomes Attributed to Adverse Event (Check all that apply):

- Death: (mm/dd/yyyy)
- Disability or Permanent Damage
- 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): 02/22/2014
4. Date of this Report (mm/dd/yyyy): 02/22/2014

5. Describe Event, Problem or Product Use Error:
   Infant admitted due to profound flushing and irritability without obvious cause had been on Hylands Teething Tablets for the last week at 3 tablets per day.

6. Relevant Tests/Laboratory Data, Including Dates:
   Complete metabolic panel, CRF, Abd X-rays and X-ray of right leg normal. WBC 29.2 with normal differential.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):
   Term infant with vaccines current, previously well after short stay in NICU for low Apgar.

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label):
   Name: Hyland's teething tablets
   Strength: Homeopathic
   Manufacturer: Hyland's Inc

2. Name:
   Strength:
   Manufacturer:

3. Lot #:
   #1: A 97113
   #2: 

4. Expiration Date (mm/dd/yyyy):
   #1: 
   #2: 

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event):
Tylenol infant drops

G. REPORTER (See confidentiality section on back)

1. Name and Address:

2. Health Professional?
   Yes

3. Occupation:
   Medical Doctor (Physician)

4. Also Reported To:
   Manufacturer
   User Facility
   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.
Individual Case Safety Report

CDER

LUNTARY reporting of
medical, product problems and
product use errors

FDA USE ONLY

Triage unit sequence # 542709

PATIENT INFORMATION

1. Patient Identifier

2. Age at Time of Event or
Date of Birth:

3. Sex

4. Weight

- Female
- Male

- 13 lb
- kg

ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

- Adverse Event
- Product Problem (e.g., defects/inefficiencies)
- Product Use Error
- Problem with Different Manufacturer of Same Medicine

Outcomes Attributed to Adverse Event

- Death:
- Disability or Permanent Damage
- Life-threatening
- Congenital Anomaly/Birth Defect
- Hospitalization - initial or prolonged
- Other Serious (Important Medical Events)
- Required Intervention to Prevent Permanent Impairment/Damage (Device)

Date of Event (mm/dd/yyyy)

03/07/2014

Date of this Report (mm/dd/yyyy)

03/09/2014

Describe Event, Problem or Product Use Error

I purchased Hyland's Baby Teething Tablets for my seven month old daughter. After giving her two tablets under her tongue, she began to cry incessantly, like never before. She aped a fever of 101.10 minutes

Relevant Tests/Laboratory Data, Including Dates

NA

CTU

MAR 11 2014

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: NA
- Allergies: NA
- Important Information: PRETERM baby born at 37 weeks gestation

PRODUCT AVAILABILITY

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

- Yes
- No

RETURNED TO MANUFACTURER

SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

- Name: Hyland's Baby Teething Tablets
- Strength: Does not say
- Manufacturer: Hyland's, Inc. Los Angeles, CA

- Name:
- Strength:
- Manufacturer:

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.
... 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.
The individual patient safety information and adverse event reporting program.

A. PATIENT INFORMATION

1. Patient Identifier:
   - Age: 5 months
   - Date of Birth: 03/07/2014

2. Sex: Male
3. Weight: 19 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

1. Adverse Event: Yes
2. Product Problem: No
3. Product Use Error: No
4. Problem with Different Manufacturer of Same Medicine: No

2. Outcomes Attributed to Adverse Event
   - Disability or Permanent Damage: No
   - Congenital Anomaly/Birth Defect: No
   - Other Serious (Important Medical Events): Yes
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices): No

3. Date of Event: 03/07/2014
4. Date of this Report: 03/08/2014

5. Describe Event, Problem or Product Use Error

We gave our 5 month old Hylans Teething tablets Friday afternoon/evening. Friday at 10pm he projectile vomited everywhere. He vomited again about 30 minutes later. We did not know it was the tablets. The next day at noon we gave him the tablets again. The same result ensued. We then learned about the issues with the Hylans product and ceased dosage. He is slowly recovering, but certainly still not feeling well. He is having trouble taking full feedings.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Presenting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
   - Race: White
   - Medical Conditions: N/A
   - Allergies: Wheat, Soy
   - Important Information: N/A

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No
- Returned to Manufacturer on:

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   - Name: Hylans Teething Tablets
   - Strength: N/A
   - Manufacturer: Hylans, Inc.

2. Name: OTC

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.
C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer):

   #1 KYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used:

   #1 2-3 TABS UP TO TID INTERM

3. Therapy Dates (If unknown, give duration in months or years estimate):

   #1

4. Diagnosis for Use (Indication):

   #1 TEMP RELIEF OF TEETHING PAIN

5. Event Abated After Use:

   #1 Yes  No  Do Ap

6. Lot #:

   #1A97111

7. Exp. Date:

   #1

8. Event Reappeared After Reintroduction:

   #1 Yes  No  Do Ap

9. NDC# or Unique ID:

   54373-3127-2

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Devl

   Health Profess  Lay User/Patien  Other:

   #1

6. Catalog #

7. Exp. Date (mm/dd/yyyy)

8. If Implantated, Give Date (mm/dd/yyyy)

9. If Explanted, Give Date (mm/dd/yyyy)

10. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

   #1 Yes  No

11. If Yes to Item No. 8, Enter Name and Address of Reprocessor

12. Device Available for Evaluation? (Do not send to FDA)

   #1 Yes  No  Returned to Manufacturer on: (mm/dd/yyyy)

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

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?

   #1 Yes  No

3. Occupation

   #1

4. Initial Reporter Ack Report to FDA

   #1 Yes  No
Individual Case Safety Report

1. Check One
   ☐ User Facility  ☐ Importer
2. UF/Importer Report Number

3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report
   ☐ Initial  ☐ Follow-up #
8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)
    Patient Code
    Device Code

11. Report Sent to FDA?
    ☐ Yes (mm/dd/yyyy)  ☐ No

12. Location Where Event Occurred
    ☐ Hospital  ☐ Outpatient Diagnostic Facility
    ☐ Home  ☐ Ambulatory Surgical Facility
    ☐ Nursing Home  ☐ Other: (Specify)

13. Report Sent to Manufacturer?
    ☐ Yes (mm/dd/yyyy)  ☐ No

14. Manufacturer Name/Address

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H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   ☐ Death  ☐ Serious Injury
   ☐ Malfunction  ☐ Other:

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
   ☐ No (Attach page to explain why not or provide code):

4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use?
   ☐ Yes  ☐ No

6. Evaluation Codes (Refer to coding manual)
   Method
   Results
   Conclusions

7. If Remedial Action Initiated, Check Type
   ☐ 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 368(f), list correction/removal reporting number:

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Received
FEB 04 2014

CDR

DSS
FEB 04 2014

FEB 05 2014

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G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
   EDYTA FRACKIEWICZ
   HYLAN'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

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:

4. Data Received by Manufacturer (mm/dd/yyyy)
   12/09/2013

5. (A)NDA #  IND #  STN #
   PM/  510(k) #
   Combination Product  ☐ Yes
   Pre-1938  ☐ Yes
   OTC Product  ☐ Yes

6. Type of Report (Check all that apply)
   ☐ 5-day
   ☐ 30-day
   ☐ 7-day
   ☐ Periodic
   ☐ 10-day
   ☐ Initial
   ☐ 15-day
   ☐ Follow-up # 1

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9. Manufacturer Report Number
   54973 AE # 1521

8. Adverse Event Term(s)
   INFANTILE SPASMS

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The public reporting burden for this collection of information has been estimated to average 60 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.
Individual Case Safety Report

PLAINT RECORD

COMPLAINT #: 2531

TAKEN BY: EDYTA FRACIEWICZ

DATE OF COMPLAINT: 12/05/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BITE1725

SIZE: 250 TABLETS

LOT NO: A87113

REPORTER:

ADDRESS:

CITY:

COUNTRY: USA

PHONE #:

E-MAIL:

GIVING CHILD 11/20/13 3 TABLETS AT BEDTIME AND THEN THE NEXT DAY HUSBAND GAVE 1 TABLET A FEW TIMES AND THEN THAT DAY THE CHILD STARTLED IN HIS CAR SEAT AND WAS SHORT OF BREATH (A FRIEND NOTICED IT). 11/22/13 SHE NOTICED THE TEETHING TABLETS 2 TABLETS ABOUT 3 TIMES THAT DAY. CHILD BECAME FUSSY THAT DAY AND SHE PUT HIM IN THE CAR SEAT AND HE STARTED CRYING AND HAVING SPASMS (HE DESCRIBES IT AS AN EXAGGERATED MORO REFLEX) REACHES OUT ARMS AND GRIPS BUT LIKE A STARTLE REFLEX WHICH WAS COMING IN CYCLES. THE CYCLES WOULD LAST MAYBE A MINUTE AND HAVING 6 OR 7 EPISODES WOKE UP AND HAD THESE EPIsODES AND MOTHER TOOK HIM TO THE ER. AT THE ER THEY FOUND AN EAR INFECTION AND GAVE HIM AN ANTIBIOTIC (AMoxicillin). THERE WAS NO FEVER. 11/25/13 WENT TO THE PEDIATRICIAN WITH A SICK CALL AND SHE VISTOPATED THE EPISODES AND THE NURSE PRACTITIONER SAID IT WAS A SEIZURE LIKE ACTIVITY RELATED TO GASTROESOPHAGEAL REFLUX (SANDIFER'S SYNDROME) BUT SHE HAS NOT FOLLOWED UP WITH HAVING AN ENDOSCOPY TO CONFIRM. SHE WENT HOME AND CHILD WAS HAVING MORE CYCLES UP TO 6 PER DAY. MOTHER CONTINUED TO GIVE CHILD MORE TEETHING TABLETS DURING THIS TIME (GARISH OR DOSES). ON 11/26/13 MOTHER WENT BACK TO ER, AND THE DOCTOR SAID THAT THE CHILD WOULD BE ADMITTED TO THE HOSPITAL. PEDIATRIC NEUROLOGIST CAME IN AND THEY DID EEG AND CONFIRMED "INFANTILE SPASMS". THIS IS RECOGNIZED UNDER THE EPILEPSY DIAGNOSIS. CHILD IS ON ZANTAC AND ACTH (FOR SEIZURES). LAST TIME OF TEETHING TABLETS WAS 12/04/13. MOTHER HEARD ABOUT THE RECALL THE OTHER DAY AND HAS CONNECTED THE INFANTILE SPASMS WITH THE TEETHING TABLETS. LAST SPASM WAS ON 12/04/13. SHE IS GOING TO TALK TO THE NEUROLOGIST ABOUT THE TEETHING TABLETS. CHILD IS BOTTLE FEED. WAS PREMATURE BY 3-4 WEEKS. OUR PHARMACIST, EDYTA FRACIEWICZ, TOLD THE MOTHER THAT IT'S POSSIBLE HER CHILD COULD BE SENSITIVE OR ALLERGIC TO THE TEETHING TABLETS OR SYMPTOMS COULD BE DUE TO SOMETHING ELSE. TOLD HER THAT IF IT IS A TRANSIENT HOMOPATRIC EFFECT THEN THE SYMPTOMS SHOULD RESOLVE AFTER PRODUCT IS DISCONTINUED. OFFERED HER A REFUND FOR THE TEETHING TABLETS AND SHE ACCEPTED. PAID $10

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/09/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACIEWICZ

SECTION III: CORRECTIVE ACTION:

12/10/13 (b) PREPARED REFUND REQUEST TOTALING $15.79. 12/27/13 (b) MAILED REFUND CHECK # 511188 TOTALING $15.79 ON ARTICLE # 7088780004652986153.

CORRECTIVE ACTION(S) COMPLETED BY: (b) (c)

DATE: 12/10/13 & 12/27/13

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON: 12/09/13

BY: EDYTA FRACIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

FEB 04 2014

DATE: 01-23-14

FEB 05 2014

DATE: 01-22-13

cc: QA / QC Production

QA / QC DIRECTOR

Packaging

Shipping / Receiving

FEB 01-22-14

Form # VD1
December 10, 2013

Dear [Name]

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
**Individual Case Safety Report**

**Complaint Record**

**Complaint #:** 2531  
**Date of Complaint:** 12/09/13

**Product:** Hyland's Baby Teething Tablets  
**Size:** 250 Tablets

**Reporter:** Ewyta Fracjewicz  
**Address:**

**City:**  
**Country:** USA  
**State:**  
**Zip Code:**

**Phone #:**

**E-mail:**

**Nature of Complaint:** Giving child 11/20/13 3 tablets at bedtime and then the next day husband gave 1 tablet a few times and then that day the child started in his car seat and was short of breath (a friend noticed it). 11/22/13 she used the teething tablets 2 tablets about 3 times that day. Child became fussy that day and she put him in the car seat and he started crying and having spasms (she describes it as an exaggerated Moro reflex). Reaches out arms and cries out like a startle reflex which was coming in cycles. The cycles would last maybe a minute and having 5 or 7 episodes. More up and had these episodes and mom took him to the ER. At the ER they found an ear infection and gave him an antibiotic (Augmentin). There was no fever. 11/25/13 went to the pediatrician with a video call and did video the episode and the nurse practitioner said it was a seizure like activity related to gastroesophageal reflux (Sandifer's Syndrome) but she has not followed up with having an endoscopy to confirm. She went home and child was having more cycles up to 6 per day. Mother continued to give child more teething tablets during this time (carious doses). On 12/05/13 mother went back to ER and the doctor said that the child would be admitted to the hospital. Pediatric neurologist came in and they did EEG and confirmed "Infantile Spasms". This is recognized under the Epilepsy Diagnosis. Child is on Zantac and Acthar (for seizures). Last dose of teething tablets was 12/04/13. Mother heard about the recall the other day and has connected the infantile spasms with the teething tablets. Last spasms was on 12/04/13. She is going to talk to the neurologist about the teething tablets. Child is bottle fed. 

**For Additional Space Please Use Reverse or Attach a Separate Sheet**

**Product Received for Inspection:** Y  
**Product Being Returned for Inspection:** N  
**Date Requested Product Be Returned:**

**Date Product Received:**

**Section II: Investigation**

**Investigation:** Please see attached investigation report.

**Adverse Event Forwarded to Pharmacist / Nurse for Evaluation:**

**Section III: Corrective Action**

12/10/13(0) PREPARED REFUND REQUEST TOTALING $15.79

**Corrective Action(s) Completed By:**

**Date:** 12/10/13

**Section IV: Adverse Event Reports**

**Adverse Event Serious:** Y  
**Adverse Event Reported On:** 12/09/13

**Section V:**

**Reviewed By Management By:**

**By:** QA/DC Director

**FEB 04 2014**
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 8,948 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 within specification of 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-0092-2013) 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: 12/13/13
**A. PATIENT INFORMATION**

1. Patient Identifier (b)(6)
2. Age at Time of Event: 1 Years
3. Sex: Male
4. Weight: lbs

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. Adverse Event or Product Problem (e.g., defects, malfunctions)
2. 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)
   - Required intervention to prevent permanent impairment/damage (Devices)
3. Date of Event (mm/dd/yyyy) 01/07/2014
4. Date of This Report (mm/dd/yyyy) 01/16/2014

**C. SUSPECT PRODUCT(S)**

1. Name (Gve labeled strength & mfr/labeler)
   a) RYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used
   a) #2 TABS HS X 1 DOSE
3. Therapy Dates (If unknown, give best estimate)
   a) #1
4. Diagnosis for Use (Indication)
   a) TEMP RELIEF TEETHING PAIN
5. Event Abated After Use Stopped
   a) Yes
6. Lot #
   a) B06713
7. Exp. Date
   a) #1
8. Event Reappeared After Reintroduction
   a) Yes
9. NDC# or Unique ID
   a) 54973-3127-1
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Catalog #
6. Serial #
7. Other #
8. If Implanted, Give Date (mm/dd/yyyy)
9. If Explanted, Give Date (mm/dd/yyyy)
10. If this a Single-use Device that was Reprocessed and Reused on a Patient?

**E. INITIAL REPORTER**

1. Name and Address
2. Health Professional? Yes
3. Occupation
4. Initial Reporter Ads Report to FDA Yes
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."
OMER COMPLAINT RECORD

COMPLAINT #: 2535

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 01/10/2014
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: 815T-1135
SIZE: 135 TABLETS
LOT NO.: 806719

REPORTER: (b) (6) [Redacted]
ADDRESS: 

CITY: (b) (6) [Redacted]
STATE: JAN 29 2014
COUNTRY: USA
ZIP CODE: CDR
PHONE #: (b) (6) [Redacted]
CELL PHONE: 

E-MAIL: 

RECEIVED

NATURE OF COMPLAINT: CHILD HAD A SEIZURE ON (b) (6) GAVE BABY TEETHING TABLETS THE NIGHT BEFORE. PUT 2 TABLETS UNDER THE TONGUE, NO VACCINATIONS AROUND THAT TIME. NO FEVER, NO ILLNESS. SEIZURE LOCKED LIKE HIS EYES OPENED AND EYES ROLLED UP INTO HIS HEAD AND HE WENT STIFF. LASTED ABOUT 2 MINUTES. WENT TO THE ER AND FOLLOWED UP WITH SOME TESTS. HAD AN EEG DONE ON (b) (6) BUT NO RESULTS AS OF YET. SEIZURE OCCURRED IN (b) (6) WHERE FAMILY LIVES 6 MONTHS OUT OF THE YEAR. PAID $8 PURCHASED IN (b) (6) WANT A REFUND. PRESENTLY FAMILY IS LIVING IN (b) (6) TRIED CALLING CUSTOMER ON 5/1/14 FOR US ADDRESS AND LEFT A MESSAGE ON CELL PHONE. TRIED CALLING THREE TIMES ON 01/14/14 BUT THERE WAS NO ANSWER. LEFT ANOTHER MESSAGE. ALSO SENT AN E-MAIL TO CUSTOMER REQUESTING THAT SHE SEND HER U.S. ADDRESS FOR A REFUND.

FOR ADDITIONAL SPACE PLEASE USE 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: 

UPS CALL TAG ISSUED: Y (CIRCLE ONE)

DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/10/2014
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

ADVERSE EVENT SERIOUS: Y (CIRCLE ONE)

ADVERSE EVENT REPORTED ON: 01/10/2014
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 

DATE: 01-20-14
DATE: 01-17-14

REVIEWED BY MANAGEMENT BY: 

DATE: 

cc: QA/QC Packaging Production Shipping / Receiving

Form # VD1

JAN 29 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 [600] 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 <10 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 #B08813] 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 [64%] of 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
JMS ADVERSE EVENT DATA FORM

AE #: 1525

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 

ADDRESS: 

CITY: USA STATE: 

COUNTRY:_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)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: __________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 01-20-14

BY: ___________________________ DATE: 01-17-14

DISTRIBUTION: FDA ADVERSE EVENT FILE
SON HAD A SEIZURE AT MIDNIGHT WHEN HE WAS ASLEEP BESIDE HIS MOTHER. IT LASTED 5 MINUTES. HIS EYES ROLLED BACK, AND "IT TOOK A WHILE FOR HIM TO COME OUT OF IT," HE TURNED PURPLE. PARENT CALLED 911 AND AN AMBULANCE BROUGHT HIM TO THE HOSPITAL.

CHILD WAS DIAGNOSED AS HAVING A SEIZURE AND WENT HOME TO FOLLOW-UP WITH HIS DOCTOR TODAY.

HOSPITAL GAVE CHILD IBUPROFEN AND PEDIALYTE. HOSPITAL TRIED TO GIVE CHILD AN IV BUT COULDN'T GET A VEIN.

CHILD HAD A LOW GRADE FEVER OF 100.6F. PRIOR TO THE SEIZURE CHILD WAS GIVEN TYLENOL AT 8 PM AND 3 TABLETS OF BABY TEETHING TABLETS AT 10 AM AND AT 5 PM. 24 HOURS PRIOR CHILD HAD BEEN RESTLESS, CRANKY AND CUTTING 3 TEETH. HE HAD BEEN GIVEN TYLENOL FOR THE TEETHING BEFORE WITH NO SYMPTOMS. HIS LAST IMMUNIZATION WAS 3 MONTHS AGO, AND HE HAD NO REACTION. NO ALLERGIES OR PRE-EXISTING CONDITIONS.
COMPLAINT #: 2536
DATE OF COMPLAINT: 02/01/2014
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET---T40
SIZE: 40 TABLETS
LOT NO.: 226113
REPORTER: TUTTI GOULD
ADDRESS:
CITY: USA
COUNTRY: USA
PHONE #: (800) 247-4477
E-MAIL:

NATURE OF COMPLAINT:
SON HAD A SEIZURE AT MIDNIGHT WHEN HE WAS ASLEEP BESIDE HIS MOTHER. IT LASTED 5 MINUTES. HIS EYES ROLLED BACK, AND IT TOOK A WHILE FOR HIM TO COME OUT OF IT. HE TURNED PURPLE. PARENT CALLED 911 AND AN AMBULANCE BROUGHT HIM TO THE HOSPITAL. MEDICAL CARE: HE WAS DIAGNOSED AS HAVING HAD A SEIZURE AND WAS SENT HOME TO FOLLOW-UP WITH HIS DOCTOR TODAY. HE HAD A LOW GRADE FEVER OF 109.8°F. PRIOR TO THE SEIZURE HE WAS GIVEN TYLENOL AT 8 PM AND 3 TABLETS OF BABY TEETHING TABLETS AT 10 AM AND AT 5 PM. AT THE HOSPITAL HE WAS GIVEN IBUPROFEN AND PEDIATELYTE. 24 HOURS PRIOR TO HIS BIRTH, HE HAD BEEN RESTLESS, CROOKY AND CUTTING 3 TEETH. HE HAD BEEN GIVEN TYLENOL FOR THE TEETHING BEFORE WITH NO SYMPTOMS. THE MOTHER SAID THE ONLY THING THAT WAS DIFFERENT WAS SHE GAVE HIM TEETHING TABLETS TWICE THAT DAY. HE HAS NO ALLERGIES OR PRE-EXISTING CONDITIONS. HIS LAST IMMUNIZATION WAS 3 MONTHS AGO, AND HE HAD NO REACTION. AT THE HOSPITAL THEY TRIED TO GIVE HIM AN IV BUT COULDN'T GET A VEIN. BLOOD TESTS FOR STREP AND FLU WERE NEGATIVE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N
FOLLOW-UP CALLS: 01/29/14, 01/30/14; LEFT MESSAGE BOTH TIME TO CALL 1-800-324-6599 WITH ANY NEWS FROM THE DOCTOR'S VISIT.

PRODUCT BEING RETURNED FOR INSPECTION: Y N
DATE REQUESTED PRODUCT BE RETURNED:
UPS CALL TAG ISSUED: Y N
DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 02/01/14
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
ADVERSE EVENT SERIOUS: Y N
ADVERSE EVENT REPORTED ON: 02/01/2014
BY: TUTTI GOULD

SECTION V:
REVIEWED BY MANAGEMENT BY:

BY:
QA / QC DIRECTOR

cc: QA / QC
Production
Satisfaction / Operations
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 30 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 ≤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 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.
SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (b)(6)
ADDRESS: 
CITY: 
COUNTRY: USA
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)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ____________________________ DATE: ____________

SECTION IV:

 Reviewed by Management by: ____________________________ DATE: 02-07-14

 BY: ____________________________ DATE: 02-07-14

QA/ QC DIRECTOR
**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at Time of Event or Date of Birth</th>
<th>3. Sex</th>
<th>4. Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unspecified</td>
<td>0 (0)</td>
<td>Female</td>
<td>17 lb</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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
   - [ ] Death (mm/dd/yyyy)
   - [ ] Disability or Permanent Damage
   - [ ] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Other Serious (Important Medical Events)
   - [ ] Other

3. Date of Event (mm/dd/yyyy)
   - 03/25/2014

4. Date of this Report (mm/dd/yyyy)
   - 03/25/2014

**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)**

<table>
<thead>
<tr>
<th>1. Name, Strength, Manufacturer (from product label)</th>
<th>2. Name, Strength, Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Name: Hyland's Teething Tablets</td>
<td>#2 Name:</td>
</tr>
<tr>
<td>Strength:</td>
<td>Strength:</td>
</tr>
</tbody>
</table>

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name
   - [ ]

2. Common Device Name
   - [ ]

3. Manufacturer Name, City and State
   - [ ]

4. Model #
   - [ ]

5. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy)
   - [ ]

7. If Implanted, Give Date (mm/dd/yyyy)
   - [ ]

**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
   - Name: (b)(6)
   - Address:

2. Health Professional?
   - [ ] Yes
   - [ ] No

3. Occupation
   - [ ]

4. Also Reported to:
   - [ ] Manufacturer
   - [ ] User Facility
   - [ ] Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: [ ]

**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.
The FDA safety information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier
   (b) (6)
2. Age at Time of Event or Date of Birth:
   2 years
3. Sex
   □ Female
   □ Male
4. Weight
   or lb
   or kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ Life-threatening
   □ Congenital Anomaly/Birth Deformity
   □ Hospitalization - initial or prolonged
   □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)
   04/30/2014
4. Date of this Report (mm/dd/yyyy)

5. Describe Event, Problem or Product Use Error
   My son did not get his first tooth until almost after a year old. A friend of mine told me about Hylands because I do NOT just give my child medication. I thought it was natural and safe. I used it as needed occasionally over a course 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 deep thought and my mother did too. I'm with my son every day and I barely miss a thing. Over a course of a few days they came more often. The ONLY thing I ever gave my son was Hylands teething tablets. He had an EEG and which came ...

6. Relevant Tests/Laboratory Data, Including Dates
   EEG positive for seizures. MRI within normal limits

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: None
   Allergies: None
   Important Information:

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: Teething tablets
   Strength: Hylands
   Manufacturer:

   #2 Name: Strength:
   Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   CTU

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #
   Lot #

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ 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 8, Enter Name and Address of Reprocessor

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

2. Health Professional
   □ Yes □ No

3. Occupation
   □ Health Professional
   □ User Facility
   □ Distributor/Importer

4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

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.
... back positive for seizures. Which I suspected. 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 sensitive to a lot of things, and I believed he was poisoned by these without me knowing.
A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event or Date of Birth:
   1 Years
3. Sex
   [ ] Female
   [ ] Male
4. Weight
   19.9 lb
   or kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. [ ] Adverse Event
2. [ ] Product Problem (e.g., defects/malfunctions)
3. [ ] Product Use Error
4. [ ] Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   [ ] Death: (mm/dd/yyyy)
   [ ] Disability or Permanent Damage
   [ ] 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):
   09/26/2013
4. Date of this Report (mm/dd/yyyy):
   05/07/2014

5. Describe Event, Problem or Product Use Error
   Single seizure: brief staring episode at home, appearing awake but unresponsive that lasted seconds, and then "seemed more out of it than usual". No report of loc. No tonic/clonic shaking, vomited after event, fatigued for an hour after event. Took Hyland's teething tablets prior to event. After event tablets stopped- has not had another seizure like episode since.

6. Relevant Tests/Laboratory Data, Including Dates
   EEG n1, cbc/ lytes normal

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) previously healthy, no preexisting conditions.

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)
   [ ] Name: Hyland's teething tablets
   [ ] Strength:
   [ ] Manufacturer: Hyland's

2. Dose or Amount
   [ ] as directed
   [ ] PRN/as needed

3. Dates of Use (If unknown, give duration from/to (or best estimate)
   #1 09/19/2013 - 09/26/2013

4. Diagnosis or Reason for Use (Indication)
   #1 teething

5. Event Altered After Use Stopped or Dose Reduced?
   #1 Yes  #2 No  #3 Doesn't Apply

6. Lot #
   #1

7. Expiration Date
   #1

8. Event Reappeared After Reintroduction?
   #1 Yes  #2 No  #3 Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State
   MAY 8 2014

4. Model#

5. Operator of Device
   [ ] Healthcare Professional
   [ ] Lay User/ Patient
   [ ] Other:

6. Catalog #

7. Expiration Date (mm/dd/yyyy)

8. If Implantable, Give Date (mm/dd/yyyy)

9. If Explanted, Give Date (mm/dd/yyyy)

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)
none

G. REPORTER (See confidentiality section on back)
1. Name and Address
   (b)(6)

2. Phone #
   (b)(6)

3. E-mail
   (b)(6)

4. Also Reported to:
   [ ] Manufacturer
   [ ] User Facility
   [ ] 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.
5. Describe Event, Problem or Product Use Error

3 episodes of seizure activity involving arms/legs, all occurring on the same day. Hospitalized for 24hrs. For the 5 days prior to seizure, patient had started taking Hyland's teething tablets. This was discontinued on the day of admission. The patient's EEG, MRI were all normal. There was no family history of seizures or any history of febrile seizures. She has not had any seizures or Hyland's teething tablets since this time.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

prior 38 week twin, other twin unaffected. no preexisting health issues, no family history of seizures or neurologic problems

C. PRODUCT AVAILABILITY

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

Yes ☑ No ☐ Returned to Manufacturer on:

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Name: Hyland's Teething Tablets

Strength: unsure

Manufacturer: Hyland

2. Name:

Strength:

Manufacturer:

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.
Individual Case Safety Report

1. Patient Identifier (ID) (9) (8) [ ]
   2. Age at Time of Event (mm/dd/yyyy)
      or
      Date of Birth (mm/dd/yyyy) [ ]
      or
      In Confidence

   3. Sex
      [ ] Female
      [ ] Male

   4. Weight (in lbs)

   In confidence

   5. B. ADVERSE EVENT OR PRODUCT PROBLEM
      [ ] Adverse Event
      [ ] Product Problem

      1. Outcomes Attributed to Adverse Event:
         [ ] Death
         [ ] Disability or Permanent Damage
         [ ] Life-threatening
         [ ] Congenital Anomaly/Birth Defect
         [ ] Other Serious (Important Medical Events)
         [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

      2. Date of Event (mm/dd/yyyy) 05/13/2014
      3. Date of This Report (mm/dd/yyyy) 05/23/2014

      4. Describe Event or Problem:
      CHILD WITH ALTERED MENTAL STATUS DESCRIBED AS
      CLUMSINESS, FALLING DOWN, IRRITABILITY, SOMNOLENCE.

      5. C. SUSPECT PRODUCT (S)
         1. Name (Give labeled strength, lot number, batch number)
            #1 HYLAND'S BABY TEETHING PELLETS
         2. Dose, Frequency & Route Used
            #1 2-3 TABS QID 1X MONTH
         3. Therapy Dates (If unknown, give duration)
            #1
            #2

         4. Diagnosis for Use (Indication)
            #1 TEMPERATURE TREATMENT PAIN
         5. Event Abated After Use Stopped or Date Reduced?
            Yes
            No

         6. Lot #
            #1
            #2

         7. Exp. Date
            #1
            #2

9. NDC# or Unique ID
   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
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   [ ] Health Professional
   [ ] Lay User/Patient
   [ ] Other
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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

      (Continue on page 3)

10. If Yes to Item No. 9, Enter Name and Address of Reprocessor

      (Continue on page 3)

11. Device Available for Evaluation? (Do not send to FDA)
   Yes
   No
   Returned to manufacturer on (mm/dd/yyyy)

E. INITIAL REPORTER
1. Name and Address
2. Health Professional?
   Yes
   No
3. Occupation
   Physician
4. Initial Reporter Also Sent Report to FDA
   Yes
   No
   Unk
**Individual Case Safety Report**

### 1. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Correction</td>
</tr>
<tr>
<td>Serious Injury</td>
<td>Additional Information</td>
</tr>
<tr>
<td>Malfunction</td>
<td>Response to FDA Request</td>
</tr>
<tr>
<td></td>
<td>Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacture Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
<td>mm/dd/yyyy</td>
</tr>
<tr>
<td>Yes</td>
<td>Evaluation Summary Attached</td>
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<tr>
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</table>

<table>
<thead>
<tr>
<th>5. Labeled for Single Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Event Problem and Evaluation Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code</td>
</tr>
<tr>
<td>--------------</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td>Initial Use of Device</td>
</tr>
<tr>
<td>Notification</td>
<td>Repair</td>
</tr>
<tr>
<td>Replace</td>
<td>Inspection</td>
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<tr>
<td>Patient Monitoring</td>
<td>Unknown</td>
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<tr>
<td>Relabeling</td>
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</tr>
<tr>
<td>Modification/Adjustment</td>
<td>Other:</td>
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<tbody>
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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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstuff@dhs.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."
TAKEN 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:  
CITY: USA  
STATE: (b) (6)  
COUNTRY: USA  
ZIP CODE:  
PHONE #: (b) (6)  
E-MAIL: N/A  
MOM HAS BEEN GIVING HYLAND'S BABY TEETHING TABLETS POSSIBLE UPTO 2 - 3 TIMES A DAY. CHILD PRESENTS WITH ALTERED MENTAL STATUS DESCRIBED AS CLUMSINESS, FALLING DOWN, IRRITABILITY, SOMNOLENCE. HOSPITALIZED. SERQUEL ALSO PRESENT IN THE HOME. DOCTOR REQUESTED MORE INFORMATION ABOUT HYLAND'S BABY TEETHING TABLETS. CT SCAN, MRI, LABS, X-RAY NORMAL. TOLD HIM THAT I WOULD FILE A REPORT WITH THE FDA SINCE CHILD HOSPITALIZED. TOLD PHYSICIAN THAT CUSTOMER USING PRODUCT FOR LONGER THAN RECOMMENDED DURATION COULD CAUSE A HOMEOPATHIC EFFECT, OR CHILD COULD BE SENSITIVE OR ALLERGIC TO AN ACTIVE OR INACTIVE INGREDIENT, OR SYMPTOMS COULD BE DUE TO SOMETHING ELSE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N  
PRODUCT BEING RETURNED FOR INSPECTION: Y N  
DATE REQUESTED PRODUCT BE RETURNED:  
UPS CALL TAG ISSUED: Y N  
DATE PRODUCT RECEIVED:  

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/21/2014
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
ADVERSE EVENT SERIOUS: Y / N  
ADVERSE EVENT REPORTED ON: 05/21/2014  
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:  
DATE: 06-02-14

DATE: 06-02-14

cc: QA / QC Packaging  
Production  
Shipping / Receiving  
QA / QC DIRECTOR

Form #: VD1
Product in Inventory:

The reporter was only provided 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 50 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

JUN 11 2014

JUN 10 2014
A. PATIENT INFORMATION
1. Patient Identifier (SSN) [8(9)]
2. Age at Time of Event: 10 Months
3. Sex ☐ Female ☐ Male
4. Weight ___ lbs or ___ kgs
5. Date of Birth: 

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   ☐ Death: (mm/dd/yyyy) ☐ Disability or Permanent Damage
   ☐ Life-threatening ☐ Congenital Anomaly/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) 04/30/2014
4. Date of This Report (mm/dd/yyyy) 05/16/2014
5. Describe Event or Problem
   CHILD HAD 1 OR 2 DOSES RANDOMLY OF TEETHING TABLETS. MAYBE 4 THIS A DAY A FEW WEEKS AGO. SHE WAS FINE FOR A COUPLE WEEKS THEN SHE STARTED TO DO THIS WEIRD THING AND TURNED BLUE. TOOK HER TO THE ER AND SHE WAS MISDIAGNOSED WITH PNEUMONIA. THE EVENTS WHERE SHE STOPPED BREATHING AND TURNED BLUE KEPT HAPPENING AGAIN ON MOTHER'S DAY. THEY WENT TO THE HOSPITAL. THEY HOOKED HER UP TO A MACHINE AND SAW SHE WAS HAVING 20 OR MORE SEIZURES IN 1 DAY. HER MRI WAS CLEAR. THEY LEFT HER TWO NIGHT AND SHE IS NOW TAKING KEEFRA. SHE HAD NOT TAKEN ANY TEETHING TABLETS FOR A FEW WEEKS BEFORE SHE HAD THE SEIZURE. MOTHER READ ON INTERNET ABOUT RECALL AND WAS CONCERNED.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & form/labeling)
   #1 HYLAND'S BABY TEETHING TABLETS
   #2
2. Dose, Frequency & Route Used
   #1 TABLETS AS NEEDED
   #2
3. Therapy Dates (If unknown, give duration)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN
   #2
5. Event Abated After Use
   Stopped or Dose Reduced?
   #1 Yes ☐ No ☐ Doesn't Apply
   #2 Yes ☐ No ☐ Doesn't Apply
6. Let # ☑
   1113149
   1113149
7. Exp. Date
   #1
   #2
8. NDC or Unique ID
   54973-3127-2
9. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   ☐ Health Professional ☐ Lay User/Patient ☐ Other
6. Catalog #
7. Expiration Date (mm/dd/yyyy)
8. Serial #
9. Unique Identifier (UDI) #

DSS

E. INITIAL REPORTER
1. Name and Address
2. Health Professional? Yes ☐ No ☐
3. Occupation
4. Initial Reporter Also Sent Report to FDA Yes ☐ No ☐
**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

3. **Device Evaluated by Manufacturer?**
   - [ ] Yes
   - [ ] No (Attach page to explain why not or provide code)

4. **Device Manufacture Date (mm/yyyy)**

5. **Labeled for Single Use?**
   - [ ] 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**
   - [ ] Recall
   - [ ] Repair
   - [ ] Inspection
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modification
   - [ ] Adjustment
   - [ ] Other: (Specify)

8. **Usage of Device**
   - [ ] Initial Use of Device
   - [ ] Reuse
   - [ ] Unknown

9. **If action reported to FDA under 21 USC 351(h), list correction/removal reporting number:**

10. **Additional Manufacturer Narrative and/or**

11. **Corrected Data**

---

**G. ALL MANUFACTURERS**

1. **Contact Office (and Manufacturing Site for Devices)**
   - **Name:** ALISON MC PEAK
   - **Address:** NYLAND'S, INC.
   - **Location:** 154 W. 131ST STREET
   - **City:** LOS ANGELES
   - **State:** CA
   - **Country:** U.S.
   - **Telephone:** 310-768-0700

2. **Phone Number**
   - **Contact Person:**
   - **Phone Number:**

3. **Report Source (Check all that apply)**
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

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

5. **A/NDA #**
   - **IND #**
   - **BLA #**
   - **PMA/510(k) #**

6. **Type of Report (Check all that apply)**
   - 5-day
   - 10-day
   - 15-day

7. **Type of Report Number**
   - 54973 AR: # 1536

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**DSS**

**JUN 11 2014**

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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@fas.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."
INDIVIDUAL CASE SAFETY REPORT

DATE OF COMPLAINT: 05/15/2014

PRODUCT: HYLAND'S BABY TEETHING TABLETS

COMPLAINT #: 2546

TAKEN BY: ALISON MC PEAK

DATE REQUESTED PRODUCT BE RETURNED:

PRODUCT RECEIVED FOR INSPECTION:

05/16/14

PRODUCT BEING RETURNED FOR INSPECTION:

Y (CIRCLE ONE)

UPSA CALL TAG ISSUED:

Y (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDRED TO PHARMACIST / NURSE FOR EVALUATION ON:

05/15/14

ADVERSE EVENT FORWARDRED TO PHARMACIST / NURSE FOR EVALUATION BY:

ALISON MC PEAK

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: JUN 11, 2014

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS:

Y / N

ADVERSE EVENT REPORTED ON:

05/16/14

BY:

ALISON MC PEAK

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 05-28-14

DATE: 05-27-14

cc: QA / QC Packaging Production Shipping / Receiving Form # VD1
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) 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 ≤(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 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

Signature

Date

5/23/14

DSS

JUN 11 2014

JUN 10 2014

CC-0307-2014

AE-0163-2014
Individual Case Safety Report

VENT DATA FORM

AE #: 1536
COMPLAINT #: 2546

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME: 
ADDRESS: 
CITY: (b) (6) STATE: (b) (6) ZIP CODE: 

COUNTRY: USA PHONE #: (b) (6)

E-MAIL: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: REVIEWED BY MANAGEMENT BY: 
DATE: 

By: QA / QC DIRECTOR 
DATE: 

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SA201
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event or Date of Birth: 9 Months
3. Sex: □ Female □ Male
4. Weight: 21 lb or _____ kg

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: (mm/dd/yyyy) □ Disability or Permanent Damage
   □ Life-threatening □ Congenital Anomaly/Birth Defect
   □ Hospitalization - initial or prolonged □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanente Damage/Defect

3. Date of Event (mm/dd/yyyy): 05/21/2014
4. Date of Report (mm/dd/yyyy): 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 just excitement jerks or something, one day he started doing it a lot more than ever before so I took him to hospital 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 and 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 Pre-existing 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:
   Manufacturer:

2. Dose or Amount
   #1 2 to 3 tablets
   #2

3. Dates of Use (If unknown, give duration from/to)
   #1 03/10/2014 - 05/20/2014
   #2

4. Diagnosis or Reason for Use (Indication)
   #1 Teething - I was told it worked better than oral gel's
   #2

5. Event Abated After Use
   Stopped or Dose Reduced?
   #1 Yes □ No □ Doesn't Apply
   #2

6. Lot #
   #1
   #2

7. Expiration Date
   #1
   #2

E. SUSPECT MEDICAL DEVICE
1. Brand Name
   CTU

   JUN 23 2014

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:

   Catalog #

   Expiration Date (mm/dd/yyyy)

   Serial #

   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, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

DSS
JUN 23 2014

G. REPORTER (See confidentiality section on back)
1. Name and Address
   (b)(6)

   Phone #
   (b)(6)

   E-mail
   (b)(6)

2. Health Professional?
   □ Yes □ No

3. Occupation

4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distribution/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.
B.3. Describe Event or Problem (continued)

I...ncluding use of teething tablets for teething and then I came across a recall for his tablets. I then made an appointment with his doctor, 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 23 2014
Individual Case Safety Report

10257359-01-00-03

DSS
JUN 23 2014
**INDIAN WARS**

**FORM FDA 3500A (2/13)**

**Page 1 of 5**

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**A. PATIENT INFORMATION**

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<td>Female</td>
<td>lbs</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>or kg</td>
</tr>
</tbody>
</table>

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**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)

---

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & manufacturer)

   - HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

   - 1 TABS QD FRM X 9 MOS

3. Therapy Dates (If unknown, give dating from/to or best estimate)

   - #1
   - #2

---

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

---

**E. INITIAL REPORTER**

1. Name and Address (SSN)

   - USA

   - MD

   - JUN 2 4 2014

---

**RECEIVED**

JUN 2 4 2014

CDH

Please Type or Use Black Ink

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**Submission of a report does not constitute an admission that product personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.**
<table>
<thead>
<tr>
<th>F. FOR USE BY USER FACILITY or IMPORTER (Devices Only)</th>
<th>H. DEVICE MANUFACTURERS ONLY</th>
</tr>
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<tbody>
<tr>
<td>1. Check One</td>
<td></td>
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<tr>
<td>User Facility</td>
<td>Importer</td>
</tr>
<tr>
<td>2. U/I Importer Report Number</td>
<td></td>
</tr>
<tr>
<td>3. User Facility or Importer Name/Address</td>
<td></td>
</tr>
<tr>
<td>4. Contact Person</td>
<td></td>
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<tr>
<td>5. Phone Number</td>
<td></td>
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<tr>
<td>6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)</td>
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<tr>
<td>7. Type of Report</td>
<td></td>
</tr>
<tr>
<td>Initial</td>
<td>Follow-up #</td>
</tr>
<tr>
<td>8. Date of This Report (mm/dd/yyyy)</td>
<td></td>
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<tr>
<td>9. Approximate Age of Device</td>
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<tr>
<td>10. Event Problem Codes (Refer to coding manual)</td>
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<tr>
<td>Patient Code</td>
<td></td>
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<tr>
<td>Device Code</td>
<td></td>
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<tr>
<td>11. Report Sent to FDA?</td>
<td></td>
</tr>
<tr>
<td>Yes (mm/dd/yyyy)</td>
<td>No (mm/dd/yyyy)</td>
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<td>12. Location Where Event Occurred</td>
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<tr>
<td>Hospital</td>
<td>Outpatient Diagnostic Facility</td>
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<td>Home</td>
<td>Other:</td>
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<tr>
<td>Nursing Home</td>
<td>Ambulatory Surgical Facility</td>
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<td>13. Report Sent to Manufacturer?</td>
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<tr>
<td>Yes (mm/dd/yyyy)</td>
<td>No (mm/dd/yyyy)</td>
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<tr>
<td>14. Manufacturer Name/Address</td>
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<th>G. ALL MANUFACTURERS</th>
</tr>
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<tbody>
<tr>
<td>1. Contact Office (and Manufacturing Site for Devices)</td>
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<tr>
<td>2. Phone Number</td>
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<tr>
<td>EDTA FRAKIDIMICZ</td>
</tr>
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<td>3. Report Source (Check all that apply)</td>
</tr>
<tr>
<td>Foreign</td>
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<tr>
<td>Study</td>
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<td>Literature</td>
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<tr>
<td>4. Date Received by Manufacturer (mm/dd/yyyy)</td>
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<td>36/06/2014</td>
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<td>5. IF IND, Give Protocol #</td>
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<td>BLA #</td>
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<td>PMA/510(k) #</td>
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<td>Other:</td>
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<td>7. Type of Report (Check all that apply)</td>
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<td>5-day</td>
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ORB 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

COMPLAINT #: 2552
DATE OF COMPLAINT: 06/06/14

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: BABY TEETHING TABLETS

SIZE: 135 TABLETS

REPORTER: (0) (0)

ADDRESS: 

CITY: 

COUNTRY: USA

STATE: (0) (0)

PHONE #: (0) (0)

NATURE OF COMPLAINT: VOICE MAIL MESSAGE. MOTHER CALLED REGARDING DAUGHTER STATEING IN VOICE MAIL MESSAGE THAT SHE RECENTLY STARTED HAVING SEIZURE ACTIVITY. DOCTOR TOLD HER NOT TO USE BABY TEETHING TABLETS AND SHE HAS USED PRODUCT FOR 6 - 8 MONTHS. SPOKE WITH MOTHER 06/17/14. MOTHER RECENTLY NOTICE SOME SPEECH DELAY WHICH SHE ATTRIBUTES TO THE HYLAND'S TEETHING TABLETS BECAUSE SEIZURE ACTIVITY SLOWS THE BRAIN ACTIVITY AND CAUSES DELAYS IN SPEECH. THREW BABY TEETHING TABLETS AWAY ON FRIDAY 06/06/14. WAS GIVING CHILD 4 TABLETS EVERY DAY FOR 9 MONTHS WHEN HER TEETH HURT. DESCRIBES SEIZURES AS CHILD HOLDING HER BREATH, PASSING OUT, LEGS WILL START SHAKING AND SHE WILL BITE DOWN. SEIZURES GOING ON SINCE SHE WAS 9 MONTHS OLD SO FOR ABOUT 9 MONTHS. DOCTOR SAID THAT TEETHING TABLETS WERE CAUSING THE SEIZURES. NO TESTS FOR SEIZURES ADMINISTERED BY DOCTOR AT THIS TIME. MOTHER STOPPED THE TABLETS ON FRIDAY. CHILD HAS THE SEIZURES ONCE A DAY, BUT STOPPED HAVING THEM FRIDAY AFTERNOON AFTER DISCONTINUING TEETHING TABLETS. CUSTOMER DID NOT REQUEST A REFUND OR REPLACEMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: ( ) Y ( ) N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: ( ) Y ( ) N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/06/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: ( ) Y / ( ) N

ADVERSE EVENT REPORTED ON: 06/06/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: 

DATE: 06-17-14

DATE: 06-16-14

QA / QC DIRECTOR

CC: QA / QC Packaging

Production

Shipping / Receiving

Form # VD1
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 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 0 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
JUN 25 2014
SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

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)

SECTION III: CORRECTIVE ACTION:

DSS
JUN 25 2014

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: ___________________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 06-17-14

BY: ___________________________ DATE: 06-16-14

QA / QC DIRECTOR
My 18 month old daughter has been using the Hyland's teething tablets for 3 weeks now. In the last two weeks she has had a horrible rash appearing as similar to the looks of ring worm, but all over her body. It would stay for 12-24 hours then disappear for a day or two. When this rash would pop up I needed to have her use her nebulizer to help with her breathing. I brought her to the doctor's yesterday 06/26/14. They have referred her to an allergist hoping to maybe find out what causes it, that appointment is 07/21/14.
8.6. 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.
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
ER Needs: N/A
OTC Needs: N/A

Individual Case Safety Report

10272692-01-00-03

DSS
JUN 30 2014
Individual Case Safety Report

THE FDA SAFETY INFORMATION AND Adverse Event Reporting Program

1. Patient Identifier
   (b)(6) [Redacted]

2. Age at Time of Event or Date of Birth:
   [Redacted]

3. Sex
   [Redacted]

4. Weight
   [Redacted]

5. Event Abated After Use Stopped or Dose Reduced?
   Yes [Redacted]

6. Diagnosis or Reason for Use (indication)
   #1 Teething purposes

7. Lot #
   [Redacted]

8. Expiration Date
   [Redacted]

9. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
   Race: Black/African American

For additional information see B7 below.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
   Yes [Redacted]

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   #1 Name: Hylands
   Strength: Teething Tablets
   Manufacturer:

2. Name:
   [Redacted]

3. E-mail
   [Redacted]

4. Also Reported to:
   Manufacturer
   User Facility
   Distributor/Importer

*Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.*
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 or 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. (Signature) 

Individual Case Safety Report

10272885-01-00-02

DSS
JUN 30 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 30 2014
The patient is 14 months old. She was taking Hyland's teething tablets. She had a seizure, had breathing problems, and was extremely fatigued. I am curious if this will cause long-term effects and what can be done.

Relevant Tests/Laboratory Data, Including Dates

My doctor has ...

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.
Individual Case Safety Report

10275530-01-00-02

DSS

JUN 30 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: Amoxicillin antibiotic for ear infection

OTC Meds: Tylenol, elastin, axajil.
REPORT INFORMATION

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  38BEF529-163F02F2-AE84280-8829111D-D466698C-F8392863E-2A8FAC1B-46A682C1

Report Identifying Information

Please enter a title to help you identify this report. Hyland's Teething Tablets
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

DSS  JUL 03 2014
**Contact Information - Your Contact Information**

Do you wish to remain anonymous to the FDA? No

First name (b) (6)  
Last name  
Email  
Confirm email  
Phone  
Country United States  
Street address line 1  
Street address line 2 <blank>  
City/Town (b) (6)  
State  
Mail/ZIP code  

Have you reported the event to any of the following? <blank>

Are you a healthcare professional? No

**Relevant Details**

Patient/Consumer identifier (b) (6)  
Gender Male  
Age at time of event, <i>if unknown, please enter Date of birth below</i> 2  
Select unit of measure Month(s)  
Date of birth (b) (6)  
Weight 13  
Select unit of measure Pound(s)  
Height 25  
Select unit of measure Inch(inches)  

**Problem Details**

Outcomes attributed to adverse event (check all that apply) Other 000002

DSS JUL 03 2014
If other, please describe symptoms like spasms

Please describe the event or problem

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.):

N/A

Do you have any relevant tests/laboratory data information to report? No

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 Other

Full name of product as it appears on the package label Homeopathic Hyland's Baby Teething Tablets

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 <blank>

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 03 2014
Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:

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? Yes
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 Belladonna 12X HPUS
Ingredient amount <blank>
Select unit of measure <blank>

Ingredient Details

Ingredient name Calcarea Phosphorica 6X HPUS
If other, please describe Calcarea Phosphorica 6X HPUS
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

I have reviewed the ingredients listed for
Concomitant Product Information

Concomitant Product Relevant Details

HL7 Batch Information

HL7 Batch Control Information

Submitting Organization Id

HL7 Batch Sender Information

Sender Id: GuestAccount

HL7 Batch Receiver Information

Batch Receiver (Root): USFDA
Batch Receiver (Extension): US Food and Drug Administration

DSS

JUL 03 2014

HL7 Message Information

HL7 Message Control Information

Unique Sender Identifier: F606E6
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 03 2014
C. SUSPECT PRODUCT(S)

1. Name (Gives tablet strength & niflulabacer)
   HYLAND'S BABY TEETHING TABLETS
   #1
   #2

2. Dose, Frequency & Route Used
   #1 1-2 TABS Q4H
   #2

3. Therapy Dates (If unknown, give duration)
   #1 Or (best estimate)
   #2

4. Diagnosis for Use (Indication)
   #1 TEMP
   #2 RECOVERING OVERALL PAIN

5. Event Abated After Use
   Stopped or Dose Reduced?
   #1 Yes #2 No

6. Lot #
   #1
   #2

7. Exp. Date
   #1 JUL
   #2 2 2014

9. NDC# or Unique ID CDR
   #1 54973-3127-1
   #2

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
    TYLENOL

(DC on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device

   - Health Professional
   - User/Patient
   - Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Implanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   #1 Yes #2 No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

JUL 08 2014

10. Device Available for Evaluation? (Do not send to FDA)
   #1 Yes #2 No

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

(Continued on page 3)

E. INITIAL REPORTER

1. Name and Address

   (b) (5)

2. Health Professional?
   #1 Yes #2 No

3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA
   #1 Yes #2 No

(Continued 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.
**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

3. **Device Evaluated by Manufacturer?**
   - [ ] Yes
   - [ ] No
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code

4. **Device Manufacture Date**
   - (mm/dd/yyyy)

5. **Labeled for Single Use?**
   - [ ] 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**
   - [ ] 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 360(i), list correction/ removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

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 60 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.
CUSTOMER COMPLAINT RECORD

SECTION: COMPLAINT

TAKEN BY: TUTTI GOULD

PRODUCT: HYLAND'S BABY TEETHING TABLETS

SIZE: 135 TABLETS

REPORTER: 

ADDRESS: 

CITY: 

COUNTRY: USA

PHONE #: 

E-MAIL: 

DATE OF COMPLAINT: 06/20/14

COMPLAINT #: 2554

ITEM CODE: BTET—T135

LOT NO.: NOT AVAILABLE

NATURE OF COMPLAINT: FATHER CALLED WONDERING IF HIS 2 YEAR OLD DAUGHTER'S SEIZURE FROM A YEAR AGO COULD HAVE BEEN CAUSED BY BABY TEETHING TABLETS. SHE WENT TO THE HOSPITAL AND ALL TESTS WERE NORMAL. DOCTOR COULD NOT DETERMINE CAUSE. CHILD WAS IMMUNIZED 6 MONTHS PRIOR, HAD TAKEN TYLENOL THE NIGHT BEFORE. JUST PRIOR TO THE SEIZURE SHE HAD BEEN PLAYING IN THE WATER WITH HOSE, AND WAS CRYING. FATHER SAID THEY CONSIDERED WHETHER SHE MAY HAVE "DROWNED AND COME BACK" FROM TOO MUCH WATER. SEIZURE SYMPTOMS: LEFT ARM AND BODY SHAKE, SOME FOAM FROM MOUTH, ALWAYS ABLE TO BREATHE, EYES GLAZED, STARING, UNRESPONSIVE TO HER NAME, LASTED 1 MINUTE. CHILD CONTINUED TO TAKE THE REMEDY UNTIL PRESENT. THERE WAS ONLY ONE INCIDENT OF THE SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y / N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y / N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y / N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/20/14

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

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 06/20/14

BY: TUTTI GOULD

SECTION V: REVIEWED BY MANAGEMENT BY: 

DATE: 06-25-14

SECTION VI: BY: 

DATE: 06-25-14

CC: QA / QC

Packaging

Production

Shipping / Receiving

Form # VD1
Individual Case Safety Report

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 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 ≤0.05 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.
OTC

Form FDA 3500A (9/10)

Page 1 of 5

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event: 3 1/2 Months
   - Date of Birth:
   - In confidence:
3. Sex: Male
4. Weight: lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - 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): 05/04/2014
4. Date of This Report (mm/dd/yyyy): 06/20/2014
5. Describe Event or Problem

REPORTER STATES HER SON WOULD HAVE A DRY MOUTH AFTER GIVING THE TEETHING TABLET 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 STOPPINS.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & weight/labeler)
   - HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   - 1 TAB SL PRN, UP TO 4X/DY

3. Therapy Dates (if unknown, give duration) (from or best estimate)

4. Diagnosis for Use (Indication)
   - TEMP RELIEF TEETHING PAIN

5. Event Abated After Use Stopped or Dose Reduced?
   - Yes
   - No
   - Doesn't Apply

6. Lot #
   - 1827313
7. Exp. Date
   - #1

8. ND# or Unique ID
   - 54373-3127-3

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

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #

5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - 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, Enter Name and Address of Reprocessor

DSS
JUL 03 2014

E. INITIAL REPORTER
1. Name and Address
2. Health Professional?
   - Yes
   - No
3. Occupation
   - NA
4. Initial Reporter Also Sent Report to FDA
   - Yes
   - No
   - Unknown

JUL 02 2014

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.
The public reporting burden for this collection of information has been estimated to average 56 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.
CUSTOMER COMPLAINT RECORD

COMPLAINT #: 2553
DATE OF COMPLAINT: 06/19/14
ITEM CODE: BTET-T40
LOT NO.: B27313

RECEIVED
JUL 02 2014

CDR

NATURE OF COMPLAINT:
CAME BECAUSE SHE SAW SOMETHING ON FACEBOOK ABOUT THE PRODUCT BEING RECALLED AND IT
CAUSING SEIZURES IN CHILDREN. WANTED INFORMATION. AFTER PROVIDING SAFETY INFORMATION, SAID
THAT SHE NOTICED HER SON WOULD HAVE A DRY MOUTH AFTER GIVING THE TEETHING TABLETS TO HIM AND THAT HIS BODY INCLUDING LIMBS
WOULD SHAKE ALL OVER AND KEEP SHAKING. REPORTER 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. REPORTER STATES THIS OCCURRED EVERY TIME
SHE GAVE THE CHILD THE PRODUCT, UP TO FOUR TIMES PER DAY WHEN DOING THE PRODUCT, UNTIL SHE DISCONTINUED THE PRODUCT.
UNSURE OF THE EXACT NUMBER OF TIMES THE CHILD EXPERIENCED THESE SYMPTOMS. THE CHILD HAS NOT HAD A DRY MOUTH OR ANY
SHAKING SINCE STOPPING THE PRODUCT A FEW DAYS AGO. ADVISED REPORTER TO CONTACT THEIR PHYSICIAN TO DISCUSS SYMPTOMS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

INVESTIGATION
PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
06/19/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:
(b) (5)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON:
06/20/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-24-14

DATE: 06-23-14

cc: QA / QC
Production
Shipping / Receiving
Form # VD1
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 604 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 500 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.
A. PATIENT INFORMATION

1. Patient Identifier
   [Redacted]
2. Age at Time of Event: 10 Months
3. Sex: Male
4. Weight: [Redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defect/malfunction)

2. Outcomes Attributed to Adverse Event (Check all that apply)
   - Death: [Redacted]
   - Disability or Permanent Damage
   - 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) 06/24/2014
4. Date of This Report (mm/dd/yyyy) 06/25/2014

5. Describe Event or Problem
   CHILD WITH SEIZURE LIKE ACTIVITY THAT RESOLVED WHEN BABY TEETHING TABLETS WERE DISCONTINUED.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/batch)
   #1 HYLAND’S BABY TEETHING TABLETS
   #2

2. Dose, Frequency & Route Used
   #1 UNPROVOKED DOSE X 6 MONTHS
   #2

3. Therapy Dates (If unknown, give duration)
   #1 temp relief of teething pain
   #2

4. Diagnosis to Assess Use (Indication)
   #1 TEMP RELIEF OF TEETHING PAIN
   #2

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #
5. Lot #

6. If implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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

10. Device Available for Evaluation? (Do not send to FDA)
   Yes No Returned to Manufacturer:
   [Redacted]

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

E. INITIAL REPORTER

1. Name and Address
2. Health Professional?
3. Occupation: NA
4. Initial Reporter Also Sent 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.
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 40 TABLETS
REPORTER: [Redacted]
ADDRESS: 
CITY: 
STATE: 
COUNTRY: USA
ZIP CODE: 
PHONE #: 
E-MAIL: [Redacted]

NATURE OF COMPLAINT: CUSTOMER SENT EMAIL THAT HER CHILD HAD SEIZURE LIKE ACTIVITY WHILE USING HYLAND'S BABY TEETHING TABLETS. TOOK TO A NEUROLOGIST AND TESTS WERE NORMAL. SEIZURE ACTIVITY STOPPED AFTER BABY TEETHING TABLETS WERE DISCONTINUED. CUSTOMER SENT EMAIL THAT LOT # IS 827213 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 RECEIVED FOR INSPECTION: Y N (CIRCLE ONE) PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED: 
UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

DATE ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION: 06/24/2014
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
ADVERSE EVENT SERIOUS: Y N
ADVERSE EVENT REPORTED ON: 06/24/2014 BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 
DATE: 07-01-14

CC: QA / QC Packaging Production Shipping / Receiving

DATE: 07-01-14

JUL 10 2014

JUL 09 2014

Form # VD1.
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 50,000 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 within specification of 50 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 09 2014
SE EVENT DATA FORM

AE #: 1549

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: [Redacted]

ADDRESS: 

CITY: 
STATE: 

COUNTRY: USA
ZIP CODE: 

PHONE #: [Redacted]

E-MAIL: [Redacted]

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE,

AFFIX COPY OF OUTER CARTON HERE
INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ______________________ DATE: ______________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ______________________ DATE: 07-01-14

BY: ______________________ DATE: 07-01-14

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUL 09 2014
A. PATIENT INFORMATION

1. Patient Identifier (6)
2. Age at Time of Event: 7 Months
   or _________________________
   Date of Birth: ________________
   in confidence
3. Sex
   □ Male or ______ kg
   □ Female or ______ lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. 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
   □ Life-threatening
   □ Congenital Anomaly/Birth Defect
   □ Hospitalization - initial or prolonged
   □ Other Serious Medical Conditions
   □ Required intervention to prevent permanent damage

3. Date of Event (mm/dd/yyyy) 06/24/2014
4. Date of This Report (mm/dd/yyyy) 06/24/2014
5. Describe Event or Problem

CHILD HAS BEEN EXPERIENCING SEIZURES FOR THE PAST 4 MONTHS. DESCRIBED AS CHILD STARTS SHAKEING AND EYES ROLL BACK IN HIS HEAD.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength and manufacturer)
   #1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 TAB SL QD X 4 MONTHS

3. Therapy Dates (If unknown, give duration)
   #1
   #2

4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN

5. Event Abated After Use Stopped Or Does Reduced?
   #1 Yes No Doesn't Apply
   #2

6. Lot #
7. Exp. Date
   #1 850413
   #2

8. NDC or Unique ID
   #1 54973-3127-1
9. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:
   Catalog #
   Expiration Date (mm/dd/yyyy)
   Serial #
   Unique Identifier (UDI) #
   If Implanted, Give Date (mm/dd/yyyy)
   If Explanted, Give Date (mm/dd/yyyy)

6. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   □ Yes □ No
7. If Yes to Item No. 6, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
    □ Yes □ No □ Returned to Manufacturer on: ____________________________

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

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   □ Yes □ No

3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA
   □ Yes □ No □ Unknown

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.
## H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Event Type Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Death</td>
</tr>
<tr>
<td>Serious Injury</td>
<td>Serious Injury</td>
</tr>
<tr>
<td>Malfunetion</td>
<td>Malfunetion</td>
</tr>
</tbody>
</table>

### 3. Device Evaluated by Manufacturer

- [ ] Not Returned to Manufacturer
- [ ] Evaluation Summary Attached
- [ ] No (Attach page to explain why not) or provide code:

### 4. Device Manufacture Date

- [ ] (mm/dd/yyyy)

### 5. Labeled for Single Use?

- [ ] Yes
- [ ] No

### 6. Event Problem and Evaluation Codes (Refer to coding manual)

<table>
<thead>
<tr>
<th>Code</th>
<th>Code</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7. If Remedial Action Initiated, Check Type

- [ ] Recall
- [ ] Notification
- [ ] Repair
- [ ] Inspection
- [ ] Replace
- [ ] Patient Monitoring
- [ ] Relabeling
- [ ] Modification/Adjustment
- [ ] Other:

### 8. Usage of Device

- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

### 9. If product reported to FDA under 21 USC 360(k), list correction/removal reporting number:

- [ ]

## G. ALL MANUFACTURERS

### 1. Contact Office (and Manufacturing Site for Devices)

- **Name**: MARY E. FRACKELTON
- **Address**: HYLAND'S, INC.
  154 W. 131ST STREET
  LOS ANGELES, CA 90061
  **Email Address**: STANDARD@HYLANDS.COM

### 2. Phone Number

- 310-769-0700

### 3. Report Source (Check all that apply)

- [ ] Foreign
- [ ] Study
- [ ] Literature
- [ ] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

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

- 06/19/2014

### 5. IND, GLA Protocol #

- [ ] A5000

### 6. Type of Report

- [ ] 5-day
- [ ] 30-day
- [ ] 7-day
- [ ] Periodic
- [ ] 10-day
- [ ] Initial
- [ ] 15-day

### 7. Manufacturer Report Number

- 54973 AE # 1546

### 8. Adverse Event Terms

- SEIZURES

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**Section Note:** 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 56 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."
PRODUCT: HYLANUS BABY TEETHING TABLETS
SIZE: 135 TABLETS
REPORTER: 
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: 
E-MAIL: 

COMPLAINT #: 2556
DATE OF COMPLAINT: 06/19/14
ITEM CODE: BTET---T135
LOT NO.: B50413

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.
06/24/14 FOLLOW-UP: CONTACTED THE CUSTOMER FOR FOLLOW-UP INFORMATION AND SHE TOLD ME SHE HAD STOPPED BABY TEETHING TABLETS ON 06/19/14 AND THAT CHILD HAD A SEIZURE ON 06/24/14 THAT LASTED 10 SECONDS.

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT REPORTED ON: 06/19/14 
BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: 
DATE: 06.27.14

DSS JUL 09 2014

JUL 09 2014

cc: QA / QC Packaging
Production Shipping / Receiving

Form # VD1
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 (3) 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 (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 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

6/26/2014

Date

DSS
JUL 10 2014

JUL 09 2014
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier (6)

2. Age at Time of Event: 6 Months

3. Sex: Male

4. Weight: lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defect, malfunction, etc.)

2. Outcomes Attributed to Adverse Event

   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Other Serious (Important Medical Events)
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 05/24/2014

4. Date of This Report (mm/dd/yyyy): 06/24/2014

5. Describe Event or Problem

CHILD STARTED HAVING TREMORS FROM HEAD TO TOES [MINI SEIZURES] MEMORIAL DAY WEEKEND AND THE SEIZURES ARE COMING MORE FREQUENTLY, ALMOST ON DAILY BASIS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & refill below)
   #1: HYLAND'S TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1: 3 TABS QD X 2 MONTHS

3. Therapy Dates (If unknown, give duration from/to or [best estimate])
   #1:
   #2:

4. Diagnosis for Use (Indication)
   #1: TEMP RELIEF TEETHING PAIN

5. Event Aborted After Use Stopped or Dose Reduced?
   #1: Yes
   #2: No

6. Lot #
   #1: 109341

7. Exp. Date
   #1: 1
   #2: 2

9. NDC or Unique ID
   S4973-7504-1

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model#

5. Operator of Device
   Health Professional
   Lay User/Patient
   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, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
    Yes
    No
    Returned to Manufacturer on:

11. Concomitant Medical Products and Therapy Dates (Excludes treatment of event)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional? Yes

3. Occupation

4. Initial Report Also Sent Report to FDA
   Yes
   No
   Unk.
CALLER'S GRANDSON STARTED TEETHING IN MAY. THE WEEKEND OF MEMORIAL DAY CHILD STARTED HAVING TREMORS FROM HEAD TO TOE (MINI SEIZURES). SEIZURES COMING MORE FREQUENTLY ALMOST ON DAILY BASIS. EEG WAS SET UP. STILL HAVING SEIZURES AND GOT HIS FIRST TOOTH. GRANDMOTHER'S SON HAS SEIZURE DISORDER. DAUGHTER WAS GIVING 3 TABS EVERY DAY SINCE APRIL. LAST DOSE WAS YESTERDAY AFTER SHE SAW THE FACEBOOK POST. DOES NOT WANT A REFUND OR REPLACEMENT EVEN AFTER I OFFERED IT TO HER. SHE CONFIRMED THAT SHE PURCHASED THIS RECALLED BOTTLE AT WALMART IN FEBRUARY 2014. SHE WANTED TO READ LITERATURE ON THE 2010 RECALL OF HYLAND'S TEETHING TABLETS AND I DIRECTED HER TO THE FDA WEBSITE AND WWW.HYLAINES.COM. TOLD HER NOT TO USE THE TABLETS. TOLD HER THE REASONS FOR THE 2010 RECALL. TOLD HER THAT SHE HAS A RECALLED BOTTLE AND NOT TO USE. SHE SAID THAT SHE WILL NOT BE USING THE TABLETS.
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 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 [Signature]

Date: 6/27/14

DSS
JUL 10 2014

CC-0430-2014
AE-0245-2014
SAE 164

JUL 09 2014
Received
OCT 28 2014

CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, nephrological dysfunction, etc.)
NONE

(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.
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

3. Device Evaluated by Manufacturer?
   - Yes
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code.

4. Device Manufacture Date
   - (mm/dd/yyyy)

5. Labeled for Single Use?
   - 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
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modification
   - Adjustment
   - Other

8. Usage of Device
   - Initial Use of Device
   - Reuse
   - Returned
   - Unknown
   - Other

9. If action reported to FDA under 21 USC 386(k), list correction/ removal reporting number:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name
   - Address
   - Email Address

2. Phone Number
   - 310-769-9700

3. Report Source
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 30/06/2014

5. If IND, Give Protocol #
   - IND #
   - BLA #
   - PMA/ 510(k) #
   - Comb. Product
   - Yes
   - Pre-1538
   - Yes
   - OTC Product
   - Yes
   - 5-day
   - 30-day
   - Initial
   - 15-day
   - Follow-up #

6. Adverse Event Term(s)
   - SUICIDE LIKE ACTIVITY
   - SLEEPLESSNESS, CRYING, PUSSY

7. Manufacturer Report Number
   - 54973 AE # 1545

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."
CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 06/19/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET-T40

SIZE: 40 TABLETS LOT NO.: A79913

REPORTER:

ADDRESS:

CITY:

COUNTRY: USA

PHONE #: (b) (6)

EMAIL:

NATURE OF COMPLAINT:
TABLETS BECAME MOLDS. WAS GIVING 1 TABLET QD X 2 MONTHS. GAVE CHILD A FEW MOLDS 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 WAS SHAKING, EYES ROLLED BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN FLOSSY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING. CRYING. HER FRIENDS HAVE ALSO COMPLAINED ABOUT THE BABY TEETHING TABLETS BEING MOLDS, DID NOT WANT A REPLACEMENT, WANTS A REFUND FOR $4. WE WILL SEND A REFUND. DO NOT USE MOLDS TABLETS. CONTACT YOUR DOCTOR REGARDING THE SYMPTOMS. TOLD HER SHE HAS BEEN USING THE PRODUCT FOR LONGER THAN DIRECTED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION:

06/26/14: PREPARED REFUND REQUEST TOTALING $4.00. 07/19/14: MAILED REFUND CHECK # 811549 TOTALING $4.00.

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 06/19/14

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 07/16/14

DATE: 10-02-14

DATE: 09-30-14

QA / QC DIRECTOR

cc: QA / QC Packaging Production Shipping / Receiving

Form # VDI1
June 26, 2014

Dear [Name],

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,

[Signature]

Dan Krombach
President

Enc: Refund Check - $4.00
CUSTOMER COMPLAINT RECORD

SECTION: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 06/19/14
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: 8TET-T40
SIZE: 40 TABLETS
LOT NO.: A79613
REPORTER:
ADDRESS:
CITY:
STATE:
COUNTRY: USA
ZIP CODE:
PHONE #:
E-MAIL:

NATURE OF COMPLAINT:
TABLETS BECAME MOLDY. WAS GIVING 1 TABLET QD X 2 MONTHS. 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 WAS SHAKING, EYES ROLLED IN BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP, HAS BEEN ACTING WEIRD SINCE THEN FLUSHY, AND EVERY OTHER NIGHT WAKING UP IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING. HER FRIENDS HAVE ALSO COMPLAINED ABOUT THE BABY TEETHING TABLETS BEING MOLDY. DID NOT WANT A REPLACEMENT, WANTS A REFUND FOR $4. WE WILL SEND A REFUND. DO NOT USE MOLDY TABLETS. CONTACT YOUR DOCTOR REGARDING THE SYMPTOMS. TOLD HER SHE HAS BEEN USING THE PRODUCT FOR LONGER THAN DIRECTED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 06/19/14
BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 06-27-14

AE #: 1545

DATE: OCT 24 2014

DATE: OCT 23 2014

DSS

OCT 24 2014

OCT 23 2014

DATE: 06-27-14

DATE: 06-27-14

QA / QC DIRECTOR

cc: QA / QC Packaging Production Shipping / Receiving Form #: VD1
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 69(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 within specification of 0(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 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

Date

Individual Case Safety Report

OCT 24 2014

OCT 23 2014
ADVERSE EVENT DATA FORM

Initiated By: EDYTA FRACKIEWICZ

Date: 6/19/2014

AE #: 1545

Complaint #: 2555

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & mf/labeled)
   #1 HYLAND'S BABY TEETHING TABLETS
   #2

2. Dose, Frequency & Route Used
   #1 1 TABLET EVERY DAY OR TWICE A DAY X 2 MONTHS
   #2

D. INITIAL REPORTER
1. Name and Address

2. Health Professional? No
3. Occupation MOTHER

4. Initial Reporter Also Sent Report to FDA Yes

5. All MANUFACTURERS

HYLANDS, INC.
210 W. 131ST STREET
LOS ANGELES, CA, 90061

6. Contact Office - Name/Address

7. Phone Number 310-766-0700

8. Report Source

   (Check all that apply)
   [ ] Foreign
   [ ] Study
   [ ] Literature
   [ ] Consumer
   [ ] Health Prof.
   [ ] User Facility
   [ ] Company Rep
   [ ] Distributor
   [ ] Other:

9. Manufacturer Report Number (AE #)

   54573 AE # 1545

FORM AE 01

A. PATIENT INFORMATION
1. Patient Identifier (In confidence)

2. Age at Time of Event: 1 YEAR OLD

3. Sex
   [ ] Female
   [ ] Male

4. Weight: lbs.

D. INITIAL REPORTER
5. All MANUFACTURERS

HYLANDS, INC.
210 W. 131ST STREET
LOS ANGELES, CA, 90061

6. Contact Office - Name/Address

7. Phone Number 310-766-0700

8. Report Source

   (Check all that apply)
   [ ] Foreign
   [ ] Study
   [ ] Literature
   [ ] Consumer
   [ ] Health Prof.
   [ ] User Facility
   [ ] Company Rep
   [ ] Distributor
   [ ] Other:

9. Manufacturer Report Number (AE #)

   54573 AE # 1545

FORM AE 01

A. PATIENT INFORMATION
1. Patient Identifier (In confidence)

2. Age at Time of Event: 1 YEAR OLD

3. Sex
   [ ] Female
   [ ] Male

4. Weight: lbs.

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event
2. Product Problem

3. Outcomes Attributed to Adverse Event (Check all that apply)
   [ ] Death
   [ ] Life-threatening
   [ ] Disability or Permanent
   [ ] Congenital Anomaly/Birth
   [ ] Defect
   [ ] Other Serious (Important
   [ ] Medical Events)
   [ ] Required intervention to Prevent
   [ ] Permanent Impairment/
   [ ] Damage (Devices)

4. Date of Event (mm/dd/yyyy)
   06/12/2014

5. Date Submitted to FDA (mm/dd/yyyy)
   06/19/2014

6. Required intervention to Prevent
   Permanent Impairment/
   Damage (Devices)

7. Time of Event:

8. Pre-existing Conditions / Diagnosis:
   NONE

9. 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, CRYING.
MEDWATCH
FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION
1. Patient Identifier (Rx): [Redacted]

2. Age at Time of Event: 1 years
   Date of Birth: 06/12/2014

3. Sex: Female

4. Weight: 15 lbs
   or
   kg

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event and/or Product Problem (e.g., defect, malfunction)
   [Redacted]

2. Outcomes Attributed to Adverse Event (Check if this applies)
   - Death
   - Disability or Permanent Damage
   - Life-threatening (within 30 days)
   - 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): 06/12/2014 - 06/19/2014
4. Date of This Report (mm/dd/yyyy): 06/24/2014

5. Describe Event or Problem
   GAVE CHILD A FEW MOLDY TABLETS (I TAB AM AND I 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 BACK OF HEAD, WOULD NOT STOP CRYING, WOULD NOT GO TO SLEEP. HAS BEEN ACTING WEIRD SINCE THEN - FUSSY, AND EVERY OTHER NIGHT WAKING IN THE MIDDLE OF THE NIGHT SHAKING, EYES ROLLING BACK OF HEAD, NOT SLEEPING, CRYING.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength and/or tab/label)
   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 TAB QD OR BTD X 2 MOS.
   #2

3. Therapy Dates (if unknown, give duration) (from info or best estimate)
   #1
   #2

4. Diagnosis for Use (Indicator)
   #1 TEMP RELIEF TEETHING PAIN

5. Event Aborted After Use Stopped or Dose Reduced?
   Yes

6. Lot #
   #1 A79913
   #2

7. Exp. Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   No

9. NDC# or Unique ID
   54973-3127-3

10. Concomitant Medical Products and Therapy Dates (Exclude repeated events)

D. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Lot #

6. Operator of Device
   [Redacted]

7. Catalog #

8. Expiration Date (mm/dd/yyyy)

9. If implanted, Give Date (mm/dd/yyyy)

10. If Explanted, Give Date (mm/dd/yyyy)

11. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   Yes

12. If Yes to Item No. 11, Enter Name and Address of Reprocessor

E. INITIAL REPORTER
1. Name and Address
   [Redacted]

2. Health Professional?
   Yes

3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA
   Yes

(Continue on page 3)
### H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - [ ] Death
   - [ ] Severe 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
   - [ ] No
   - [ ] (Attach page to explain why not or provide code)

4. **Device Manufacturer Date (mm/dd/yyyy)**

5. **Label for Single Use?**
   - [ ] Yes
   - [ ] No

6. **Event Problem and Evaluation Codes (Refer to coding manual)**
   - **Patient Code**
   - **Device Code**
   - **Method**
   - **Results**
   - **Conditions**

7. **If Remedial Action Initiated, Check Type**
   - [ ] 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 351(e), attach correction removal reporting number:**

### G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
   - **Name:** EDYTA FRACKiewicz
   - **Address:** MYLAND'S, INC.
     154 W. 131ST STREET
     LOS ANGELES, CA 90061
   - **Email Address:** STDARDDHYLAND.COM

2. **Phone Number**
   - 310-766-0700

3. **Report Source (Check all that apply)**
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

4. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 06/19/2014

5. **IND #**
   - [ ] ANDA #
   - [ ] IND #
   - [ ] BIA #
   - [ ] PMA/510(k) #

6. **Type of Report (Check all that apply)**
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
   - [ ] Initial
   - [ ] 15-day
   - [ ] Follow-up #

7. **Manufacturer Report Number**
   - 54973 AE # 1545

8. **Adverse Event Term(s)**
   - SEIZURE LIKE ACTIVITY
   - SLEEPLESSNESS
   - CRYING
   - FUSSY

---

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
PRASstaff@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.
**FORM FDA 3500A (2/13)**

### A. PATIENT INFORMATION

1. **Patient Identifier**
   - (b) (6)

2. **Age at Time of Event:**
   - 2 Years

3. **Sex**
   - Male

4. **Weight**
   - lbs

5. **Date of Birth:**

6. **Adverse Event or Product Problem**
   - Yes
   - No

7. **Outcomes Attributed to Adverse Event**
   - (Check all that apply)
   - Severity
   - [ ] Disability or Permanent Damage
   - [ ] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Other Serious (Important Medical Events)
   - [ ] Required intervention to Prevent Permanent Impairment/Damage (Devices)

8. **Date of Event**
   - 06/06/2014

9. **Date of This Report**
   - 06/26/2014

10. **Describe Event or Problem**
    - CHILD WITH SPEECH DELAY REQUIRES THERAPY.

### C. SUSPECT PRODUCT(S)

1. **Name**
   - (Give generic strength & manufacturer)
   - HYLANO'S BABY TEETHING TABLETS

2. **Dose, Frequency & Route Used**
   - UNKNOWN DOSE FOR 1 YEAR

3. **Therapy Dates**
   - (If unknown, give duration from (best estimate)

4. **Diagnosis for Use (Indication)**
   - TEMP RELIEF TEETHING PAIN

5. **Event Abated After Use Stopped or Dose Reduced?**
   - Yes
   - No

6. **Lot #**

7. **Event Reappeared After Reintroduction?**
   - Yes
   - No

8. **NDC or Unique ID**
   - 54973-3127-3

9. **Concomitant Medical Products and Therapy Dates**
   - (Exclude treatment of event)

### D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

3. **Manufacturer Name, City and State**

4. **Model #**

5. **Lot #**

6. **Catalog #**

7. **Serial #**

8. **Operator of Device**
   - Health Professional
   - Lay User/Patient
   - Other

9. **If Implanted, Give Date**

10. **If Explanted, Give Date**

11. **Other Relevant History, Including Preexisting Medical Conditions**
    - Allergies
    - Race
    - Pregnancy
    - Smoking
    - Alcohol use
    - Hepatitis
    - Dysfunction

### E. INITIAL REPORTER

1. **Name and Address**

2. **Health Professional?**

3. **Occupation**

4. **Initial Reporter Also Sent 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.
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

3. Device Evaluated by Manufacturer?
   - No
   - Yes
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code.

4. Device Manufacture Date
   (mm/dd/yyyy)

5. Labeled for Single Use?
   - 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
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modification/Adjustment
   - Other:

8. Usage of Device
   - Initial Use of Device
   - Repair
   - Reuse
   - Unknown
   - Other:

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

10. Additional Manufacturer Narrative
    and/or

11. Corrected Data

---

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 96 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
PRASstaff@fas.hhs.gov

Please DO NOT RETURN this form to the above PRA Staff e-mail address.
COMPLAINT #: 2558
DATE OF COMPLAINT: 06/22/14
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET
SIZE: NOT PROVIDED
LOT NO.: NOT PROVIDED
REPORTER: [Redacted]
ADDRESS: [Redacted]
CITY: [Redacted] STATE: [Redacted]
COUNTRY: USA ZIP CODE: [Redacted]
PHONE #: [Redacted]
E-MAIL: [Redacted]
NATURE OF COMPLAINT: MOTHER SENT E-MAIL THAT CHILD USING TEETHING TABLETS FROM BIRTH TO ONE YEAR OF AGE. CHILD 2 YEARS OLD AND HAS BAD SPEECH DELAY AND GOING TO THERAPY. MOTHER DID NOT RESPOND TO E-MAIL SENT BY PHARMACIST AND DID NOT CALL CELL PHONE OF PHARMACIST.

FOR ADDITIONAL SPACE PLEASE USE 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: [Redacted]
UPS CALL TAG ISSUED: Y (CIRCLE ONE) DATE PRODUCT RECEIVED: [Redacted]

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/22/14
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION
CORRECTIVE ACTION(S) COMPLETED BY: [Redacted] DATE: [Redacted]

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 06/22/14 BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: [Redacted] DATE: 06-30-14
BY: [Redacted] DATE: 06-30-14

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VO1

DSS JUL 11 2014

QA / QC DIRECTOR

JUL 10 2014
AE #: 1548
COMPLAINT #: 2558

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (Redacted)
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: (Redacted)
E-MAIL: (Redacted)

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: JUL 11 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: 
DATE: 06-30-14

BY: 
DATE: 06-30-14

DSS
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 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 0.0 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
JUL 11 2014
A. PATIENT INFORMATION
1. Patient Identifier (b) (6) [Confidential]
2. Age at Time of Event: 13 Months
3. Sex: □ Female □ Male
4. Weight: □ lbs □ kg
   In Confidence
B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event and/or □ Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   □ Death: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ 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) 06/25/2014
4. Date of This Report (mm/dd/yyyy) 06/30/2014
5. Describe Event or Problem
   CUSTOMER POSTED ON (b) (6) THAT ON WED JUNE 25TH 20 MIN
   AFTER GIVE HER 13 MONTH OLD 2 TEETHING TABLETS WENT
   INTO SEIZURE. SINCE THEN HE'S HAD HIGH FEVERS, VOMITING,
   RAPID HEARTBEAT, MUSCLE WEAKNESS, RASH, DAZED/CONFUSION,
   IRRITABILITY, Tiredness, Lethargy.

JUL 16 2014

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepaticorenal dysfunction, etc.)
   UNKNOWN

(Continue on page 3)

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & mfr/labeler)
   #1 HYLAND'S BABY TEETHING TABLETS
   #2
2. Dose, Frequency & Route Used
   #1 2 TABS ON 06/25/14
   #2
3. Therapy Dates (If unknown, give duration in years or best estimate)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN
   #2
5. Event Altered After Use Stopped or Dose Reduced?
   #1 Yes #2 No
   #1 Doesn't Apply
6. Lot #
   #1
   #2
7. Exp. Date
   #1
   #2
8. NDC# or Unique ID
   54973-3127-3
9. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

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
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:
   Catalog #
   Explication Date (mm/dd/yyyy)
   □ Yes □ No
   □ Doesn't Apply
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
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)
2. Health Professional? □ Yes □ No
3. Occupation
   NA
4. Initial Reporter Also Sent Report to FDA
   □ Yes □ No □ Unknown
   USA

(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.
Individual Case Safety Report

1. Check Box
   - User Facility
   - Importer

2. U/S/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report
   - Initial
   - Follow-up #

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

9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)

Patient Code
Device Code

11. Report Sent to FDA?
   - Yes (mm/dd/yyyy)
   - No

12. Location Where Event Occurred
   - Hospital
   - Outpatient Diagnostic Facility
   - Home
   - Ambulatory Surgical Facility
   - Nursing Home
   - Other...

13. Report Sent to Manufacturer?
   - Yes (mm/dd/yyyy)
   - No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS
1. Contact Office (and Manufacturing Site for Devices)
2. Phone Number
3. Report Source
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other

4. Date Received by Manufacturer (mm/dd/yyyy)
5. IND #
6. BLA #

7. Type of Report
   - Combination Product
   - Pre-1538
   - QTC Product

8. Adverse Event Term(s)
   - Seizure, fevers, vomiting, tachycardia, muscle weakness, rash, confusion, irritability, lethargy

9. Manufacturer Report Number
10. Additional Manufacturer Narrative
11. Corrected Data

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

3. Device Evaluated by Manufacturer?
   - Yes
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - Yes
   - No

6. Event Problem and Evaluation Codes (Refer to coding manual)
   - Patient Code
   - Device Code

7. If Remedial Action Initiated, Check Type
   - 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 380(f), list correction/ removal reporting number:

10. Corrected Data:

   DSS
   Jul 17 2014

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
FRASIAF@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA address.
Individual Case Safety Report

COMPLAINT RECORD

COMPLAINT #: 2962
DATE OF COMPLAINT: 06/30/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET

SIZE: UNKNOWN
LOT NO.: UNKNOWN

REPORTER: (b) (6) UNKNOWN
ADDRESS: 

CITY: 
STATE: 
ZIP CODE: 

COUNTRY: 
PHONE #: NOT PROVIDED
E-MAIL: 

NATURE OF COMPLAINT: CUSTOMER POSTED ON (b) (6) ON WED JUNE 26TH, 20 MIN AFTER GIVING HER 13 MONTH OLD 2 TEETHING TABLET WENT INTO SEIZURE. SINCE THEN HE'S HAD HIGH FEVERS, VOMITING, RAPID HEARTBEAT, MUSCLE WEAKNESS, RASH, DAZED/CONFUSION, IRRITABILITY, TIREDNESS, LETHARGY. IS IT YOUR PRODUCT THAT HAS CAUSED THIS. CUSTOMER DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT THE COMPANY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) PRODUCT BEING RETURNED FOR INSPECTION: N (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 pharmacist/nurse for evaluation on 

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

ADVERSE EVENT SERIOUS: Y: N

ADVERSE EVENT REPORTED ON: 06/30/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: 

DATE: 07-08-14

BY: (Signature)
QA/QC DIRECTOR

DSS JUL 17 2014

07-08-14

CC: QA/QC
Production
Packaging
Shipping/Receiving

Form # 01

JUL 16 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 Scopalamine levels and was found to meet the specification of 500 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:  
Date: 07-07-14

DSS  
JUL 17 2014  
Page 1 of 1
Individual Case Safety Report

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

FORM FDA 3500A (2/13)

Page 1 of 5

C. SUSPECT PRODUCT(S)

1. Name (Give labeled and other information):
   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   INTERMITTENTLY Q 3-4 HRS

3. Therapy Dates (If unknown, give duration)
   #1

4. Diagnosis for Use (Indication)
   TEMP RELIEF OF TEETHING PAIN

5. Event Altered After Use
   Yes

6. Lot #
   #1

7. Exp. Date
   #1

8. NDC or Unique ID
   54973-3127-1

9. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
   UNKNOWN NAUSEA AND VOMITING MEDICATION (ONE DOSE)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   Health Professional

6. Catalog #

7. Expiration Date (mm/dd/yyyy)

8. Serial #

9. Unique Identifier (UDI) #

10. Device Available for Evaluation? (Do not send to FDA)

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

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional? Yes

3. Occupation NA

4. Initial Reporter Also Sent Report to FDA Yes

(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.
<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)</strong></td>
<td>1. Check One&lt;br&gt; - User Facility&lt;br&gt; - Importer&lt;br&gt; 2. UF/Importer Report Number&lt;br&gt; 3. User Facility or Importer Name/Address&lt;br&gt; 4. Contact Person&lt;br&gt; 5. Phone Number&lt;br&gt; 6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)&lt;br&gt; 7. Type of Report&lt;br&gt; - Initiate&lt;br&gt; - Follow-up #&lt;br&gt; 8. Event Problem Codes (Refer to coding manual)&lt;br&gt; 9. Approximate Age of Device&lt;br&gt; 10. Patient Code&lt;br&gt; 11. Report Sent to FDA?&lt;br&gt; - Yes (mm/dd/yyyy)&lt;br&gt; - No (mm/dd/yyyy)&lt;br&gt; 12. Location Where Event Occurred&lt;br&gt; - Hospital&lt;br&gt; - Outpatient Diagnostic Facility&lt;br&gt; - Home&lt;br&gt; - Nursing Home&lt;br&gt; - Outpatient Treatment Facility&lt;br&gt; - Other: (Specify)&lt;br&gt; 13. Report Sent to Manufacturer?&lt;br&gt; - Yes (mm/dd/yyyy)&lt;br&gt; - No (mm/dd/yyyy)&lt;br&gt; 14. Manufacturer Name/Address&lt;br&gt;</td>
</tr>
<tr>
<td><strong>G. ALL MANUFACTURERS</strong></td>
<td>1. Contact Office (and Manufacturing Site for Devices)&lt;br&gt; - Name&lt;br&gt; - Address&lt;br&gt; 2. Phone Number&lt;br&gt; - 310-768-0700&lt;br&gt; 3. Report Source (Check all that apply)&lt;br&gt; - Foreign&lt;br&gt; - Study&lt;br&gt; - Literature&lt;br&gt; - Consumer&lt;br&gt; - Health Professional&lt;br&gt; - User Facility&lt;br&gt; - Company Representative&lt;br&gt; - Distributor&lt;br&gt; - Other: (Specify)&lt;br&gt; 4. Date Received by Manufacturer (mm/dd/yyyy)&lt;br&gt; - 36/25/2014&lt;br&gt; 5. If IND, Give Protocol #&lt;br&gt; - IND #&lt;br&gt; - BLA #&lt;br&gt; - MA #&lt;br&gt; - Other: (Specify)&lt;br&gt; 6. Type of Report (Check all that apply)&lt;br&gt; - 5-day&lt;br&gt; - 7-day&lt;br&gt; - 10-day&lt;br&gt; - 15-day&lt;br&gt; - Initial&lt;br&gt; 7. Manufacturer Report Number&lt;br&gt; - 54973 AE # 1551&lt;br&gt; 8. Adverse Event Term(s)&lt;br&gt; - SEIZURES&lt;br&gt;</td>
</tr>
<tr>
<td><strong>H. DEVICE MANUFACTURERS ONLY</strong></td>
<td>1. Type of Reportable Event&lt;br&gt; - Death&lt;br&gt; - Serious Injury&lt;br&gt; - Malfunction&lt;br&gt; 2. If Follow-up, What Type?&lt;br&gt; - Correction&lt;br&gt; - Additional Information&lt;br&gt; - Response to FDA Request&lt;br&gt; - Device Evaluation&lt;br&gt; 3. Device Evaluated by Manufacturer?&lt;br&gt; - Yes&lt;br&gt; - Evaluation Summary Attached&lt;br&gt; - No (Attach page to explain why not or provide code)&lt;br&gt; 4. Device Manufacture Date (mm/dd/yyyy)&lt;br&gt; 5. Labeled for Single Use?&lt;br&gt; - Yes&lt;br&gt; - No&lt;br&gt; 6. Event Problem and Evaluation Codes (Refer to coding manual)&lt;br&gt; - Patient&lt;br&gt; - Code&lt;br&gt; - Device&lt;br&gt; - Code&lt;br&gt; 7. If Remedial Action Initiated, Check Type&lt;br&gt; - Recall&lt;br&gt; - Notification&lt;br&gt; - Repair&lt;br&gt; - Inspection&lt;br&gt; - Replace&lt;br&gt; - Patient Monitoring&lt;br&gt; - Relabeling&lt;br&gt; - Modification/Adjustment&lt;br&gt; - Other: (Specify)&lt;br&gt; 8. Usage of Device&lt;br&gt; - Initial Use of Device&lt;br&gt; - Reuse&lt;br&gt; - Unknown&lt;br&gt; 9. If action reported to FDA under 21 USC 360.1(f), list correction/removal reporting number&lt;br&gt; 10. Additional Manufacturer Narrative and/or 11. Corrected Data&lt;br&gt;</td>
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**DSS**<br> JUL 18 2014

**JUL 17 2014**

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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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRStat@FDA.HHS.gov
Please DO NOT RETURN this form to the above PRA Staff email address.
**I. COMPLAINT RECORD**

**COMPLAINT #:** 2661  
**DATE OF COMPLAINT:** 06/25/14  
**PRODUCT:** HYLAND'S BABY TEETHING TABLETS  
**ITEM CODE:** BTET-T136  
**SIZE:** 135 TABLETS  
**LOT NO.:** DOESN'T HAVE BOTTLE  
**REPORTER:**  
**ADDRESS:**  
**CITY:**  
**COUNTRY:** USA  
**PHONE #:**  
**E-MAIL:**  
**STATE:**  
**ZIP CODE:**  

**NATURE OF COMPLAINT:**  
MOTHER / REPORTER CALLED THE PIS PHONE LINE TO DISCUSS THE TEETHING TABLET RUMOR. ONE OF HER CHILDREN HAD A SEIZURE EPISODE THAT OCCURRED IN JULY 2013.  
THE NATURE OF THE INCIDENT TOOK PLACE AT THE Placeholder:  
PLACEHOLDER, WHICH COINCIDED WITH THE USE OF BABY TEETHING TABLETS. NOW SHE IS CALLING BECAUSE THE REPORTER HAS 2 YOUNGER CHILDREN (OTHER THAN THE ACTUAL PATIENT) AND SHE WANTS TO CONSIDER PURCHASING THE TEETHING TABLETS FOR THEM BUT HAS RECENTLY HEARD ABOUT SEIZURE RUMORS AND NOW MOTHER ALSO WONDERS IF THIS COULD HAVE BEEN RELATED TO HER CHILD'S SEIZURE IN JULY 2013. THE BABY'S SEIZURES OCCURRED EARLY IN THE MORNING AND EACH EPISODE GOT PROGRESSIVELY WORSE. THE MOTHER TOOK HER BABY TO THE HOSPITAL AND THE BABY CONTINUED TO HAVE SEIZURES IN THE HOSPITAL. CHILD WAS HOSPITALIZED FOR 4 DAYS. MOTHER STATES THAT BABY WAS 'PUKING' AND WENT TO  
HOSPITAL THE DAY BEFORE. BABY TOOK NAUSEA AND VOMITING MEDICINES. NEXT DAY SHE HAD SEIZURE. NAUSEA VOMITING MEDICINE IS UNKNOWN. BABY HAS JUST ONE DOSE. MOTHER WAS SICK AS WELL. MOTHER RECALLS THAT THE BABY DIDN'T FEEL TOO WARM AND STATED MAYBE 96 TO 100 DEGREES TEMPERATURE. BABY NOW HAS SEIZURE MEDICINE ON HAND - DIAPAM 5 MG SUPPOSITORIES AS NEEDED. NO SEIZURES SINCE ORIGINAL EPISODE. NO OTHER MEDICAL CONDITIONS. EEG - NORMAL. FOLLOW-UP 1 MONTH LATER WAS "NOTHING ELSE WRONG"; FOLLOW-UP IN 1 YEAR AND SO FROM THERE. NO KNOWN DRUG ALLERGIES. NO KNOWN ENVIRONMENTAL ALLERGIES. NO KNOWN FOOD ALLERGIES.  

**FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET**

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<tr>
<th>PRODUCT RECEIVED FOR INSPECTION:</th>
<th>Y</th>
<th>N</th>
<th>PRODUCT BEING RETURNED FOR INSPECTION:</th>
<th>Y</th>
<th>N</th>
<th>DATE REQUESTED PRODUCT BE RETURNED:</th>
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<td><strong>UPS CALL TAG ISSUED:</strong></td>
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<td><strong>DATE PRODUCT RECEIVED:</strong></td>
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**SECTION II: INVESTIGATION**

**INVESTIGATION:** PLEASE SEE ATTACHED INVESTIGATION REPORT.  

**JUL 16 2014**

**ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:**  
06/25/14  

**ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:**  
(d) (6)  

**SECTION III: CORRECTIVE ACTION**

**CORRECTIVE ACTION(S) COMPLETED BY:**  

**SECTION IV: ADVERSE EVENT REPORTS**

**ADVERSE EVENT SERIOUS:** Y | N  
**ADVERSE EVENT REPORTED ON:**  
06/25/14  

**SECTION V:**

**REVIEWED BY MANAGEMENT BY:**  

**BY:**  

**DATE:**  

**DSS JUL 18 2014**

**SECTION VI:**

**REVIEWED BY MANAGEMENT BY:**  

**DATE:**  

**DATE:** 07-07-14  

**DATE:** 07-03-14  

**cc: QA / QC Packaging Production Shipping / Receiving**

**Form #: V01**
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 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 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.
ADVERSE EVENT DATA FORM

AE #: 1551
COMPLAINT #: 2561

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V21)

NAME: 
ADDRESS: 
CITY: 
COUNTRY: USA 
PHONE #: 
E-MAIL: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV:
REVIEWED BY MANAGEMENT BY: 
DATE: 07-07-14
BY: 
DATE: 07-07-14

DISTRIBUTION: FDA ADVERSE EVENT FILE
FORM SA201
Individual Case Safety Report

LUNTARY reporting of serious, product problems and product use errors

A. PATIENT INFORMATION
1. Patient Identifier (b) (c) 
2. Age at Time of Event or Date of Birth: 
   6 Months
3. Sex: 
   Male
4. Weight: 
   18 lb
   or _______ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects, malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

Outcomes Attributed to Adverse Event
1. Death: 
2. Disability or Permanent Damage
3. Life-threatening
4. Congenital Anomaly/Birth Defect
5. Hospitalization - initial or prolonged
6. Other Serious (Important Medical Events)
7. Required Intervention to Prevent Permanent Impairment/Damage (Devices)

Date of Event (mm/dd/yyyy): 12/25/2006
Date of this Report (mm/dd/yyyy): 07/31/2014

5. Describe Event, Problem or Product Use Error
   When my son, (b) (c) (b) (c) was an infant, we used Gracie and found that it didn't work quite well. I started using Hyland's Teething Tablets, which seemed to help his teething pains. On (b) (c) (b) (c) he started experiencing seizures. He has used several different seizure medications, prescribed by several different doctors. He has undergone MRI, EEG, EKG and other medical testing. There is no neurological abnormalities. Doctors diagnosed him with Generalized Epilepsy with Febrile Seizures. (19 Febrile seizures, 13 Epileptic Seizures.)

6. Relevant Tests/Laboratory Data, Including Dates
   MRI- 2013 EEG- ...

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, fuse, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
   Race: White
   For additional information see #7 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)
   Name: teething tablets
   Strength: Hyland's Teething Tablets
   Manufacturer:

2. Name: 
   Strength: 
   Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name
   CTU

2. Common Device Name

3. Manufacturer Name, City and State
   AUG - I 2014

4. Model #
5. Operator of Device
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ Other:

6. Catalog #
7. Expiration Date (mm/dd/yyyy)

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Expired, 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 8, Enter Name and Address of Reprocessor

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
   (b) (c)

2. Phone #
3. E-mail
   (b) (c)

4. Also Reported to:
   ☐ Manufacturer
   ☐ User Facility
   ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

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

Individual Case Safety Report
8.7. 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 15mg Adderall 15mg Clonidine 0.1mg

OFC Meds:

Individual Case Safety Report

10359541-01-00-03

DSS
AUG 01 2014
A. PATIENT INFORMATION

1. Patient Identifier (b)(6)

2. Age at Time of Event: 9 Months

3. Sex: Female

4. Weight: lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/ malfunctions)

2. Outcomes Attributed to Adverse Event

   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Hospitalization - Initial or Prolonged
   - Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy):
   04/09/2013 -- 06/09/2014

4. Date of This Report (mm/dd/yyyy):
   07/25/2014

5. Describe Event or Problem

CHILD SUFFERING FROM SEIZURES SINCE APRIL 2013 DIAGNOSED AS FEBRILE IN ORIGIN. MOTHER STATES THAT OCCURRENCE OF SEIZURES COINCIDES WITH DOSSING OF BABY TEETHING TABLETS. SINCE DISCONTINUING BABY TEETHING TABLETS CHILD HAS NOT HAD A SEIZURE IN THE PAST 1.5 MONTHS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & concentrate)

   a. RYLAND’S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

   a. UNKNOWN DOSE X 1 YEAR

3. Therapy Dates (If unknown, give duration from onset (or best estimate))

   a. #1

4. Diagnosis for Use (Indication)

   a. TEMP RELIEF TEETHING PAIN

5. Event Altered After Use

   a. Yes [ ] No [ ] Doesn't Apply

6. Lot #

7. Exp. Date

   a. #1

8. NGO or Unique ID

   54973-3127-1

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

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

3. Manufacturer Name, City and State

4. Model #

5. Lot #

6. Operator of Device

   - Health Professional
   - Lay User/Patient
   - Other

7. If Implanted, Give Date (mm/dd/yyyy)

8. If Explanted, Give Date (mm/dd/yyyy)

9. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

   [ ] Yes [ ] No

10. If Yes to Item 9, Enter Name and Address of Reprocessor

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

2. Health Professional?

   [ ] Yes [ ] No

3. Occupation

   NA

4. Initial Reporter Also Sent Report to FDA

   [ ] Yes [ ] No [ ] Link

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)

1. Check One  
   - [ ] User Facility  
   - [ ] Importer

2. U/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

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

7. Type of Report
   - [ ] Initial
   - [ ] Follow-up #

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
    - Patient Code
    - Device Code

11. Report Sent to FDA?  
    - [ ] Yes (mm/dd/yyyy)
    - [ ] No

12. Location Where Event Occurred  
    - Hospital
    - Nursing Home
    - Other:

13. Report Sent to Manufacturer?  
    - [ ] Yes (mm/dd/yyyy)
    - [ ] No

14. Manufacturer Name/Address

### G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - [ ] 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:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 07/23/2014

5. IND #

6. BLA #

7. Type of Report (Check all that apply)
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] 10-day  
   - [ ] 15-day  
   - [ ] Other:

8. Manufacturer Report Number
   - [ ] 54373 AE # 1554

9. Adverse Event Term(s)
   - [ ] SEIZURES

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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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASuppress@hsph.harvard.edu  

Please DO NOT RETURN this form to the above PRA Staff email address.
Individual Case Safety Report

COMPLAINT RECORD

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)
ADDRESS:

CITY: 
STATE: (b)(6)
COUNTRY: USA
ZIP CODE: 
PHONE #: (b)(6)
E-MAIL: (b)(6)

CUSTOMER SENT THE FOLLOWING E-MAIL BUT DID NOT RESPOND TO HYLAND'S E-MAIL: MESSAGE: I THOUGHT I WOULD SEND YOU A MEMO ABOUT MY CHILD, MY CHILD HAS BEEN SUFFERING FROM FEBRILE SEIZURES SINCE 04/13 - 9 MONTHS OLD. I CONTINUED TO GIVE HIM TEETHING TABLETS DURING HIS TEETHING ESP DURING THE MONTH OF JULY BECAUSE HE WAS TEETHING, WELL HE WAS HAD ABOUT 4 SEIZURES IN THAT MONTH. THEY KEPT SAYING IT WAS HIS EARS AND EAR INFECTIONS. IN SEPTEMBER WE GOT TUBES IN HIS EARS AFTER HE GOT SICK AGAIN AND HAD A SEIZURE THAT LAST ALMOST AN HOUR. HE STILL CONTINUED TO HAVE SEIZURES. WELL HE STARTED HAVING SEIZURES AGAIN IN APRIL. AND I KNOW I HADN'T BEEN PUSHING TEETHING TABLETS ON HIM AS MUCH PRIOR TO THAT CUZ HE REALLY WASN'T TEETHING MUCH. WELL HE ENDED UP HAVING TWO MORE SEIZURES IN MAY AND JUNE... BUT EACH TIME I REMEMBER GIVING HIM TEETHING TABLETS WITHIN 24 HOURS PRIOR TO. SO I DECIDED TO DO A TRIAL AND ERROR AND THROW AWAY THE BOTTLES... AND WE ARE A MONTH AND A HALF FREE OF SEIZURES... AND HE IS NOW 2 YEARS OLD. I'M NOT SUING YOU IN ANY MEANS BUT I WILL CONTINUE TO WORK ON THIS TRIAL... IF HE HAS ANOTHER SEIZURE THEN I WILL CRASH MY THEORY BUT RIGHT NOW... I AM HAPPY NOT SEEING MEDICAL BILLS FOR EVERYTIME WE WERE GOING FOR THE SEIZURES. CHILD'S GRANDMOTHER HAD SEIZURES 40 YEARS AGO PRIOR TO BEING DIAGNOSED WITH CRONEN'S DISEASE. CHILD'S AUNT HAD A SEIZURE AT THE AGE OF 3 AS A RESULT OF AN ILLNESS THAT STARTED WITH LETTER R. MRI SHOWED HIPPOCAMPAL MALFORMATION, EEG NORMAL...

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED: 

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 

ADVERSE EVENT REPORTED TO PHARMACIST / NURSE FOR EVALUATION BY: 

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N 

ADVERSE EVENT REPORTED ON: 07/23/14 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: 

DATE: 08-01-14

DATE: 07-31-14

cc: QA/QC Packaging Production Shipping / Receiving

Form # VD1
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 20 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

7/31/14

Date

DSS

AUG 13 2014

AUG 12 2014
VERSE EVENT DATA FORM

AE #: 1554
COMPLAINT #: 2564

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: __________________________
ADDRESS: _________________________
CITY: _____________________________ STATE: ___________________________
COUNTRY: USA ZIP CODE: ______________________
PHONE #: _________________________ E-MAIL: (b)(6)

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: __________________________ DATE: _____________

SECTION IV:

REVIEWS BY MANAGEMENT BY: __________________________ DATE: 08-01-14
BY: __________________________ DATE: 07-31-14
QA/QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE
Seizure activity

On 5-8-14 she was sleeping in her own swing and started screaming & shuddering. I had to wake her up and she continued to shudder. We woke her up and she continued to shudder. We had the baby bathed and X-rayed to rule out blood work and cradle cap. Then we referred us to a neurologist.

For more information, visit http://www.fda.gov/MedWatch
**Ion B - About the Products**

Name of the company that makes the product: Hyland

<table>
<thead>
<tr>
<th>Expiration date (mm/dd/yyyy)</th>
<th>Lot number</th>
<th>NDC number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A 22514</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Strength (for example, 250 mg per 500 mL or 1 g)</th>
<th>Quantity (for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)</th>
<th>Frequency (for example, twice daily or at bedtime)</th>
<th>How was it taken or used (for example, by mouth, by injection, or on the skin)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 to 3 tablets</td>
<td>Every 4 hours under the tongue</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date the person first started taking or using the product (mm/dd/yyyy): 4/6/2014

Date the person stopped taking or using the product (mm/dd/yyyy): 5/28/2014

Did the problem stop after the person reduced the dose or stopped taking or using the product? Yes [ ] No [ ]

Did the problem return if the person started taking or using the product again? Yes [ ] No [ ] Didn't restart [ ]

Why was the person using the product (such as, what condition was it supposed to treat)? Feeding

Do you still have the product in case we need to evaluate it? (Do not send the product to FDA. We will contact you directly if we need it.) Yes [ ] No [ ]

**Section C - About the Medical Device**

Name of medical device

Name of the company that makes the medical device

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Was someone operating the medical device when the problem occurred? Yes [ ] No [ ]

If yes, who was using it?

- The person who had the problem [ ]
- A health professional (such as a doctor, nurse, or aide) [ ]
- Someone else (Please explain who) [ ]

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in (mm/dd/yyyy): [ ]

Date the implant was taken out (if relevant) (mm/dd/yyyy): [ ]

**Go to Section D**
Individual Case Safety Report

Please list all allergies (such as to drugs, foods, pollen, or others).

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

tylenol baby

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information. Your name will not be given out to the public.

Last name (b) (6) First name (b) (6)

Number/Street (b) (6) City and State/Province (b) (6)

Country USA ZIP or Postal code

Telephone number (b) (6) Email address

Did you report this problem to the company that makes the product (the manufacturer)?

[ ] Yes [ ] No

May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?

[ ] Yes [ ] No

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA.

Mail or fax the form to:

Mail:
MedWatch
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Fax:
1-800-332-0178 (toll-free)

DSS
AUG 14 2014

Thank you for helping us protect the public health.

For more information, visit http://www.fda.gov/MedsWatch

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
She started to shake and scream for about 15 minutes. She had no strength to stand or sit up and that's not normal for her. I called the Dr., he was very concerned.

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.

DSS
AUG 14 2014
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.

Patient Information

<table>
<thead>
<tr>
<th>Name (MRN)</th>
<th>Sex</th>
<th>Age</th>
<th>DOB</th>
<th>Dept Info</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>0.41</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

You were seen by

MD

Diagnoses this visit

Your diagnosis was EPISODE OF SHAKING.

Allergies as of

No Known Allergies (drug, envir, food or latex)

Take only the medications listed below. DO NOT use any other medications without first checking with your doctor. Contact your doctor to confirm your home medications.

Medication List

As of 6:26 AM

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 healthcare appointments. Carry it with you at all times in case of emergency. Update your list whenever you start a new medication, change the dose of a current medication, or stop a prior medication. Remember to include over-the-counter medications and supplements such as vitamins and herbs.

ED Disposition

Discharge

Summary of Tests and Procedures

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
Laboratory Tests Pending Results

<table>
<thead>
<tr>
<th>Order</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood culture</td>
<td>In process</td>
</tr>
<tr>
<td>(PEDS ONLY)</td>
<td></td>
</tr>
</tbody>
</table>

Follow-up Information

Follow up with Division of Child Neurology. (New onset seizure clinic)

Contact information:

---

Discharge Instructions

Give her prune or pear juice if she doesn't have a bowel movement.

Call the new onset seizure clinic above for an appointment for further evaluation.

Patient/Parent-Guardian Signature: ________________________________ Date: __________________

Invidual Case Safety Report

CaseID: 10390459

OTC

FORM FDA 3500a (2015)

A. PATIENT INFORMATION

1. Patient Identifier (b) (0):

2. Age at Time of Event: or Date of Birth:

3. Sex:

4. Weight:

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defect/malfunctions):

2. Outcomes Attributed to Adverse Event (Check all that apply)

   - Death (dd/mm/yyyy)
   - Disability/Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
   - Required Intervention to Prevent Permanent Impairment/Gurtage (Devices)

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

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

5. Describe Event or Problem

   Woman had Severe Pain from a Dental Extraction and 5 days later returned to the Dentist who recommended Teething Tablets along with Pain Medication (Hydrocodone acetaminophen, qualitest Narco: Aleve, naproxen alternating). After taking 3 tablets, she felt shaky with her heart beating too fast, edgy, like something was wrong, like an allergy. She experienced feeling nausea, numbness and tingling in her nose and hands. While watching TV, she closed her eyes and according to her boyfriend was shaking. She called her name and was not aware of what was going on as though she had a blackout for a few seconds. She thought it was an allergic reaction and went to urgent care with a CT Scan, MRI. Patient described her pain as 10/10. Urgent Care assessed her symptoms as "minor seizure" and sent her to emergency to attend to the dental pain. In the past few months, she has used the baby's bladders irritation, earache, drool, and vaginitis without adverse symptoms. She has been to the emergency 3 times because of pain, once after the "seizure", and twice since due to extreme dental pain.

6. Relevant Tests/Laboratory Data, Including Dates

   CT SCAN: PULMONARY PAIN FROM EXTRACTED TOOTH (11/11).
   MRI: PULMONARY PAIN FROM EXTRACTED TOOTH (04/14).
   MRI: PULMONARY PAIN FROM EXTRACTED TOOTH (02/14).

   (continue on page 3)

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer):

   #1: NYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

   #1: 3 TABLETS ONCE ORALLY

3. Therapy Dates (If Known, give duration)

   #1: (Tooth & Ear)

4. Diagnosis for Use (Indication)

   #1: TEMP RELIEF TEETHING PAIN

5. Event Abated After Use

   #1: No

   #2: No

6. Lot #

   #1: A22114

7. Exp. Date

   #1: 02/14

   #2: 02/14

8. NDAC or Unique ID

   54973-3127-1

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

   NICONE, CLARITIN, COMPZINE, AMITRIPTYLINE, CUMTIDINE, PRILIGIE, FLUOSOLIDE, TOLTERODINE-TARTRATES. ALSO TAKEN ACTIVATED CHARCOAL TABLETS. HYDROCODONE ACETAMINOPHEN, QUALITEST NARCO: ALEVE, NAPROXEN ALTERNATING. ALSO

   (continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Lot #

6. Operator of Device

   - Health Professional
   - Lay User/Patient
   - Other

7. Catalog #

8. Expiration Date (mm/dd/yyyy)

9. Unique Identifier (UDI) #

10. If Implanted, Give Date (mm/dd/yyyy)

11. If Implanted, Give Date (mm/dd/yyyy)

12. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

   - Yes
   - No

13. If Yes to Item No. 6, Enter Name and Address of Reprocessor

   DSS

   SEP 05 2014

14. Device Available for Evaluation? (Do not send to FDA)

   - Yes
   - No

15. If Returned to Manufacturer on (mm/dd/yyyy)

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

   (continue on page 3)

E. INITIAL REPORTER

1. Name and Address

   (continue on page 3)

2. Health Professional?

   - Yes
   - No

3. Occupation

   NA

4. Initial Reporter Also Sent Report to FDA

   - Yes
   - No

5. Other Relevant History, Including Previous Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, previous medical conditions, etc.)

   History of vertigo 5 years ago and diziness but never a Seizure. No Family History of Seizures. Asthma controlled since childhood. Inhaler for emergencies: Anaphylaxis allergies -- symptoms that may occur include: Cough uncontrolled, hives in back of throat, closed throat, can't breathe, uses adrenal or benadryl, etc. Present. pre-existing conditions: tinnitus, chronic nausea, esophagitis, gut, vulvodynia, 1BS with diarrhea

   (continue on page 3)
**Individual Case Safety Report**

**CaseID:** 10390459

### H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Death</td>
<td>□ Correction</td>
</tr>
<tr>
<td>□ Serious Injury</td>
<td>□ Additional Information</td>
</tr>
<tr>
<td>□ Malfunction</td>
<td>□ Response to FDA Request</td>
</tr>
<tr>
<td>□ Malfunction</td>
<td>□ Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Not Returned to Manufacturer</td>
<td></td>
</tr>
<tr>
<td>□ Yes □ Evaluation Summary Attached</td>
<td></td>
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<tr>
<td>□ No (Attach page to explain why not) or provide code:</td>
<td></td>
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</tbody>
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<tr>
<th>5. Labeled for Single Use?</th>
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<tbody>
<tr>
<td>□ Yes □ No</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Event Problem and Evaluation Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>Device Code: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>Method: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<td>Results: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<td>Conclusions: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<th>7. If Medical Action Initiated, Check Type</th>
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<tbody>
<tr>
<td>□ Recall [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Notification [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Repair [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Inspection [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Replace [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Patient Monitoring [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Relabeling [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Modification/Adjustment [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Other [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Initial Use of Device [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Reuse [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Unknown [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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</table>

| 9. If action reported to FDA under 21 USC 360(h), list correction/ removal reporting number: |

### G. ALL MANUFACTURERS

<table>
<thead>
<tr>
<th>1. Contact Office (and Manufacturing Site for Devices)</th>
<th>2. Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: EDYTA FRACKIEWICZ</td>
<td>Phone Number: 310-768-0790</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Report Source (Check all that apply)</th>
</tr>
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<tbody>
<tr>
<td>□ Foreign [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Study [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<td>□ Literature [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Consumer [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Health Professional [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ User Facility [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ Company Representative [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<td>□ Distributor [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<td>□ Other [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<thead>
<tr>
<th>4. Date Received by Manufacturer (mm/dd/yyyy)</th>
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<tbody>
<tr>
<td>37/30/2014 [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<thead>
<tr>
<th>5. (A)NDA #</th>
<th>IND #</th>
<th>BLA #</th>
<th>PMA/SPL #</th>
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<tr>
<th>6. If IND, Give Protocol #</th>
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</thead>
<tbody>
<tr>
<td>Protocol # [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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</table>

<table>
<thead>
<tr>
<th>7. Type of Report (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ 5-day [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ 30-day [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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<tr>
<td>□ 7-day [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Periodic [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ 10-day [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Initial [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ 15-day [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
</tr>
<tr>
<td>□ Follow-up # [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]</td>
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</table>

<table>
<thead>
<tr>
<th>8. Manufacturer Report Number</th>
<th>9. Adverse Event Term(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>54973 AZ # 1555</td>
<td>SEIZURES</td>
</tr>
</tbody>
</table>

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**DSS**

**SEP 05 2014**

**SEP 04 2014**

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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**

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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."
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)

PCOS (POLYCYSTIC OVARYS), BIPOLAR

ALLERGIES: "ALMOST EVERYTHING": BEE AND WASP STINGS, SHELLFISH, CHLORINE, FLUORIDE, DOMESTICONE (SILICONE), MEDICATIONS: IBUPROFEN, SOMA, RANITIDINE, FERROUS SULFATE, Q-VAR (INHALER), CAYENNE HORSERADISH, SEASONAL TREES, POLLEN, MOLD, PETS.

Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish)
Percocet, Dilaudid, Demerol.

DSS
SEP 05 2014

SEP 04 2014

Other Remarks
COMPLAINT RECORD

COMPLAINT #: 2565
DATE OF COMPLAINT: 07/20/14
ITEM CODE: BTET---T135
LOT NO.: A22114

PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS

REPORTER:

ADDRESS:

CITY:

COUNTRY: USA

PHONE #: (0)(0)

E-MAIL:

NATURE OF COMPLAINT: WOMAN HAD SEVERE PAIN FROM A DENTAL EXTRACTION AND 5 DAYS LATER RETURNED TO THE DENTIST WHO RECOMMENDED TEETHING TABLETS ALONG WITH PAIN MEDICATION HYDROCODONE ACETAMINOPHEN, QUALITEST NORCO: ALEVE, NEPROXER ALTERNATELY. AFTER TAKING 3 TEETHING TABLETS SHE FELT SHAKY WITH HER HEART BEATING TOO FAST, 'EDGY, LIKE SOMETHING WAS WRONG, LIKE AN ALLERGY'. SHE EXPERIENCED FEELING NAUSEA, NUMBNESS AND TINGLING IN HER NOSE AND HANDS. WHILE WATCHING TV SHE CLOSED HER EYES AND ACCORDING TO HER BOYFRIEND WAS SHAKING. HE CALLED HER NAME AND SHE WAS NOT AWARE OF WHAT WAS GOING ON AS THOUGH SHE HAD A "BLURRY" FOR A FEW SECONDS. SHE THOUGHT IT WAS AN ALLERGIC REACTION AND WENT TO URGENT CARE WHERE THEY DID A CT SCAN, MRI, EKG. MRI WAS CLEAR. CT SCAN WAS FOR THE PAIN SHE WAS HAVING IN HER SINUS AREA THAT CORRESPONDED TO THE AREA OF HER TOOTH EXTRACTION. IT WAS "INCONCLUSIVE". SHE HAS BEEN ON DIFFERENT PAIN MEDICATIONS SINCE THE EXTRACTION 5 DAYS PREVIOUSLY AND DESCRIBES HER PAIN AS 10/10. THERE IS A HISTORY OF VERTIGO 6 YEARS AGO AND DIZZINESS BUT NEVER A SEIZURE. NO FAMILY HISTORY OF SEIZURES. URGENT CARE ASSESSED HER SYMPTOMS AS "MINOR SEIZURE" AND SENT HER TO EMERGENCY TO ATTEND TO THE DENTAL PAIN. IN THE LAST FEW MONTHS SHE HAS USED HYLAND'S BLADDER IRITATION, EARACHE DROPS AND VAGINITIS WITH NO ADVERSE SYMPTOMS. SHE HAS BEEN TO THE EMERGENCY 3 TIMES BECAUSE OF PAIN, ONCE AFTER THE "SEIZURE", AND TWICE SINCE DUE TO EXTREME DENTAL PAIN. RECENTLY SHE HAS BEEN ON PERCOCET, DILAUDID, DEMEROL, NONE OF WHICH IS "TOUCHING THE PAIN" (OF THE TOOTH EXTRACTION).

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y  N  (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y  N  (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y  N  (CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/20/14
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION

MAILED REFUND CHECK # 111715 TOTALING $ 7.00.
CORRECTIVE ACTION(S) COMPLETED BY: TUTTI GOULD
DATE: 06/12/14

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y  N
ADVERSE EVENT REPORTED ON: 07/30/14
AE #: 1555
BY: TUTTI GOULD

SECTION V: REVIEWS BY MANAGEMENT
REVIEWED BY MANAGEMENT BY: RENAI
DATE: 08-21-14
BY: QA/QC DIRECTOR
DATE: 08-21-14

cc: QA/QC Packaging Production Shipping / Receiving

FORM # VD1

DSS SEPO 5 2014
July 31, 2014

Dear [Name]

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,

[Signature]

Dan Krombach
President

Enc: Refund Check - $7.00
COMPLAINT RECORD

COMPLAINT #: 2955
DATE OF COMPLAINT: 07/30/14
ITEM CODE: BTE#-1135
LOT NO.: A22114

REPORTER: TUTTI GOLDFIELD
ADDRESS:
CITY:
COUNTRY: USA
PHONE #:
E-MAIL:

PROBLEM:
WOMAN HAD SEVERE PAIN FROM A DENTAL EXTRACTION AND 3 DAYS LATER RETURNED TO THE DENTIST. WHO PROPOSED TAKING 2 TEETHING TABLETS EACH DOSE, WITH A PAIN MEDICATION (HYDROCODONE-ACETAMINOPHEN). QUALITY TESTED, ALL; AE (EVE, BPOXEN ALTERNATELY). AFTER TAKING 3 TEETHING TABLETS SHE FELT SHAKY WITH HER HEART BEATING TOO FAST, "EDGY, LIKE SOMETHING WAS WRONG, LIKE AN ALLERGY." SHE EXPERIENCED FEELING Nausea, Numbness and Tingling in her NOSE and HANDS. WHILE WATCHING TV SHE CLOSED HER EYES AND ACCORDING TO HER BOYFRIEND WAS SHAKING. HE CALLED HER NAME AND SHE WAS NOT AWARE OF WHAT WAS GOING ON AS THOUGH SHE HAD A "BLACKOUT" FOR A FEW SECONDS. SHE THOUGHT IT WAS AN ALLERGIC REACTION AND WENT TO URGENCY CARE WHERE THEY DROSE CT SCAN, MRI, EKG. MRI WAS CLEAR. CT SCAN WAS FOR PAIN SHE WAS HAVING IN HER SINUS AREA THAT CORRESPONDED TO THE AREA OF HER TOOTH EXTRACTION. IT WAS "INCONCLUSIVE." SHE HAS BEEN ON DIFFERENT PAIN MEDICATIONS SINCE THE EXTRACTION 5 DAYS PREVIOUSLY AND DESCRIBED HER PAIN AS 10/10. THERE IS A HISTORY OF VERTIGO 5 YEARS AGO AND DIZZINESS BUT NEVER A SEIZURE. NO FAMILY HISTORY OF SEIZURES. URGENCY CARE ASSESSED HER SYMPTOMS AS "MINOR SEIZURE." SHE WAS SENT TO EMERGENCY TO ATTEND TO THE DENTAL PAIN. IN THE PAST FEW MONTHS SHE HAS USED HYLAND'S BLADDER IRRITATION, EARACHE, DROPS AND VAGINITIS WITH NO ADVERSE SYMPTOMS. SHE HAS BEEN TO THE EMERGENCY 3 TIMES BECAUSE OF PAIN ONCE AFTER THE "SEIZURE," AND TWICE SINCE DUE TO EXTREME DENTAL PAIN. RECENTLY SHE HAS BEEN ON PERCOCET, DILAUDID, DEMEROL, NONE OF WHICH IS "TOUCHING THE PAIN OF THE TOOTH EXTRACTION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED:
UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED:

INVESTIGATION:
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
07/30/14
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:
TUTTI GOLDFIELD

CORRECTIVE ACTION:
CORRECTIVE ACTION(S) COMPLETED BY:
DATE:
SECTION IV:
ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS:
Y N
ADVERSE EVENT REPORTED ON:
07/30/14
BY:
TUTTI GOLDFIELD

SECTION V:
REVIEWED BY MANAGEMENT:
DATE: 08-06-14
BY:
QA/QC DIRECTOR
DATE: 08-06-14

cc: QA/QC
Packaging
Shipping/Receiving
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 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 within specification of 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-0455-2014) 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.

Prepared by

Date

8/6/2014
Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)

2. Age at Time of Event or Date of Birth: 6 months
3. Sex: Male
4. Weight: 9.7 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
- Adverse Event
- Product Problem (e.g., defects/injuries)
- Product Use Error
- Problem Different Manufacturer of Same Medicine

Outcomes Attributed to Adverse Event
- Death: (mm/dd/yyyy)
- Disability or Permanent Damage
- Life-threatening
- Congenital Anomaly/Birth Defect
- Hospitalization - initial or prolonged
- Other Serious (Important Medical Events)
- Required Intervention to Prevent Permanent Impairment/Damage (Device)

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):
   - Name: Orajel
   - Strength: 7.5%
   - Manufacturer: [redacted]

2. Name, Strength, Manufacturer (from product label):
   - Name: [redacted]
   - Strength: [redacted]
   - Manufacturer: [redacted]

E. SUSPECT MEDICAL DEVICE
1. Brand Name: CTU
2. Common Device Name: CTU
3. Manufacturer Name, City and State: Aug 19, 2014
4. Model #: "[redacted]"
5. Operator of Device
   - Health Professional
6. Catalog #: [redacted]
7. Expiration Date (mm/dd/yyyy): [redacted]
8. Serial #: [redacted]
9. Unique Device Identifier (UDI) #: [redacted]

E. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)
None

F. REPORTER (See confidentiality section on back)
1. Name and Address:
   - Name: [redacted]
   - Address: [redacted]
   - City: [redacted]
   - Phone #: [redacted]
   - E-mail: [redacted]

2. Health Professional: Yes
3. Occupation: Physician
4. Also Reported to:
   - Manufacturer
   - User Facility
   - Distributor/Importer

Form FDA 3500 (2/13)
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
B.5. Describe Event or Problem (continued)

Note:

Per "http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm

[Note: Lidocaine contains topical medications]

"Is NOT approved by FDA to treat teething pain"

but

tube from which mother got medication clearly states name of med as: "Orajel Teething Pain Medicine"
Patient Information

1. Patient Identifier: [Redacted]
2. Age at Time of Event: ADULT
3. Sex: Female
4. Weight: lbs
5. Date of Birth: [Redacted]

Adverse Event or Product Problem

1. Adverse Event: Yes
2. Outcomes Attributed to Adverse Event:
   - Death: [Redacted]
   - Life-threatening: [Redacted]
   - Hospitalization - initial or prolonged: [Redacted]
   - Disability or Permanent Damage: [Redacted]
   - Congenital Anomaly/Birth Defect: [Redacted]
   - Other Serious (Important Medical Events): [Redacted]
3. Date of Event: [Redacted]
4. Date of this Report: 08/09/2014
5. Describe Event or Problem:

   SHE EXPERIENCED A SEIZURE AFTER TAKING 3 TABLETS OF OUR HYLAND'S TEETHING TABLETS. THINGS HAVE SETTLED DOWN SOME, BUT SHE STILL HAS A REALLY DIZZY / SHAKY FEELING.

Suspect Product(s)

1. Name (See labeled strength & manufacturer):
   #1 HYLAND'S BABY TEETHING TABLETS
   #3 HYLAND'S TEETHING TABLETS

   1) PAIN RELIEF TEETHING PAIN
   2) PAIN RELIEF TEETHING PAIN

   5. Event Altered After Use Stopped or Dose Reduced:
      #1: Yes, No: [Redacted]
      #2: Yes, No: [Redacted]

   7. Event Reappeared After Reintroduction:
      #1: Yes, No: [Redacted]
      #2: Yes, No: [Redacted]

   9. NDC or Unique ID:
      54973-3127-1 / 54973-7504-1

Concomitant Medical Products and Therapy Dates

D. Suspect Medical Device

1. Brand Name:
2. Common Device Name:
3. Manufacturer Name, City and State:
4. Model #: [Redacted]
5. Operator of Device:
   - Health Professionals
   - Lay User/Patient
   - Other:
6. If Implant Ever, Give Date:
7. If Explanted, Give Date:

Is this a Single Use Device that was Reprocessed and Reused on a Patient?

Yes: No: [Redacted]

If Yes to Item No. 8, Enter Name and Address of Reprocessor:

10. Device Available for Evaluation? (Do not send to FDA)
    Yes: No: [Redacted]

E. Initial Reporter

1. Name and Address:
2. Health Professional: Yes: No: [Redacted]
3. Occupation: [Redacted]
4. Initial Reporter Also Sent Report to FDA: Yes: No: [Redacted]

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.
**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

3. **Device Evaluated by Manufacturer?**
   - [ ] Not Returned to Manufacturer
   - [ ] Evaluation Summary Attached
   - [ ] No/Attatch page to explain why not or provide code:

4. **Device Manufacture Date**
   (mm/dd/yyyy)

5. **Labeled for Single Use?**
   - [ ] 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**
   - [ ] 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 360(i), list correction/removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

**G. ALL MANUFACTURERS**

1. **Contact Office**
   - Name: EDITA FRACKIEWICZ
   - Address: HYLAND'S, INC., 154 W. 131ST STREET, LOS ANGELES, CA 90061
   - Email Address: STANDARD@HYLANDS.COM

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:

4. **Date Received by Manufacturer**
   - 07/28/2014

5. **IND #**
   - BLA #
   - PMN #
   - S006 #

6. **Type of Report**
   (Check all that apply)
   - 5-day
   - 30-day
   - 7-day
   - Periodic
   - 10-day
   - Initial
   - 15-day
   - Follow-up

7. **Manufacturer Report Number**
   - 54973 AE # 1556

8. **Adverse Event Term(s)**
   - SEIZURE, DIZZY, SHAKY

---

**DSS AUG 20 2014**

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**Please DO NOT RETURN this form to the above PRA Staff email address.**
INDIVIDUAL CASE SAFETY REPORT

PRODUCT: Hyland's Baby Teething Tablets or Hyland's Teething Tablets
SIZE: UNKNOWN
REPORTER: (B6)
ADDRESS: _______________________
CITY: _______________________
COUNTRY: USA
PHONE #: (B6)
E-MAIL: _______________________

NATURE OF COMPLAINT: She experienced a seizure after taking teething tablets. I took three tablets once.

Things have settled down some, but I still have a really dizzy / shaky feeling. Has taken all of the ingredients contained in this product in other forms, so she knows it was not an allergic reaction.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N
PRODUCT BEING RETURNED FOR INSPECTION: Y N
DATE REQUESTED PRODUCT BE RETURNED:
UPS CALL TAG ISSUED: Y N
DATE PRODUCT RECEIVED:

INVESTIGATION:

INVESTIGATION:
See attached pm 8/11/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/28/2014
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CATHERINE DOW

CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: _______________________
DATE: _______________________

ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N
ADVERSE EVENT REPORTED ON: 07/28/2014
BY: CATHERINE DOW

REVIEWED BY MANAGEMENT BY:

DATE: 08/11/14
DATE: 08/11/14

cc: QA / QC
Production
Packaging
Shipping / Receiving
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 ≤30 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.
A. PATIENT INFORMATION

1. Patient Identifier (0) (0)
2. Age at Time of Event: 4 Months
3. Sex
4. Weight

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects, malfunctions)
2. Outcomes Attributed to Adverse Event
   - (Check all that apply)
   - Death
   - Life-threatening
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Other

3. Date of Event (mm/dd/yyyy) 08/03/2014
4. Date of This Report (mm/dd/yyyy) 08/10/2014

5. Describe Event or Problem
   MONTH OLD BABY WAS GIVEN 1 BABY TEETHING TABLET DISSOLVED IN BABY SIZE SYRINGEFUL OF WATER AND STOPPED BREATHING. HER EYES WERE LARGE, AND HER BODY WAS LIMP. MOTHER HAD TO HIT HER ON THE BACK TO GET HER BREATHING AGAIN; THE BABY BEGAN TO BREATHE NORMALLY. FATHER RECEIVED A CALL FROM A MEDICAL DOCTOR WHILE WE WERE ON THE LINE.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/brand)
   - HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   - 1 TAB DISSOLVED SYRINGE

3. Therapy Dates (If unknown, give duration)

4. Diagnosis for Use (Indication)
   - TEMP RELIEF TEETHING PAIN

5. Event Abated After Use?
   - Stopped or Dose Reduced

6. Lot #
7. Exp. Date
   - A22314

9. NDC or Unique ID
   - 54973-3127-1

10. Concomitant Medical Events and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #
5. Operator of Device

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

10. Device Available for Evaluation? (Do not send to FDA)
   - Yes
   - No

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

E. INITIAL REPORTER

1. Name and Address
   - USA

2. Health Professional
   - Yes

3. Occupation
   - NA

4. Initial Reporter Also Sent Report to FDA
   - Yes
   - No
   - Link
**H. DEVICE MANUFACTURERS ONLY**

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
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<tbody>
<tr>
<td>Death</td>
<td>Correction</td>
</tr>
<tr>
<td>Serious Injury</td>
<td>Additional Information</td>
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<tr>
<td>Malfunction</td>
<td>Response to FDA Request</td>
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<tr>
<td>Device Evaluation</td>
<td>Device Evaluation</td>
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<tr>
<th>3. Device Evaluated by Manufacturer?</th>
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<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
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<tr>
<td>Evaluation Summary Attached</td>
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<tr>
<td>Yes</td>
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<td>No</td>
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<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
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<th>5. Labelled for Single Use?</th>
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<tbody>
<tr>
<td>Yes</td>
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<td>No</td>
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<tr>
<th>6. Event Problem and Evaluation Codes (Refer to coding manual)</th>
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<tbody>
<tr>
<td>Patient Code</td>
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<tr>
<td>Device Code</td>
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<td>Results</td>
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<tr>
<td>Conclusions</td>
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<th>7. If Remedial Action Initiated, Check Type</th>
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<tbody>
<tr>
<td>Recall</td>
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<tr>
<td>Notification</td>
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<td>Repair</td>
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<td>Inspection</td>
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<td>Replace</td>
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<td>Patient Monitoring</td>
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<td>Relabeling</td>
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<td>Modification/Adjustment</td>
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<td>Other:</td>
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<th>8. Usage of Device</th>
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<tbody>
<tr>
<td>Initial Use of Device</td>
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<tr>
<td>Reuse</td>
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<tr>
<td>Unknown</td>
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| 9. If action reported to FDA under 21 USC 366(f), list correction/removal reporting number: |
|                                                                                          |

<table>
<thead>
<tr>
<th>10. Additional Manufacturer Narrative</th>
<th>11. Corrected Data</th>
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**G. ALL MANUFACTURERS**

<table>
<thead>
<tr>
<th>1. Contact Office (and Manufacturing Site for Devices)</th>
<th>2. Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDDY T. FRACKELWICZ</td>
<td>310-768-0700</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Report Source (Check all that apply)</th>
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<tbody>
<tr>
<td>Foreign</td>
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<tr>
<td>Study</td>
</tr>
<tr>
<td>Literature</td>
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<table>
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<tr>
<th>4. Date Received by Manufacturer (mm/dd/yyyy)</th>
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<tbody>
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<table>
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<tr>
<th>5. AY/NDA #</th>
<th>INN #</th>
<th>BLA #</th>
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<table>
<thead>
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<th>6. IF INO, Give Protocol #</th>
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<tbody>
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<table>
<thead>
<tr>
<th>7. Type of Report (Check all that apply)</th>
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<tbody>
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</tr>
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<td>7-day</td>
</tr>
<tr>
<td>Periodic</td>
</tr>
<tr>
<td>10-day</td>
</tr>
<tr>
<td>Initial</td>
</tr>
<tr>
<td>15-day</td>
</tr>
<tr>
<td>Follow-up #</td>
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<th>8. Manufacturer Report Number</th>
<th>9. Adverse Event Term(s)</th>
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<tbody>
<tr>
<td>54973 AE # 1558</td>
<td>STOPPED BREATHING</td>
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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: Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, Paperwork Reduction Act (PRA) Staff, OIRA Staff<br />Email: ira@odac.hhs.gov <br />For more information, see the OMB control number: 0910-0681. Please DO NOT RETURN this form to the above PRA Staff email address.
COMPLAINT #: 2568
DATE OF COMPLAINT: 08/03/14
ITEM CODE: BTET-T136
LOT NO.: A22314

PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS
REPORTER: 
ADDRESS: 
CITY: 
STATE: 
COUNTRY: USA
ZIP CODE: 
PHONE #: 
E-MAIL: 

NATURE OF COMPLAINT: A 4-MONTH-OLD BABY WAS GIVEN 1 BABY TEETHING TABLET DISSOLVED IN BABY SIZED SYRINGEFUL OF WATER AND STOPPED BREATHING. HER EYES WENT LARGE, AND HER BODY LIMP. MOTHER HAD TO HIT HER ON THE BACK TO GET HER BREATHING AGAIN. THE BABY BEGAN TO BREATHE NORMALLY. FATHER RECEIVED A CALL FROM A MEDICAL DOCTOR WHILE WE WERE ON THE LINE. CHILD ALSO TAKES MEDICATION FOR ACID REFLUX AND COLIC.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED: 
UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/03/14
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
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 08/03/14
BY: TUTTI GOULD

SECTION V:
REVIEWED BY MANAGEMENT BY: 
DATE: 08-15-14
DATE: 08-15-14

cc: QA / QC
Packaging
Production
Shipping / Receiving

AUG 22 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 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 ≤(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 # 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

[Signature]

Date

8/13/14

DSS

AUG 25 2014

CC-0566-2014

AE-0329-2014

AUG 22 2014
Section I: Patient Information (If different from reporter on Form V01)

Name: (Redacted)
Address: 
City: 
Country: USA
Phone #: (Redacted)
E-mail: 

Section II: Packaging Information:

Affix packaging label here

Affix copy of outer carton here
(Include Drug Facts and Principal Display Panels)

Section III: Corrective Action:

Corrective action(s) completed by: 
Date: 

Section IV:

Reviewed by management by: 
Date: 

By: [Signature]

Date: 

Distribution: FDA Adverse Event File
MEDWATCH
FORM FDA 3500A (6/10)

A. PATIENT INFORMATION
1. Patient Identifier: Unknown
2. Age at Time of Event: 9 months
3. Sex: Male
4. Weight: lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event or Product Problem (e.g., defect, malfunction)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - 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): 08/29/2014

C. SUSPECT PRODUCT(S)
1. Name: (Give labeled strength & statement)
   #1 Propranolol (Propranolol)
   #2 Teething gel

2. Dose, Frequency & Route Used
   - #1 (mg/kg, (cont.)) 2
   - #2 (DF)

3. Therapy Dates (If unknown, give duration)
   - #1 (Unknown)
   - #2 (Unknown)

4. Diagnosis for Use (Indication)
   - #1 Haemangioma
   - #2 Teething

5. Event Abated After Use
   - Stopped or Dose Reduced?
   - #1 Yes No Doesn't Apply
   - #2 Yes No Doesn't Apply

6. Event Reappeared After
   Reintroduction
   - #1 Yes No Doesn't Apply
   - #2 Yes No Doesn't Apply

D. ALL MANUFACTURERS
1. Contact Office - Name/Address
   (and Manufacturing Site for Devices)
   NorthStar Healthcare Holdings,
   Joseph Mastronardy, Ph. D.
   Quality Regulatory Consultants,
   1966 Anglers Cove, Vero Beach,
   FL 32963 USA

2. Phone Number: 434-326-1014

3. Report Source
   - Foreign
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor

4. Date Received by Manufacturer (mm/dd/yyyy): 08/22/2014

5. (AINDA) #
   - #76-213
   - IND #
   - STN #
   - PMA/ 510(k) #
   - Combination Product
   - Pre-1938 Product
   - OTC Product

6. If IND, Give Protocol #
   - #

7. Type of Report
   (Check all that apply)
   - 5-day
   - 7-day
   - 10-day Initial
   - 15-day Follow-up

8. Manufacturer Report Number
   - NSR_01615_2014

9. Adverse Event Term(s)
   - Hypoglycaemic seizure
   - (cont.)

DSS
SEP 03 2014

E. INITIAL REPORTER
1. Name and Address
   (b)(6)
   United Kingdom

2. Health Professional?
   - Yes No

3. Occupation
   - Unknown

4. Initial Reporter Also Sent Report to FDA
   - Yes No Unknown

Received
SEP 02 2014

CDR

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.

3500A Facsimile
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 CEB in the early hours of the morning. Treatment included oral Dextroglu, 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 hypoglycaemia. The authors stated, "Informing parents about the risk of hypoglycaemia 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.

G2. Dose, frequency and route used for suspect product #1 (continued)
daily [given in two divided doses]

G3. Report source (continued)
Foreign: United Kingdom

G8. Adverse event terms (continued)
Drug interaction
### B6. Lab Data

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<th>Panel</th>
<th>Test</th>
<th>Results</th>
<th>Units</th>
<th>Low Normal</th>
<th>High Normal</th>
<th>Normal?</th>
<th>Test Date</th>
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<td>&lt;3.5</td>
<td>mmol/L</td>
<td>Normal</td>
<td>Normal</td>
<td>Depressed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(hypoglycemia)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Capillary blood glucose</td>
<td>persistently low CBG</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>Capillary blood glucose</td>
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<td>mmol/L</td>
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<td>Serum glucose</td>
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<td>mmol/L</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>Urinalysis</td>
<td>positive for ketones</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vital signs</td>
<td>Body temperature</td>
<td>35.4</td>
<td>degrees</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

1. Patient/Identifier

2. Age at Time of Event:
   - 10 Months
   - Date of Birth:

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defects, malfunctions)

2. Outcomes Attributed to Adverse Event
   - Death:
   - Disability or Permanent Damage:
   - Life-Threatening:
   - Congenital Anomaly/Birth Defect:
   - Hospitalization - Initial or Prolonged:
   - Other Serious (Important Medical Events):
   - Required Intervention to Prevent Permanent Impairment/Damage (Denies):

3. Date of Event (mm/dd/yyyy)
   - 05/31/2014

4. Date of This Report (mm/dd/yyyy)
   - 06/28/2014

5. Description of Event or Problem
   - THE WEEK OF USING THE TABLETS CHILD HAD SEIZURE TYPE SYMPTOMS - TENSING UP, SHAKING THAT LASTED 5 - 10 SECONDS AND OCCURRED ABOUT 10 TIMES OVER A PERIOD OF A WEEK. WENT TO THE EMERGENCY ROOM BUT SYMPTOMS WERE NOT OCCURRING AT THE TIME. DOCTOR COULD NOT TELL IF THIS WAS SEIZURE BUT STATED IT COULD BE SEIZURE TYPE ACTIVITY. SINCE STOPPING BABY TEETHING TABLETS, THE CHILD HAS NOT HAD ANY SEIZURE TYPE SYMPTOMS.

(Continue on page 2)

D. SUSPECT MEDICAL DEVICE

1. Brand Name:

2. Common Device Name:

3. Manufacturer Name, City and State:

4. Model #

5. Lot #

6. Operator of Device
   - Health Professional
   - Lab User/Patient
   - Other:

7. Catalog #

8. Expiration Date (mm/dd/yyyy):

9. Serial #

10. Unique Identifier (UDI) #

11. If Implanted, Give Date (mm/dd/yyyy):

12. If Explanted, Give Date (mm/dd/yyyy):

13. Is this a Single-Use Device that was Reprocessed and Reused on a Patient?
   - Yes
   - No

14. If Yes to Item No. 8, Enter Name and Address of Reprocessor:

15. Device Available for Evaluation? (Do not send to FDA)
   - Yes
   - No

16. If Returned to Manufacturer or Other:

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

E. INITIAL REPORTER

1. Name and Address:

2. Health Professional?
   - Yes
   - No

3. Occupation:
   - NA

4. Initial Reporter Also Sent 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.
II. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   - Death
   - Serious Injury
   - Malfunction

2. If Follow-up, What Types?
   - Correction
   - Additional Information
   - Response to FDA Request
   - Device Evaluation

3. Device Evaluated by Manufacturer?
   - Yes
   - No
   - Evaluation Summary Attached
   - No (Attach page to explain why not or provide code)

4. Device Manufacturer Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - 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
   - Recall
   - Repair
   - Replacement
   - Patient Monitoring
   - Repackaging
   - Modifications
   - Adjustment
   - Other

8. Usage of Device
   - Initial Use of Device
   - Reuse
   - Unknown

9. If action reported to FDA under 21 U.S.C. 360(i), list correction/removal reporting number:

10. Additional Manufacturer Narrative

11. Corrected Data

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name: EDITA FRACKIWICZ
   - Address: HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: STANDARD@HYLANDS.COM

2. Phone Number
   - 310-768-0700

3. Report Sources
   - (Check all that apply)
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 06/26/2014

5. IND # (A)FDA #

6. IF IND, Give Protocol #

7. Type of Report
   - (Check all that apply)
   - 5-day
   - 10-day
   - Follow-up #

8. Manufacturer Report Number
   - 54973 RE # 1550

9. Adverse Event Term(s)
   - SEIZURE SYMPTOMS, SHAKING, PENSING

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 96 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
Papework Reduction Act (PRA) Staff
OMB Control Number: 0910-0080
Please DO NOT RETURN this form to the above PRA Staff email address.
Individual Case Safety Report

PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS
REPORTER: 
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: 
E-MAIL: 

DATE OF COMPLAINT: 06/25/14
ITEM CODE: BTET-T136
LOT NO.: 812113

NATURE OF COMPLAINT: A 3 YEAR OLD CHILD HAD SEIZURE TYPE SYMPTOMS - TENSING UP, SHAKING THAT LASTED 5 - 10 SECONDS - THIS HAPPENED ABOUT 10 TIMES OVER THE WEEK. WENT TO THE EMERGENCY ROOM BUT SYMPTOMS WERE NOT OCCURRING AT THE TIME. DOCTOR COULD NOT TELL IF THIS WAS SEIZURE BUT STATED IT COULD BE SEIZURE TYPE ACTIVITY. ER DOCTOR DID NOT RUN TESTS AND HE SAID THAT IF SHE CONTINUES TO HAVE SYMPTOMS SHE SHOULD BE EVALUATED BY HER PRIMARY DOCTOR. SINCE STOPPING BABY TEETHING TABLETS, THE CHILD HAS NOT HAD ANY SEIZURE TYPE SYMPTOMS. FATHER EXPRESSED THAT HE THINKS THAT MORE STUDIES SHOULD BE DONE ON THE TEETHING TABLETS. HE RECOMMENDS PUTTING KIDS IN A HOSPITAL BEDDING AND GIVING THEM TEETHING TABLETS AND OBSERVING THEM. HE IS A CONCERNED PARENT AND IS NOT GOING TO SUE. FATHER'S BROTHER HAS A HISTORY OF GRAND MAL SEIZURES, WOULD LIKE A REFUND FOR 2 BOTTLES.

COMMENTS TO REPORTER: WILL SEND A REFUND. TOLD HIM THAT SOMETIMES A CHILD COULD BE SENSITIVE TO AN INGREDIENT IN THE BABY TEETHING TABLETS OR THE SYMPTOMS COULD BE DUE TO SOMETHING ELSE. PROVIDED INFORMATION ABOUT THE INGREDIENTS IN THE BABY TEETHING TABLETS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION:

SECTION IV: ADVERSE EVENT REPORT:
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 06/25/2014

SECTION V: REVIEWED BY MANAGEMENT:

DATE: 07-02-14
DATE: 07-01-14

cc: QA / QC
Production
Packaging
Shipping / Receiving

Form #: V01

DSS SEP 05 2014

QA / QC DIRECTOR

SEP 04 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 [8(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 within specification of 50 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.

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

Prepared by ___________________________ Date 6/26/14

DSS SEP 05 2014

CC-0438-2314
AE-0253-2014

SEP 04 2014
C. SUSPECT PRODUCT(S)
1. Name (Give Full Name, Strength & Dose/Route)

- Hyland's Baby Teething Tablets

2. Dose, Frequency & Route Used

- 1 Tablet SL PRN x 1 MO

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

4. Diagnosis for Use (Indication)

- Temp Relief Teething Pain

5. Event Altered After Use/Stopped or Dose Reduced?

- #1: Yes ☑ No ☐ Doesn't Apply

6. Lot #

- #1

7. Exp. Date

- #1

- #2

8. Event Reappeared After Reintroduction?

- #1: Yes ☑ No ☐ Doesn't Apply

9. NDC# or Unique ID

- 54973-3127-3

10. Concurrent Medical Products and Therapy Dates (Exclude treatment of event) CRAJEL

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name 2b. Proceeds

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device

- Health Professional

- Lay User/Patient

- Other:

6. Catalog #

7. Expiration Date (mm/dd/yyyy)

8. If Implant, Give Data (mm/dd/yyyy)

9. Operator of Device

10. If Yes to item No. 8. Enter Name and Address of Reprocessor

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

(Continue on page 3)

E. INITIAL REPORTER
1. Name and Address

- USA

2. Health Professional?

- Yes ☑ No ☐

3. Occupation

- NA

4. Initial Reporter Also Sent Report to FDA

- Yes ☑ No ☐ (Unk.)

(Continue on page 3)
H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Request
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] No
- [ ] Yes
  - [ ] Evaluation Summary Attached

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
- [ ] 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
- [ ] Recall
- [ ] Notification
- [ ] Repair
- [ ] Inspection
- [ ] Replacement
- [ ] Patient Monitoring
- [ ] Relabeling
- [ ] Design/Manufacturing Change
- [ ] Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. 21 USC 360(f), list correction or removal reporting number:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name:
   - Address:
   - Email Address:

2. Phone Number
   - 310-768-0700

3. Report Source
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 08/17/2014

5. 4. IND, Give Protocol #
   - IND #
   - BLA #
   - PMA #
   - 510(k) #

6. Type of Report
   - Combination Product
   - Pre-1988 Product
   - OTC Product
   - [ ] Yes
   - [ ] No

7. Manufacturer Report Number
   - 54973 AE # 1559

8. Adverse Event Terms
   - 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@fas.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.
CALLER REPORTS THAT APPROXIMATELY ONE MONTH AGO, HE GAVE HIS 6 MONTH OLD SON BABY TEETHING TABLETS. HE CLAIMS THAT SOON AFTER, HIS SON HAD A SEIZURE. CALLER AND HIS GIRLFRIEND TOOK THEIR SON TO THE EMERGENCY ROOM SOON AFTERWARDS. THE CHILD WAS STABILIZED AND WAS RETURNED HOME. AFTER AN UNKNOWN AMOUNT OF TIME, CALLER GAVE HIS SON ANOTHER DOSE OF TEETHING TABLETS AND CLAIMS THAT HE HAD ANOTHER SEIZURE APPROXIMATELY 6 - 8 HOURS LATER. CALLER THREATENED LEGAL ACTION IF HE DID NOT HEAR FROM SOMEONE BY TOMORROW.

EDYTA FRACKIEWICZ FOLLOWED UP, SPOKE WITH CUSTOMER ON 06/17/14. HE WAS USING ORAGEL AND THEN STARTED USING THE TEETHING TABLETS. CHILD STARTED SPACING OUT, THEN EYES STARTED SHIFTING, SHAKING, COULD NOT BREATHE, UNRESPONSIVE. CALLED 911 AND IN THE HOSPITAL THEY SAID CHILD LOOKED FINE AND SENT HIM HOME. EEG AND MRI WERE NORMAL. WANTS TO KNOW WHY BELIADONNA IS IN THE TABLETS. CHILD GOT KEMPRA IN THE HOSPITAL. HAD ANOTHER EPISODE WHERE HE TOOK A TEETHING TABLET AND HAD A SEIZURE. CHILD STILL HAVING SEIZURES NOW. HE CLAIMS NO FAMILY HISTORY OF SEIZURES. DOCTORS DON'T KNOW CAUSE OF SEIZURES BECAUSE ALL MEDICAL TESTS ARE NORMAL. GOING TO THE LAWYER TO PURSUE LEGAL ACTION AND WILL CALL THE FDA TODAY. OFFERED HIM A REFUND FOR THE TABLETS AND HE REFUSED. HE REFUSED TO PROVIDE THE LOT #

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE) PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

INVESTIGATION

ADVERSE EVENT REPORTED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/17/2014 ADVERSE EVENT REPORTED TO PHARMACIST / NURSE FOR EVALUATION BY:

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 06/18/2014

SECTIONS: REVIEWED BY MANAGEMENT BY:

DATE: 08-20-14

DATE: 08-20-14

cc: QA / QC
Packaging
Production
Shipping / Receiving
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 Clostridium botulinum have been "negative" and the total Atropine and Scopolamine levels have been found to meet the specification of 50 cpm.

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.
EVENT DATA FORM

AE #: 1559                  COMPLAINT #: 2569

SECTION I:                      PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V21)

NAME: (b)(6)
ADDRESS:

CITY: __________________________  STATE: (b)(6)
COUNTRY: USA
PHONE #: ________________________
E-MAIL: _________________________

SECTION II:                      PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III:                     CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: __________________________  DATE: __________________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: __________________________  DATE: 08-20-14

BY: __________________________  DATE: 08-20-14
QA / QC DIRECTOR

DSS  SEP 05 2014

SEP 04 2014
OLUNTARY reporting of events, product problems and product use errors

A. PATIENT INFORMATION
1. Patient Identifier
(6)
2. Age at time of Event or Date of Birth
2 Months
3. Sex
[ ] Female
[ ] Male
[ ] Unknown
4. Weight
13 lb
5. Date of Event (mm/dd/yyyy)
06/26/2014
6. Date of this Report (mm/dd/yyyy)
09/28/2014
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.

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. [ ] Adverse Event
2. [ ] Product Problem (e.g., defects/malfunctions)
3. [ ] Product Use Error
4. [ ] Product with Different Manufacturer of Same Medicine
5. [ ] Death
6. [ ] Disability or Permanent Damage
7. [ ] Life-threatening
8. [ ] Congenital Anomaly/Birth Defect
9. [ ] Hospitalization - initial or prolonged
10. [ ] Other Serious (Important Medical Events)
11. [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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)
   Name: Hylands Best Teething Tablets
   Strength:
   Manufacturer:
2. Name:
   Strength:
   Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name
CTU
2. Common Device Name
SEP 29 2014
3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   [ ] Health Professional
   [ ] Lay User/Patient
   [ ] Other:
   [ ] Serial #
   [ ] Other #

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)
DSS
SEP 29 2014

G. REPORTER (See confidentiality section on back)
1. Name and Address
   (b)(6)
   Phone #
   (b)(6)
   E-mail (b)(6)

2. Health Professional?
   [ ] Yes
   [ ] No

3. Occupation
   (b)(6)

4. Also Reported to:
   [ ] Manufacturer
   [ ] User Facility
   [ ] Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:
[ ]

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.
My son was a very fussy baby since birth in [redacted]. He may be teething early and to try teething tablets. I started him on Hyland's 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 [redacted] Hospital in [redacted] 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 meningitis but it came back with blood. They did the spinal tap two times and both times had blood so they decided to do a cat scan. 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 performed. 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 Hyland's 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. I'm desperately asking you to review this please and get back to me as soon as possible at [redacted].

I have emailed Hyland's 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 29 2014
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 disabilities but it's too early to tell.
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: GERD (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 mean all issue and told her, Orajel Toothpaste medicine

Individual Case Safety Report

10483550-01-00-04

DSS
SFP 20314
### A. PATIENT INFORMATION

1. **Patient Identifier**
   - 00(0)

2. **Age at Time of Event or Date of Birth**
   - 6 Months

3. **Sex**
   - Female
   - Male

4. **Weight**
   - 20 lb
   - kg

#### B. ADVERSE EVENT, PRODUCT PROBLEM, OR ERROR

1. **Check all that apply:**
   - Adverse Event
   - Product Problem (e.g., defects/malfunctions)
   - Product Use Error
   - Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event**
   - Death
   - Disability or Permanent Damage
   - 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**
   - 06/10/2014

4. **Date of this Report**
   - 09/29/2014

5. **Describe Event, Problem or Product Use Error**
   - See page 2 for complete text.

6. **Relevant Tests/Laboratory Data, Including Dates**
   - See page 3 for complete text.

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.

### C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No
- Returned to Manufacturer on

### D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer (from product label)**
   - #1 Name: Hylands Best Teething tablets
   - Strength:
   - Manufacturer:

   - #2 Name:
   - Strength:
   - Manufacturer:

### E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
   - CTU

2. **Common Device Name**
   - SEP 30 2014

3. **Manufacturer Name, City and State**

4. **Model #**

5. **Lot #**

6. **Operator of Device**
   - Health Professional
   - Lay User/Patient
   - Other:

7. **Catalog #**

8. **Expiration Date**
   - mmm/dd/yyyy

9. **Serial #**

10. **Other #**

11. **If implanted, Give Date**
   - mmm/dd/yyyy

12. **If Explanted, Give Date**
    - mmm/dd/yyyy

13. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
   - Yes
   - No

14. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

### 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**
   - 30 2014

2. **Phone #**

3. **E-mail**

4. **Also Reported to:**
   - Manufacturer
   - User Facility
   - Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:**
   - Yes
   - No

---

**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.
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 seconds later) I called his doctor. We went in for an exam and a few days later had an EEG on his brain waves. The tests did not find anything wrong. I believe now that it was due to the teething tablets.
B.5. Relevant Tests/Laboratory Data, Including Dates (continued)

EKG was inconclusive
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

CaseID: 10486049

(continued)
A. PATIENT INFORMATION
1. Patient Identifier: (ID)(B)(6)
2. Age at time of event or date of birth:
   - Years: 2
   - Months: 0
3. Sex: 
   - Female
   - Male
4. Weight:
   - 25 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - 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)
   - 09/06/2012
4. Date of this report (mm/dd/yyyy)
   - 09/29/2014

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
   - Yes
   - No
   - Returned to manufacturer:

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - Name: teething tablets
   - Strength: unsure
   - Manufacturer:

   - Name:
   - Strength:
   - Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name

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
2. Phone # (B)(6)
3. Health Professional?
   - Yes
   - No
4. Also reported to:
   - Manufacturer
   - User Facility
   - Distributor/Importer

DSS SEP 3 0 2014
CTU SEP 3 0 2014

CaseID: 10486072
I gave my son who is now 3 the teething tablets when he was an infant this recall really worries me when my son was two he began having seizures and almost died in my arms it lasted 15 minutes the first time and was hospitalized in ICU. The second time lasted 1 1/2 hours and was hospitalized. He also cries 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.
Race: White
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds: Flintstones vitamins
ADVERSE EVENT REPORTING PROGRAM

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)
   - Age or Date of Birth:
     - 14 Months

2. Sex
   - Female

3. Weight
   - 22 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
- Advanced Event
- Product Problem (e.g., defect/malfunction)
- Product Use Error
- Problem with Different Manufacturer of Same Medicine

2. Outcomes attributed to adverse event (Check all that apply)
   - Death (mm/dd/yyyy)
   - Disability or Permanent Damage
   - 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)
   - 10/03/2014

4. Date of this report (mm/dd/yyyy)
   - 10/04/2014

5. Describe event, problem or product use error
   (See page 2 for complete text.)

6. Relevant tests/laboratory data, including dates

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.)

C. PRODUCT AVAILABILITY

Product available for evaluation? (Do not send product to FDA)
- Yes
- No
- Returned to manufacturer

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   - Name: Teaching tablets
   - Strength: Hylands teaching tablets
   - Manufacturer: Hylands

2. Name:
   - Strength:
   - Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common device name

3. Manufacturer name, city and state

4. Model #

5. Operator of device
   - Health professional
   - Lay user/patient
   - 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, enter name and address of reprocessor

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
   - Name: [redacted]
   - Address: [redacted]

2. Health professional? 3. Occupation
   - Yes
   - No

4. Also reported to:
   - Manufacturer
   - User facility
   - Distributor/Importer
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 1am, 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 and over for hours. Yet she was still spaced out, not acting herself. This was a very scary event for us as parents to Witness. I know this was caused from the hylands teething tablets. Please look into this over the counter medicine.
Race: White
Medical Conditions:

Allergies:

Important Information:

RX Meds:

OTC Meds: Infant Tylenol
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6)
2. Age at time of Event or Date of Birth: 1 Years
3. Sex: □ Female □ Male
4. Weight: 35 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

2. Dose or Amount

<table>
<thead>
<tr>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route</td>
</tr>
</tbody>
</table>

5. Event Abated After Use Stopped or Dose Reduced?

<table>
<thead>
<tr>
<th>#1</th>
<th>Yes</th>
<th>No</th>
<th>Doesn't Apply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Diagnosis or Reason for Use (indication)

<table>
<thead>
<tr>
<th>#1</th>
<th>Teething</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. Event Reappeared After Reinstitution?

<table>
<thead>
<tr>
<th>#1</th>
<th>Yes</th>
<th>No</th>
<th>Doesn't Apply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

C. PRODUCT AVAILABILITY

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Returned to Manufacturer: mm/dd/yyyy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

<table>
<thead>
<tr>
<th>#1 Name:</th>
<th>Hyland's Teething Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength:</td>
<td></td>
</tr>
<tr>
<td>Manufacturer:</td>
<td></td>
</tr>
</tbody>
</table>

| #2 Name: |                         |
| Strength: |                         |
| Manufacturer: |                     |

Please type or use black ink.
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 09 2014
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
EEG: normal  MRI: stated he has a hippocampal malformation

Individual Case Safety Report

10510040-01-00-03

DSS
OCT 09 2014
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatocellular 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
Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (e.g. 0112345)
2. Age at time of Event or Date of Birth:
   
   ☐ Female (X)
   ☐ Male

3. Sex
4. Weight
   
   ☐ lb
   ☐ kg

B. AVERSE 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: (mm/dd/yyyy)
   ☐ Disability or Permanent Damage
   ☐ 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)
   10/12/2014
4. Date of this Report (mm/dd/yyyy)
   10/12/2014

5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
   See page 3 for complete text.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on:

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   
   ☐ Name: Hyland Teething Tablets
   ☐ Manufacturer: Hyland

2. Name:
   Strength:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

OCT 14 2014

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ 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, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)
See page 5 for complete text.

G. REPORTER (See confidentiality section on back)

1. Name and Address
   
   (0/0)

2. Phone #

3. E-mail

4. Also Reported to:
   ☐ Manufacturer
   ☐ User Facility
   ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

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.
Pt was given Nyland Teathing 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 during hospital stay.
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

Head CT on (redacted) and (redacted)

Individual Case Safety Report

10519215-01-00-03

DSS

OCT 14 2014
A. PATIENT INFORMATION
1. Patient Identifier (ID) (Name): [Blank]
2. Age at Time of Event: 9 Months
3. Sex: Male
4. Weight: [Blank]

B. ADVERSE EVENT-OR-PRODUCT PROBLEM
1. Adverse Event and/or Product Problem
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - Death: [Blank]
   - Disability or Permanent Damage: [Blank]
   - Life-threatening: [Blank]
   - Congenital Anomaly/Birth Defect: [Blank]
   - Hospitalization: Initial or prolonged: [Blank]
   - Other Serious (Important Medical Events): [Blank]
   - Required Intervention to Prevent Permanent Impairment/Carcinoma (Devices): [Blank]
3. Date of Event (mm/dd/yyyy): 07/01/2014
4. Date of this Report (mm/dd/yyyy): 10/01/2014

5. Describe Event or Problem

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 PAVING HIS ARMS LIKE HIS 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 THIS DOCTOR AND THE DAY 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 LONGER. HIS FACE HAS AN EVIL SMILE WHEN HE'S SHAKING (LIKE A STRAIGHT SMILE WITH NO EMOTION). HAS NOT DONE SHAKEN SINCE SHE DISPOSED OF THE TABLETS. LAST EPISODE WAS ON SUNDAY, 09/20/2014.

6. Relevant Tests/Laboratory Data, Including Dates
   NONE

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer):
   HYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used:
   #2
3. Therapy Dates (if unknown, give dataset/protocol or best estimate):
   #1 2-3 TABS SL BID X 2 MOS
   #2

D. SUSPECT MEDICAL DEVICE
1. Brand Name:
2. Common Device Name:
3. Manufacturer Name, City and State:
4. Model #:
5. Lot #:
6. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other
7. Catalog #:
8. Expiration Date (mm/dd/yyyy):
9. Serial #:
10. Unique Identifiers (UDI) #:
11. If Implanted, Give Date (mm/dd/yyyy):
12. If Explanted, Give Date (mm/dd/yyyy):
13. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   - Yes
   - No
14. If Yes to Item 13, Enter Name and Address of Reprocessor:

E. INITIAL REPORTER
1. Name and Address:
   (Name)
   (Address)
   USA
2. Phone #:
   [Blank]
3. Email Address:
   [Blank]
4. Initial Reporter Also Sent Report to FDA:
   - Yes
   - No
   - Unknown

Submit a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.
### H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Serious Injury</td>
</tr>
<tr>
<td>Malfunction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction</td>
</tr>
<tr>
<td>Additional Information</td>
</tr>
<tr>
<td>Response to FDA Request</td>
</tr>
<tr>
<td>Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Evaluation Summary Attached</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Device Manufactured Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(mm/dd/yyyy)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Labeled for Single Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Event Problem and Evaluation Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code</td>
</tr>
<tr>
<td>Device Code</td>
</tr>
<tr>
<td>Method</td>
</tr>
<tr>
<td>Results</td>
</tr>
<tr>
<td>Conclusions</td>
</tr>
</tbody>
</table>

| 7. If Remedial Action Initiated, Check | |
|---------------------------------------|
| Recall                                |
| Notification                          |
| Repair                                |
| Inspection                            |
| Replace                               |
| Patient Monitoring                    |
| Relabeling                            |
| Modification/Adjustment               |
| Other:                                |

<table>
<thead>
<tr>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Use of Device</td>
</tr>
<tr>
<td>Repair</td>
</tr>
<tr>
<td>Inspection</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. Type of Report (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-day</td>
</tr>
<tr>
<td>30-day</td>
</tr>
<tr>
<td>Periodic</td>
</tr>
<tr>
<td>10-day [1]</td>
</tr>
<tr>
<td>Initial</td>
</tr>
<tr>
<td>15-day [2]</td>
</tr>
<tr>
<td>Follow-up</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>10. Manufacturer Name/Address</th>
</tr>
</thead>
</table>

### G. ALL MANUFACTURERS

<table>
<thead>
<tr>
<th>1. Contact Office (and Manufacturing Site for Devices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDITA FRACKIEVICS</td>
</tr>
<tr>
<td>Address: HYLAND'S, INC.</td>
</tr>
<tr>
<td>154 W. 131ST STREET</td>
</tr>
<tr>
<td>LOS ANGELES, CA 90061</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>310-768-0700</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>3. Report Source (Check all that apply)</th>
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</thead>
<tbody>
<tr>
<td>Foreign</td>
</tr>
<tr>
<td>Study</td>
</tr>
<tr>
<td>Literature</td>
</tr>
<tr>
<td>Health Professional</td>
</tr>
<tr>
<td>User Facility</td>
</tr>
<tr>
<td>Company Representative</td>
</tr>
<tr>
<td>Distributor</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Date Received by Manufacturer (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/28/2014</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. A/NDA #</th>
<th>IND #</th>
<th>BLA #</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>6. Type of Report (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination Product</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Pre-1938</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>OTC Product</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Manufacturer Report Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>54973 AE # 1562</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>8. Adverse Event Term(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEIZURES</td>
</tr>
</tbody>
</table>

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_DSS OCT 17 2014_

_10529024 OCT 1 6 2014_
MOOTHER 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 MONTH OLD MALE. TAKING BABY TEETHING TABLETS 2 - 3 TABLETS UNDER TONGUE TWICE A DAY FOR 2 MONTHS.
FOLLOW-UP 09/20/14: SHE CALLED THE DOCTOR AND HE SAID SHE WILL LOOK INTO THIS WEEK AND SEND CHILD TO A NEUROLOGIST. CHILD IS
INTERACTING WITH THE MOTHER DURING SHAKING BUT EACH TIME ITS 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 LONGER. HIS FACE HAS AN EVIL SMILE WHEN HE'S SHAKING LIKE A STRAIGHT SMILE WITH NO EMOTION. HAS NOT DONE SHAKING
SINCE SHE DISPOSED OF THE TABLETS. LAST EPISODE WAS ON SUNDAY, 09/28/2014.
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 100,000 units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A46514 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 # A46514. The Baby Teething bulk lot # 123453 was tested for total Atropine and Scopolamine and the results were within specification of ≤1 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.

Prepared by

Date

OCT 17 2014

OCT 16 2014
SE EVENT DATA FORM

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME:

ADDRESS:

CITY: ___________________________ STATE: (b) (d)

COUNTRY: USA ZIP CODE: ___________________________

PHONE #: (b) (d)

E-MAIL: __________________________

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: 0ct 17 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 10-07-14

BY: ___________________________ DATE: 10-07-14

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01
**A. PATIENT INFORMATION**

1. Patient Identifier: [Redacted]
2. Age at Time of Event: 6 Months
3. Sex: Female
4. Weight: lbs

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. Adverse Event and/or Product Problem (e.g., failure/malfunction):

2. Outcome Attributed to Adverse Event (Check all that apply):
   - Death: [Redacted]
   - Disability or Permanent Damage: [Redacted]
   - Life-threatening: [Redacted]
   - Congenital Anomaly/Birth Defect: [Redacted]
   - Hospitalization - Initial or Prolonged: [Redacted]
   - Other Serious (Important Medical Events): [Redacted]

3. Date of Event: 09/09/2012 - PRESENT
4. Date of This Report: 10/01/2014

5. Describe Event or Problem:

   The reporter's daughter began taking "Baby Teething Tablets" when she was about 4 months old. The reporter stated that she gave the tablets as directed on the bottle, 1 tablet by mouth every 30 minutes, and that she was very careful about the dosage because she was very wary about giving her daughter any kind of medication or supplement. Per the report, the "Baby Teething Tablets" were only given when symptoms were present. The reporter stated that she had also been giving her daughter "arajel" for her teething. The reporter stated that her daughter had her first seizure when she was 6 months old. Per the reporter, since then she had had 5 more seizures and was diagnosed with epilepsy about 2 weeks ago. The reporter stated that her daughter had abnormal brain waves on a "brain scan". Per the 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 mal" seizures last for 5 or more minutes. The reporter stated that her daughter was not taking medication for the seizures. She stated that she discontinued using the Baby Teething Tablets" when her daughter stopped teething, at around the age of 12 months.

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name:
2. Common Device Name:
3. Manufacturer Name, City and State:
4. Model #:
5. Operator of Device:
   - Health Professional
   - Lay User/Patient
   - Other:
6. If Implantable, Give Date (mm/dd/yyyy):
7. If Explanted, Give Date (mm/dd/yyyy):

**E. INITIAL REPORTER**

1. Name and Address:
   - [Redacted]
   - [Redacted]
2. Phone #:
3. Health Professional?: Yes No
4. Email Address:

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

Case ID: 10529055

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   - Death
   - Serious Injury
   - Malfunction

2. Follow-up, What Type?
   - Correction
   - Additional Information
   - Response to FDA Request
   - Device Evaluation

3. Device Evaluated by Manufacturer?
   - Not Returned to Manufacturer
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - Yes
   - No

6. Event Problem and Evaluation Codes (Refer to coding manual)

<table>
<thead>
<tr>
<th>Patient Code</th>
<th>Device Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Location Where Event Occurred</th>
</tr>
</thead>
</table>
   | Hospital
   | Outpatient Diagnostic Facility
   | Home
   | Ambulatory Surgical Facility
   | Nursing Home
   | Other (Specify)              |

11. Location Where Event Occurred

12. Location Where Event Occurred

13. Location Where Event Occurred

7. If Remodeling Action Initiated, Check Type

   - Recall
   - Notification
   - Repair
   - Inspection
   - Replacement
   - 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 360(f), list correction/removal reporting number:

<table>
<thead>
<tr>
<th>Patient Code</th>
<th>Device Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site) for Devices

   Name: EDITA FRACKENICZ
   Address: NYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061
   Email Address: STANDARD@NYLANDS.COM

2. Phone Number

   310-788-0200

3. Report Source (Check all that apply)
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other

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

   03/29/2014

5. A/I/INDA #

6. IND #: 1564

7. PG/MA:

   510(k) #

8. Type of Report

   - 5-day
   - 30-day
   - 7-day
   - Periodic
   - 10-day
   - 15-day
   - Initial

9. Manufacturer Report Number

   54973 AD # 1564

10. Additional Manufacturer Narrative

11. Corrected Data

   Yes

12. DSS OCT 17 2014

13. 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."

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAs@FDA.HHS.gov

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 0.6 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:
B.5 Describe Event or Problem (continued)
REPORTER: HER DAUGHTER WAS NOT HAVING SEIZURES IMMEDIATELY FOLLOWING ANY OF HER DOSES OF "BABY TEETHING TABLETS". PER THE REPORTER, NOBODY CORRELATED THE SEIZURES WITH THE "BABY TEETHING TABLETS"; SHE CALLED OUR EMERGENCY LINE NOW BECAUSE SHE SAW A POST ON FACEBOOK WHICH STATED THAT THE TEETHING TABLETS CAUSED SEIZURES.

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, hepatitis, 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

Other Remarks
OCT 16 2014
PRODUCT: BABY TEETHING TABLETS
SIZE: UNKNOWN
REPORTER: 
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: 
E-MAIL: 

NATURE OF COMPLAINT:
The reporter's daughter began taking "BABY TEETHING TABLETS" when she was about 4 months old. The reporter stated that she gave the tablets as directed on the bottle, 1 tablet by mouth every 3 hours, and that she was very careful about the dosing because she was very wary about giving her daughter any kind of medication or supplement. Per the reporter, the "BABY TEETHING TABLETS" were only given when symptoms were present. The reporter stated that she had also been giving her daughter "Israel" for her teething. The reporter stated that her daughter had her first seizure when she was 6 months old. Per the reporter, since then she has had 2 more seizures and was diagnosed with epilepsy about 2 weeks ago. The reporter stated that she had abnormal brain waves on a "brain scan" per the 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 mal" seizures last for 5 or more minutes. The reporter stated that her daughter was now taking medication for the seizures. She stated that she discontinued using the "BABY TEETHING TABLETS" when her daughter stopped teething at around the age of 12 months. Per the reporter, her daughter was not having seizures immediately following any of her doses of "BABY TEETHING TABLETS". Per the reporter, nobody correlated the seizures with the "BABY TEETHING TABLETS". She called our emergency line now because she saw a post on Facebook which stated that the teething tablets caused seizures. The reporter stated that she was at work and asked if she could call her back. When she stated that she would return her call if she didn't hear from her, the reporter said, "Oh, that would be even better". She stated that she gets off of work at 3:30 PM EST.

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION:
CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 09/29/14
BY: 

SECTION V: REVIEWED BY MANAGEMENT BY: 
DATE: 10-07-14

cc: QA / QC Packaging Production Shipping / Receiving

Form #: VD1

DSS OCT 17 2014

OCT 16 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 0.05 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

10/6/14

DSS

OCT 17 2014

OCT 16 2014
SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VP1)

NAME: 
ADDRESS: 
CITY: 
COUNTRY: USA 
PHONE #: 
E-MAIL: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV:

REVIEWED BY MANAGEMENT BY: 
DATE: 10-07-14

BY: 
QA / QC DIRECTOR
DATE: 10-07-14
Individual Case Safety Report

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION
1. Patient Identifier (B) (8)
2. Age at Time of Event: 7 Months
   or Date of Birth: 08/23/2012
3. Sex □ Female □ Male
   or Weight ___ lbs __ kgt

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. □ Adverse Event and/or □ Product Problem (e.g., device malfunction)
   □ Death: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ Life-threatening (mm/dd/yyyy)
   □ Congenital Anomaly/Birth Defect
   □ Hospitalization - initial or prolonged
   □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
2. Date of Event (mm/dd/yyyy): 08/23/2012
3. Date of Report (mm/dd/yyyy): 10/01/2014

5. Describe Event or Problem
   CHILD HAD AN ACCIDENT ON 08/23/2012
   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 SWELLING. 5 DAYS LATER THE DOCTORS FOUND ANOTHER OLDER BRAIN BLEED. HE WAS DIAGNOSED WITH SHAKEN BABY SYNDROME BUT HAD NO BROKEN BONES OR OTHER SIGNS OF INJURY. BABY HAS CEREBRAL PALSY (LAG ON RIGHT SIDE WHEN HE WALKS), WEAK ON THE RIGHT SIDE, AND RETINAL HEMORRHAGING WHICH MADE HIM BLIND IN ONE EYE (NONE OF THIS PRESENT BEFORE HE FELL -- DUE TO HEAD INJURY). DOCTORS ALSO FOUND MULTIPLE LAYERS OF OLD AND NEW RETINAL HEMORRHAGE UPON EVALUATION OF THE HEAD INJURY. MOTHER HOPES TO KNOW IF OLD RETINAL BLEED THEY FOUND WAS DUE TO BABY TEETHING TABLETS BECAUSE DOCTORS THOUGHT THAT OLDER RETINAL BLEED WAS DUE TO SHAKEN BABY SYNDROME. STARTED GIVING BABY TEETHING TABLETS WHEN THE CHILD WAS 5 MONTHS OLD.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & mfr/lot#)
   #1 HYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used
   #1 1/2TABSLQD=8HRS; 1TABSL
3. Therapy Dates (if unknown, give duration)
   *Month or best estimate*
   #1
   #2
4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN
5. Event Altered After Use Stopped or Dose Reduced?
   □ Yes □ No □ Doesn't Apply
   #1
   #2
6. Lot #
   #1
   #2
7. Exp. Date
   #1
   #2
8. ND# or Unique ID
   54973-3127-3
9. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Lot #
6. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:
7. Catalog #
8. Expiration Date (mm/dd/yyyy)
9. Serial #
10. Unique Identifier (UDI) #
11. If Implantated, Give Date (mm/dd/yyyy)
12. If Implanted, Give Date (mm/dd/yyyy)
13. Is this a Single-Use Device that was Reprocessed and Reused on a Patient?
   □ Yes □ No
14. If Yes to Item No. 8, Enter Name and Address of Reprocessor

E. INITIAL REPORTER
1. Name and Address
2. Health Professional? □ Yes □ No
3. Occupation □ NA
4. Initial Reporter Also Sent Report to FDA □ Yes □ No □ Don't Know
**G. ALL MANUFACTURERS**

1. Contact Office (and Manufacturing Site for Devices)
   - **Name:** EDYTA FRACKIEWICZ
   - **Address:** HYLAND'S, INC.
     154 W. 131ST STREET
     LOS ANGELES, CA 90061
   - **Email Address:** standard@hylands.com

2. **Phone Number:** 310-768-0700

3. **Report Source**
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional

4. **Data Received by Manufacturer (m/dd/yyyy):** 09/29/2014

5. **A/NDA #:**
   - **IND #:**
   - **BLA #:**

6. **If IND, Give Protocol #:**

7. **Type of Report**
   - [ ] Combination Product
   - [ ] Pre-1988
   - [ ] OTC Product

8. **Manufacturer Report Number:** 54973 AE # 1563

9. **Adverse Event Term(s):** BRAIN AND RETINAL HEMORRHAGE, SEIZURE, HEAD INJURY, CEREBRAL PALSY, RIGHT SIDED WEAKNESS, BLIND

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**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

3. **Device Evaluated by Manufacturer?**
   - [ ] Yes
   - [ ] Equipment/Device Returned to Manufacturer
   - [ ] Evaluation Summary Attached

4. **Device Manufacturer Date (m/dd/yyyy):**

5. **Labeled for Single Use?**
   - [ ] 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**
   - [ ] 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 386(f), list correction/removal reporting number:**

---

**DSS**

**OCT 20 2014**

**CaseID: 10530766**
**COMPLAINT RECORD**

**PRODUCT:** HYLAND'S BABY TEETHING TABLETS  
**SIZE:** 135 TABLETS  
**REPORTER:**  
**CITY:**  
**COUNTRY:** USA  
**PHONE #:**  
**EMAIL:**  
**NATURE OF COMPLAINT:** Child had an accident on (b)(6) and 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 swelling. 5 days later the doctor's refused another older brain bleed. He was diagnosed with shaken baby syndrome but had no broken bones or other signs of injury. Child protective services took the baby away and parents have not had custody for the last 2 years. Baby is with husband's parents. Baby has cerebral palsy (lag on right side when he walks), weak on the 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 old and new retinal hemorrhages which were found when he went to the hospital for the head injury. Mother wants to know if the old retinal bleed they found was due to baby teething tablets because doctor's thought that the older retinal bleed was due to shaken baby syndrome. Started giving baby teething tablets when the child was 5 months. Gave 1/2 tablet in his mouth every 6 - 8 hours as needed x 2 months until child went to the hospital (at 6 months increase 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 3rd. Customer sent the following email on 9/24/14. Hello, I was wondering if you had any complications in 2012. I started giving them to my son Junsu aly 2012 and I'm (b)(6) he had an accident and had a brain bleed. I can not explain the bleed and they took my son off of me. We bought the tablets from Walmart in (b)(6).

**FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET**

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**SECTION II: INVESTIGATION**

INVESTIGATION: Please see attached investigation report.

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**SECTION III: CORRECTIVE ACTION**

CORRECTIVE ACTION(s) COMPLETED BY:  

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**SECTION IV: ADVERSE EVENT REPORTS**

ADVERSE EVENT SERIOUS: Y / N  
ADVERSE EVENT REPORTED ON: 09/29/14  
BY: EDYTA FRACKIEWICZ  

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**SECTION V:**

REVIEWED BY MANAGEMENT BY:  
BY:  

---

**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 product 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

[Signature]

Date

10/6/14

DSS

OCT 20 2014

OCT 17 2014

CC-0755-2014
AE-0444-2014
AE #: 1563
COMPLAINT #: 2573

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 
ADDRESS: 
CITY: 
COUNTRY: USA 
PHONE #: 
E-MAIL: 
STATE: 
ZIP CODE: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV:

REVIEWED BY MANAGEMENT BY: 
DATE: 

BY: 
DATE: 

DSS
OCT 20 2014

DATE: 10-07-14

FORM SAEH1

DISTRIBUTION: FDA ADVERSE EVENT FILE

CASEID: 10530766
Individual Case Safety Report

FORM FDA 3500A (2/13)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier
   (3) (6)

2. Age at Time of Event:
   (9) Months
   or
   Date
   of Birth:

3. Sex
   □ Female
   □ Male

4. Weight
   (□ lbs or
   □ kg)

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event
   □ Yes
   □ No

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death (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)
   02/00/2013 & 04/00/2013

4. Date of This Report (mm/dd/yyyy)
   10/01/2014

5. Describe Event or Problem
   BABY STARTED USING TEETHING TABLETS AT 3 MONTHS OLD IN AUGUST 2012. BABY HAD GEHR (CAH) AT ONE MONTH OLD, MOTHER SWITCHED FORMULAS AND HE WAS BETTER. NO MEDICATION WAS PRESCRIBED. CURRENT HEALTH: HE IS PRONE TO GET FEVERS SINCE THE SEIZURES, ONCE A MONTH, OR TWO. THE PARENTS CAREFULLY MONITOR HIS FEVERS AND GIVE TYLENOL AND IBUPROFEN ALTERNATELY WHEN FEVER OCCURS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   (□ mg/kg)

3. Therapy Dates (if known, give duration from/to (or best estimate)

4. Diagnosis for Use (if used)
   (□ mg/kg)

5. Event Averted After Use Stopped or Dose Reduced?
   □ Yes
   □ No

6. Lot #

7. Exp. Date

C. SUSPECT MEDICAL DEVICE

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Implanted, Give Date (mm/dd/yyyy)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   □ Yes
   □ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA
   □ Yes
   □ No
   □ Unknown
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 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Papework Reduction Act (PRA) Staff
PRASstaff@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."
PRODUCT: HYLANO'S BABY TEETHING TABLETS
SIZE: 40 TABLETS
REPORTER: (b)(6) 
ADDRESS: 
CITY: 
COUNTRY: USA 
PHONE #: (b)(6) 
E-MAIL: 

NATURE OF COMPLAINT:

SON HAD 3 SEIZURES LAST YEAR IN 2013 "COMPLEX FEBRILE SEIZURES" WITH NO FAMILY HISTORY. HAD FEVER OF 103.7°F AFTER SEIZURE AND 99.2°F PRIOR TO THE FIRST SEIZURE. HE WAS TAKING ACETAMINOPHEN AND TEETHING TABLETS AT THE TIME. FIRST SEIZURE WAS IN FEBRUARY 2013. HE WAS BORN IN (b)(6) 2009. SECOND SEIZURE WAS IN (b)(6) 2012, WHILE IN THE HOSPITAL THAT SAME DAY, HE HAD A THIRD SEIZURE. BABY STARTED USING TEETHING TABLETS AT 3 MONTHS OLD IN AUGUST 2012. CHILD HAD GERD (GAS) AT ONE MONTH OLD, MOTHER switches FORMULAS AND HE WAS BETTER. NO MEDICATION WAS PRESCRIBED. CURRENT HEALTH: HE IS PRONE TO GET FEVERS SINCE THE SEIZURES, ONCE A MONTH, OR TWO. THE PARENTS CAREFULLY MONITOR HIS FEVERS AND GIVE TYLENOL AND IBUPROFEN ALTERNATELY WHEN FEVER OCCURS. MOTHER CONTINUED TO GIVE TEETHING TABLETS UNTIL HIS LAST TEETH EMERGED IN JANUARY 2014. SHE SAID HE "GOT HIS TEETH QUICKLY". AT THE HOSPITAL THEY DID NEUROLOGICAL WORKUP (EEG, EPILEPTIC STRESS TEST) AND DIAGNOSED IT AS "COMPLEX FEBRILE SEIZURES". MOTHER SAID DOCTOR WAS CURIOUS THAT THERE WAS NO FAMILY HISTORY OF IT. BABY WAS PRESCRIBED DIAZEPAM IF HE HAS ANOTHER SEIZURE. HAS HAD NONE SINCE. DOCTORS SAID TEETHING DID NOT CAUSE FEVER BUT HE ALWAYS HAD FEVER DURING HIS TEETHING PHASES. MOTHER CALLED AFTER READING AN ONLINE POST ABOUT TEETHING TABLETS AND WONDERED IF THAT COULD EXPLAIN THE CAUSE OF HER SON'S SEIZURES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION
INVESTIGATION PLEASE SEE ATTACHED INVESTIGATION REPORT:

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION ON: 09/29/14
ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GULD

SECTION IV: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION V: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y/N
ADVERSE EVENT REPORTED ON: 09/29/14
BY: TUTTI GOULD
REVIEWED BY MANAGEMENT BY: R. WOLF
BY: QA / QC DIRECTOR

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 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.
A. PATIENT INFORMATION

1 Patient Identifier (0) (0) [0]

2 Age at Time of Event: 3½ Months

3 Sex

4 Weight

B. ADVERSE EVENT OR PRODUCT PROBLEM

1 Adverse Event [☑] and/or [☐] Product Problem (e.g., defects/malfunctions)

2 Outcomes Attributed to Adverse Event (Check all that apply)

- Death [☐] (mm/dd/yyyy)
- Disability or Permanent Damage [☐]
- Life-threatening [☐]
- Congenital Anomaly/ Birth Defect [☐]
- Hospitalization - inpatient or prolonged [☑]
- Other Serious (Important Medical Events) [☐]
- Required Intervention to Prevent Permanent Impairment/Damage (Device) [☐]

3 Date of Event (mm/dd/yyyy) 09/09/2006

4 Date of This Report (mm/dd/yyyy) 10/01/2014

5 Describe Event or Problem

From the age of 6 months to 1 year old child was using Hyland's Teething Tablets. Child is currently 11 years old. At 2 years 11 months old developed seizures and epilepsy. He had four different kinds: grand mal with limp, shaking body; absence seizures; drop attach seizures; staring spells. Resolved when he was 4 years old.

C. SUSPECT PRODUCT(S)

1 Name (Give trade name, strength & manufacturer) [☐] HYLAND'S TEETHING TABLETS [☐]

2 Dose, Frequency & Route Used

- UNKNOWN DOSE X 6 DOS #1 [☑]

3 Therapy Dates (If known, give duration) [☐] Transfer (to best estimate) [☑]

4 Diagnosis for Use (Indication) [☐] TEMP RELIEF TEETHING PAIN [☐]

5 Event Altered After Use

- Stopped or dose reduced? [☐] Yes [☐] No [☐] Doesn't Apply

6 Lot # [☐] #1 [☐] #2

7 Exp. Date [☐] #1 [☐] #2

8 NDQ or Unique ID 54973-7504-1

9 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

3 Manufacturer Name, City and State

4 Model #

5 Operator of Device

- Health Professional [☑]

6 If Implant, Give Date (mm/dd/yyyy) 10/20/2014

7 If Explanted, Give Date (mm/dd/yyyy) 10/17/2014

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

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

2 Health Professional? [☒] Yes [☐] No [☐] NA

3 Occupation

4 Initial Reporter Also Sent Report to FDA [☐] 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.

RECEIVED OCT 17 2014 CDR (Continue on page 3)

UNKNOWN TESTS

DEVELOPED SEIZURES AND EPILEPSY AT 2 YEARS 11 MONTHS OLD.

(Continue on page 3)
COMPLAINT RECORD

PRODUCT: HYLAND'S TEETHING TABLETS
SIZE: 125 TABLETS
REPORTER: (b)(6)
ADDRESS:
CITY:
COUNTRY: USA
PHONE #: (b)(6)
E-MAIL:

SAW THE FACEBOOK POST ABOUT SEIZURES FROM THE AGE OF 6 MONTHS TO 1 YEAR OLD CHILD WAS USING HYLAND'S TEETHING TABLETS. CHILD IS CURRENTLY 11 YEARS OLD. AT 2 YEARS 11 MONTHS OLD DEVELOP ED SEIZURES AND EPILEPSY. DOCTOR'S SAID THAT HE WOULD HAVE SEIZURES THE REST OF HIS LIFE BUT HE HAS NO SEIZURES NOW. HE HAD FOUR DIFFERENT KINDS: GRAND MAL WITH LUMP, SHAKING BODY, ABSENCE SEIZURES, DROP ATTACH SEIZURES, STARRING SPELLS, RESOLVED WHEN HE WAS 4 YEARS OLD WHEN ANOTHER BABY IN THE FAMILY WAS BORN. DOCTORS CAN'T EXPLAIN HOW SEIZURES RESOLVED.

FOR ADDITIONAL SPACE PLEASE USE 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:

UPS CALL TAG ISSUED: Y [CIRCLE ONE] DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/30/14
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y [CIRCLE]
ADVERSE EVENT REPORTED ON: 09/30/14

SECTION V:

REVIEWED BY MANAGEMENT BY:

BY: [Signature]

OA / QC DIRECTOR

co: QA / QC Packaging Production Shipping / Receiving

DSS

OCT 20 2014

AE #: 1556

OCT 17 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.
C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer):
   
   - 1. Hyland's Baby Teething Tablets

2. Description of Use (Indication):
   - 1. TEMP RELIEF TEETHING PAIN

3. Therapy Dates (If unknown, give duration from/to or best estimate):
   - 1. 2

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions):

2. Outcomes Attributed to Adverse Event (Check all that apply):
   - [ ] Death (mm/dd/yyyy)
   - [ ] Consciousness Impairment/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):
   - 10/01/2013 -- PRESENT

5. Describe Event or Problem:

   Child developed seizures around the age of 3 months when mother started giving him the baby teething tablets. Child shakes really badly, especially when he is sleeping, when he has the seizures. He is going to have an EEG on October 16th. Child had a fever of 99.8F with the last shaking before that. Now, he has had fevers of 101F and 102F and would also shiver. He has a history of having high fevers. Doctor does not attribute the seizures to the fevers.

6. Relevant Tests/Laboratory Data, Including Dates:

   (Continue on page 3)

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

   History of high fevers.

   No family history of 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.
Individual Case Safety Report

Page 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

3. Device Evaluated by Manufacturer?
   - Not Returned to Manufacturer
   - Evaluation Summary Attached
   - No (Attach page to explain why not) or provide code:

4. Device Manufacture Date
   - (mm/dd/yyyy)

5. Labeled for Single Use?
   - 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
   - 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 360E(f), list correction/removal reporting number:

10. [ ] Additional Manufacturer Narrative and/or

11. [ ] Corrected Data

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - [Name]

2. Phone Number
   - 310-768-9700

3. Report Source
   - (Check all that apply)
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 09/29/2014

5. [ ] IND #
   - BLA #
   - NDA #

6. If IND, Give Protocol #

7. Type of Report
   - Combination
   - Product
   - Pre-1938
   - OTC Product

8. Manufacturer Report Number
   - 54973 AE # 1569

9. Adverse Event Term(s)
   - SEIZURES, FEVERS

DSS
OCT 24 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
PRASStaff2c@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.

OCT 23 2014

CaseID: 10542710
CUSTOMER SENT THE FOLLOWING E-MAIL ON SEPTEMBER 29: SINCE I HAVE BEEN GIVING THE TEETHING TABLETS TO MY SON HE KNOWS HAS SEIZURES BECAUSE OF THE PRODUCT. I SAW ALL OVER FACEBOOK THAT YOU GUYS HAD A RECALL OUT FOR IT. I SPEAK WITH CUSTOMER ON SEPTEMBER 30TH. 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 16TH. 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 10/1/14 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 THEW THE BOTTLE AWAY. STOP USING BABY TEETHING TABLETS AND CONSULT YOUR PHYSICIAN REGARDING YOUR CHILD'S SYMPTOMS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED: ___________________________

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED: ___________________________

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/20/14

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

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON: 09/20/14

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: ___________________________

DATE: 10-10-14

BY: ___________________________

DATE: 10-10-14

cc: QA / QC

Packaging

Production

Shipping / Receiving

Form # VD1
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 ≤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.
AE #: 1569

COMPLAINT #: 2579

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME:

ADDRESS:

CITY: (b)(6) STATE: (b)(6)

COUNTRY: USA

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)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: ___________________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 10-10-14

BY: ___________________________ DATE: 10-10-14

QA / QC DIRECTOR

DISTRIBUTION: FDA Adverse Event File

Oct 24 2014

DSS
Received

OCT 23 2014

gdp

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & niflable)

#1 HYLAND'S TEETHING TABLETS

2. Dose, Frequency & Route Used

#1 AS DIRECTED ON LABEL

3. Therapy Dates (If unknown, give duration)

From/to (or best estimate)

4. Diagnosis for Use (Indication)

#1 TEMP RELIEF TEETHING PAIN

5. Event Altered After Use

Stopped or Dose Reduced?

#1 Yes \(\square\) No \(\square\) Doesn't Apply

#2

6. Lot #

#1

#2

7. Exp. Date

#1

#2

9. NDC or Unique ID

54973-7904-1

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

Lot #

5. Operator of Device

E. INITIAL REPORTER

1. Name and Address

2. Health Professional? \(\square\) Yes \(\square\) No

3. Occupation

4. Initial Reporter Also Sent Report to FDA

OCT 23 2014

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: 10542735

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

3. Device Evaluated by Manufacturer?
   - Yes
   - Evaluation Summary Attached
   - No (Attach page to explain why not)

4. Device Manufacturer Date

5. Labeled for Single Use?
   - Yes
   - No

6. Event Problem and Evaluation Codes (Refer to coding manual)
   - Patient Code
   - Device Code
   - Method
   - Results
   - Conclusions

7. If Remediual Action Initiated, Check Type
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modification/Adjustment

8. Usage of Device
   - Initial Use of Device
   - Reuse
   - Unknown

9. If action reported to FDA under 21 USC 380(f), list correction/removal reporting number:

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name: EDITA FRANKIEWICZ
   - Address: HYLAND'S, INC.
     154 W. 131ST STREET
     LOS ANGELES, CA 90061
   - Email Address: STANDARDHYLANDS.COM

2. Phone Number: 310-768-0700

3. Report Source
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 10/04/2014

5. ANVDA #
   - IND #
   - BLA #
   - PMAM 510(K) #
   - Combination Product
   - Pre-108
   - OTC Product

6. Type of Report
   - Check all that apply
   - 90-day
   - 12-month
   - 18-month
   - Follow-up

7. Manufacturer Reporting Number
   - 54973 AE # 1573

8. Adverse Event Term(s)
   - SPEECH AND MOTOR FUNCTION DELAYS

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 60 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
PRASstaff@fas.dhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

OMIG 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.

DSS
OCT 24 2014

OMIG 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.

DSS
OCT 28 2014
COMPLAINT RECORD

COMPLAINT #: 2583

PRODUCT: HYLAND'S TEETHING TABLETS

SIZE: UNKNOW

REPORTER: [redacted]

ADDRESS: [redacted]

CITY: [redacted]

STATE: [redacted]

COUNTRY: USA

ZIP CODE: [redacted]

PHONE #: [redacted]

E-MAIL: [redacted]

DATE OF COMPLAINT: 10/04/14

ITEM CODE: TEET

LOT NO.: UNKNOWN

THE CUSTOMER POSTED THE FOLLOWING ON (1) (1) ON (2) (2) I JUST FOUND OUT THAT THESE TABLETS WERE VOLUNTARILY CALLED BY THE HYLAND'S COMPANY IN 2010. THEN AFTER THEY PUT A CHILD RESISTANT LID ON THEIR PRODUCT PUT IT BACK ON THE SHELVES. THIS PRODUCT CONTAINS AN INGREDIENT CALLED BELLA DONNA NOW TO THOSE OF YOU WHO DO NOT KNOW WHAT BELLA DONNA IS HERE IS A DESCRIPTION ON WIKIPEDIA.ORG/WIKI/ATROPIN.BELLA DONNA. 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. MY 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 & 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 TABLES 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 CHILD. 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

SECTION II: INVESTIGATION

INVESTIGATION Please see attached Investigation Report.

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION ON: 10/04/14

ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 10/04/14

BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 10-14-14

BY: QA/QC DIRECTOR

DATE: 10-14-14

OCC: QA/QC Packaging, Production, Shipping / Receiving

DSS OCT 24 2014

OCT 23 2014 Form # VD1
MOTHER OF CHILD:  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 SOCIAL MEDIA 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.
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
SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (6) [Redacted]
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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: __________________________ DATE: OCT 24, 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: __________________________ DATE: 10-14-14
BY: __________________________ DATE: 10-14-14
QA / QC DIRECTOR
A 36-HOUR EEG TEST SHOWED AN EEG OF UNKNOWN ORIGIN. ALL OTHER TESTS WERE NORMAL (MRI, CAT SCAN AND BLOOD WORK). DOCTORS PRESCRIBED PHENOBARBITAL UNTIL OCTOBER 15TH WHEN ANOTHER EEG IS TO BE DONE.

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

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

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?

3. Occupation

4. Initial Reporter Also Sent Report to FDA

<table>
<thead>
<tr>
<th>Date of Event (mm/dd/yyyy)</th>
<th>09/19/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of This Report (mm/dd/yyyy)</td>
<td>10/07/2014</td>
</tr>
</tbody>
</table>

9 MONTH OLD BABY HAD A SEIZURE ON AFTER BEING ON TEETHING TABLETS FOR 4 - 5 WEEKS. IT CAME ON AFTER HIS BATH AS MOTHER WAS PUTTING 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 OBSERVED FOR 4 DAYS. MOTHER SAID THAT SHE HAD GIVEN THE BABY 3 TABLETS OF TEETHING PRODUCT THE DAY BEFORE THE SEIZURE.

C. SUSPECT PRODUCT(S)

2. Dose, Frequency & Route Used

9. NDC# or Unique ID

5. Event Altered After Use Stopped or Does Reduced?

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

4. Diagnosis for Use (indication)

7. Exp. Date

8. Event Reappeared After Retroduction?

<table>
<thead>
<tr>
<th>Name (Give labeled strength &amp; form/shape)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYLAND'S BABY TEETHING TABLETS</td>
</tr>
</tbody>
</table>

2. Date of Birth:

4. Weight

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

6. Lot #

6. Description Event or Problem

8. Operator of Device

9. Implantable, Give Date (mm/dd/yyyy)

10. Device Available for Evaluation? (Do not send to FDA)

<table>
<thead>
<tr>
<th>Date (mm/dd/yyyy)</th>
<th>OCT 23 2014</th>
</tr>
</thead>
</table>

A 36-HOUR EEG TEST SHOWED AN EEG OF UNKNOWN ORIGIN. ALL OTHER TESTS WERE NORMAL (MRI, CAT SCAN AND BLOOD WORK). DOCTORS PRESCRIBED PHENOBARBITAL UNTIL OCTOBER 15TH WHEN ANOTHER EEG IS TO BE DONE.

2. Health Professional?

3. Occupation

4. Initial Reporter Also Sent Report to FDA
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:
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: UNKNOWN
REPORTER: (b)(6)
ADDRESS:
CITY: STATE: (b)(6)
COUNTRY: USA ZIP CODE:
PHONE #: (b)(6)
E-MAIL:

NATURE OF COMPLAINT: 9 MONTH OLD BABY HAD A SEIZURE ON 9/8 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 SPREAD TO THE REST OF HIS BODY AND LASTED 20 MINUTES. 9/11 WAS CALLED AND THE POLICE AND AMBULANCE ARRIVED, BABY'S TONGUE WAS HELD DOWN BY A TONGUE DEPRESSOR. BABY WAS TRANSFERRED TO THE CHILDREN'S HOSPITAL AND STAYED FOR 4 DAYS. A 36-HOUR EEG TEST SHOWED A 'SMALL SPIKE' OF UNKNOWN ORIGIN. ALL OTHER TESTS WERE NORMAL (MRI, CAT SCAN AND BLOOD WORK). DOCTORS PRESCRIBED PHENOBARBITAL UNTIL OCTOBER 15TH WHEN ANOTHER EEG WILL BE DONE. BABY HAS BEEN ON FORMULA AND HAD THE SAME ROUTINE AND DIET IN THE 24 HOURS PRIOR TO THE SEIZURE, PLAYING WITH HIS BOUNCER AND WALKER. THERE IS NO HISTORY ANY Colds, FEVERS OR RASHES. HIS LAST IMMUNIZATION WAS JUNE 10TH, 2014. HE HAS ALSO RECEIVED REGULAR FLU SHOTS. MOTHER SAID THAT SHE HAD GIVEN THE BABY 3 TABLETS OF TEETHING PRODUCT THE DAY BEFORE THE SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED:
UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
10/02/14
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

ADVERSE EVENT SERIOUS: Y N
ADVERSE EVENT REPORTED ON: 10/02/14 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:
DATE: 10-10-14
BY: QA/QC DIRECTOR
DATE: 10-10-14

cc: QA/QC
Packaging
Production
Shipping / Receiving

OCT 24 2014

2542775-OCT 24 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 ≤ 0.03 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

10/2/14

Date

DSS  
OCT 24 2014
RSE EVENT DATA FORM

AE #: 1571
COMPLAINT #: 2581

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 
ADDRESS: 
CITY: 
STATE: 
COUNTRY: USA 
ZIP CODE: 
PHONE #: 
E-MAIL: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

AFFIX COPY OF OUTER CARTON HERE

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ______________________ DATE: ____________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ______________________ DATE: 10-10-14

BY: ______________________ DATE: 10-10-14

QA / QC DIRECTOR
A. PATIENT INFORMATION

1. Patient Identifier (ID): [Redacted]
2. Age at Time of Event: 10 Months
3. Sex: Male
4. Weight: [Redacted]
5. Date of Birth: [Redacted]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   - [ ] Death: [mm/dd/yyyy]
   - [ ] Disability or Permanent Damage:
   - [ ] Life-threatening:
   - [ ] Congenital Anomaly/Birth Defect:
   - [ ] Hospitalization - Initial or Prolonged:
   - [ ] Other Serious (Important Medical Events):
   - [ ] Required Intervention to Prevent Impairment/Damage (Devices):

3. Date of Event (mm/dd/yyyy): 08/09/2014
4. Date of This Report (mm/dd/yyyy): 10/06/2014

5. Describe Event or Problem

   A mother called after reading about Belladonna and wondered if it was related to her son's seizures-like symptoms. The symptoms seem to occur 4-5 times a month, sometimes when he was away from his mother's home. She says he seems to sleep deeply and is difficult to arouse; he is slow to respond. He has been having them for the last 2 months; during this time he has not been taking teething tablets. Her son is 1 year old, and she takes the tablets for periods 5-7 times a month. She has been using Teething RIN 7 to help him, having "forgotten" about the tablets. On the phone message, the mother reported that her son had seizures and had a "brain bleed." He has been on Nystatin and Amoxicillin for thrush, ear infections, colds, and "bacterial stomach infections," which she says seems to have started at 6 months, when he was teething and started using teething tablets. She thought he had a lowered immune system. He also vomited frequently despite formula changes, and was diagnosed as having acid reflux. He was told that there was nothing that could be done for it. Child has a history of "lots

D. SUSPECT MEDICAL DEVICE

1. Brand Name: [Redacted]
2. Common Device Name: [Redacted]
3. Manufacturer Name, City and State: [Redacted]
4. Model #: [Redacted]
5. Serial #: [Redacted]
6. Operator of Device: [Health Professional]
7. Catalog #: [Redacted]
8. Lot #: [Redacted]
9. Expiration Date (mm/dd/yyyy): [Redacted]

E. INITIAL REPORTER

1. Name and Address:
   - (b6) [Redacted]
   - (b6) USA
2. Phone #: [Redacted]
3. Email Address: [Redacted]
4. Initial Reporter Also Sent Report to FDA: [No]

GASTROESOPHAGEAL REFLUX (GERD); ACID REFLUX;
HISTORY OF BACTERIAL STOMACH INFECTIONS, EAR INFECTIONS, FRENQUENT COLDS, THRUN.
CHILD IS PRONE TO FEVERS AND DEVELOPS THEM AFTER IMMUNIZATION SHOTS.
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 60 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
PRASStaff@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."
B.5 Describe Event or Problem (continued)

OF FEVERS WITH TEETHING*. THE HIGHEST FEVER HE ELICITS IS 102F. DURING THE TIME HE WAS GIVEN TEETHING TABLETS, HE WAS ALSO GIVEN TYLENOL, AND LATER MOTRIN FOR FEVER. (MOTRIN WHEN HE WAS OLD ENOUGH.) CHILD HAS BEEN SLEEPING MORE OFTEN THAN USUAL. HIS REGULAR NAPS TEND TO BE 15 MINUTES, BUT LATELY HE HAS BEEN HAVING 4 NAPS A DAY AND ONE DAY SLEPT FOR 4 HOURS.

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)

DSS
OCT 24, 2014

Other Remarks
OCT 23, 2014
A mother called after reading about Belladonna and wondered if it was related to her son's seizure-like symptoms. The symptoms seem to occur 4-5 times a month, and sometimes when he was away from mother's home. She says that he sleeps deeply and is difficult to arouse; he is slow to respond to his name being called or mother waving his arms around. He has been having them for the last 2 months. During this time he has not been taking Teething Tablets. Her son is 1 year old, and did take Teething Tablets during his teething episodes from 6 months of age until 10 months old. At 10 months old, she just used Teething Rings to help him, having "forgotten" about the Tablets. On the phone message, the mother reported that her son had seizures and doctor had called them "brain bleeds," but she did not mention this on the phone call. He has been on Nystatin and Amoxicillin for thrush, ear infections, colds, and "bacterial stomach infections," which she says seems to have started at 6 months, when he was teething and started using Teething Tablets, she thought he had a lowered immune system. He also vomited frequently despite formula changes, and was diagnosed as having acid reflux. She was told that there was nothing that could be done for it.

Child has a history of 'lots of fevers with Teething.' The highest fever he elicits is 102°F. During the time he was given Teething Tablets, he was also given Tylenol and later Motrin for fever. (Motrin when he was old enough.) The doctor has scheduled an MRI for October 22nd. His last immunization was September 2nd. He develops fevers after the shots. He also has been sleeping more often than usual. His regular naps tend to be 15 minutes, but lately he had been having 4 naps a day and one day slept for 4 hours. All test he has received to date was a blood test for iron, which was normal.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET.
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 < 0 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.
A. PATIENT INFORMATION

1. Patient Identifier (b) (f) [illegible]

2. Age at Time of Event: [illegible]

3. Sex: [ ] Female

4. Weight: [illegible]

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [ ] Adverse Event and/or [ ] Product Problem (e.g., defect/malfunctions)

2. Outcomes Attributed to Adverse Event

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>(mm/dd/yyyy)</td>
</tr>
<tr>
<td>Life-threatening</td>
<td></td>
</tr>
<tr>
<td>Hospitalization - initial or prolonged</td>
<td></td>
</tr>
<tr>
<td>Other Serious (Important Medical Events)</td>
<td></td>
</tr>
<tr>
<td>Required Intervention to Prevent Permanent Impairment/Damage (Devices)</td>
<td></td>
</tr>
</tbody>
</table>

3. Date of Event (mm/dd/yyyy) 05/03/2014 & 09/22/2014

4. Date of This Report (mm/dd/yyyy) 10/09/2014

5. Describe Event or Problem

MOTHER CALLED CONCERNED ABOUT HER 1 YEARS OLD DAUGHTER WHO HAS BEEN TAKING TEETHING TABLETS AN ALRED 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 MAY IDENTIFIED THE SWELLING AS "BLEEDING BETWEEN THE SKIN AND SKULL".

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYLAND'S BABY TEETHING TABLETS</td>
<td></td>
</tr>
</tbody>
</table>

2. Dose, Frequency & Route Used

<table>
<thead>
<tr>
<th>Dose</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TABLETS ORALLY</td>
<td></td>
</tr>
</tbody>
</table>

3. Therapy Dates (If unknown, give duration)

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp Relief Teething Pain</td>
<td></td>
</tr>
</tbody>
</table>

4. Diagnosis (For Use (Indication))

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEBRILE SEIZURE</td>
<td></td>
</tr>
</tbody>
</table>

5. Event Abated After Stopped or Dose Reduced?

<table>
<thead>
<tr>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, No</td>
<td></td>
</tr>
</tbody>
</table>

6. Lot #

<table>
<thead>
<tr>
<th>Lot #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A10014</td>
<td></td>
</tr>
</tbody>
</table>

7. Exp. Date

<table>
<thead>
<tr>
<th>Exp. Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td></td>
</tr>
</tbody>
</table>

8. NDC# or Unique ID

<table>
<thead>
<tr>
<th>NDC# or Unique ID</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>54973-3127-1</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Medical Products</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANOMICILLIN, BABY GRAPEF (FEB. 2014)</td>
<td></td>
</tr>
</tbody>
</table>

D. SUSPECT MEDICAL DEVICE

1. Brand Name

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Description</th>
</tr>
</thead>
</table>

2. Common Device Name

<table>
<thead>
<tr>
<th>Common Device Name</th>
<th>Description</th>
</tr>
</thead>
</table>

3. Manufacturer Name, City and State

<table>
<thead>
<tr>
<th>Manufacturer Name, City and State</th>
<th>Description</th>
</tr>
</thead>
</table>

4. Model #

<table>
<thead>
<tr>
<th>Model #</th>
<th>Description</th>
</tr>
</thead>
</table>

5. Operator of Device

<table>
<thead>
<tr>
<th>Operator of Device</th>
<th>Description</th>
</tr>
</thead>
</table>

6. Relevant Tests/Laboratory Data, Including Dates

- CT SCAN -- MAY 2014, MRI TEST IS PENDING. ALL NEGATIVE AS OF YK.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hemodynamic dysfuntion, etc.)

- EAR INFECTION (SEPT. 2, 2011), FUNGAL INFECTION FROM ANOMICILLIN (SEPT.), KAWASAKI VIRUS (SEPT. 219), FEBRILE SEIZURE (SEPT. 19 OR 22).

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

- FEBRILE SEIZURE: AUGUST 10, 2014
- SPRAYED THE GARAGE FOR TERMITES IN SEPTEMBER 2014.

E. INITIAL REPORTER

1. Name and Address

| Name and Address                     | Description |

2. Health Professional? [ ] Yes [ ] No

3. Occupation NA

4. Initial Reporter Also Sent Report to FDA

[ ] Yes [ ] No [ ] Link
### F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One
   - User Facility
   - Importer

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

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

7. Type of Report
   - Initial
   - Follow-up #

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
    - Patient
    - Code
    - Device
    - Code

11. Report Sent to FDA?
   - Yes (mm/dd/yyyy)
   - No (mm/dd/yyyy)

12. Location Where Event Occurred
    - Hospital
    - Outpatient Diagnostic Facility
    - Home
    - Nursing Home
    - Outpatient Treatment Facility
    - Other: (Specify)

13. Report Sent to Manufacturer?
   - Yes (mm/dd/yyyy)
   - No (mm/dd/yyyy)

14. Manufacturer Name/Address

### 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

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/dd/yyyy)

5. Labelled for Single Use?
   - 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
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modification/Adjustment
   - Other: (Specify)

8. Usage of Device
   - Initial Use of Device
   - Repair
   - Reuse
   - Unknown

9. If action reported to FDA under 21 USC 351(k), list correction/removal reporting number:

10. Additional Manufacturer Narrative

### G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name
   - Address
   - Email Address

2. Phone Number
   - 310-766-0700

3. Report Source
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other:

4. Data Received by Manufacturer (mm/dd/yyyy)
   - 10/03/2014

5. A/NDA #

6. IND #

7. BLA #

8. Type of Report
   - Combination Product
   - Pre-1938
   - OTC Product

9. Manufacturer Report Number
   - 54973 AE # 1574

10. Adverse Event Term(s)
    - SWELLING AND SEIZURE

---

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 65 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
PRASStaff@fda.hhs.gov

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

---

DSS
OCT 24 2014
OCT 23 2014
COMPLAINT RECORD

COMPLAINT #: 2564
DATE OF COMPLAINT: 10/09/14

PRODUCT: HYLANDS BABY TEETHING TABLETS
ITEM CODE: BTET---T135
LOT NO.: A10014 BOTTLE
A10114 BOX

REPORTER: (B)(6)
ADDRESS:

CITY: (B)(6) STATE:
COUNTRY: USA
ZIP CODE: (B)(6)
PHONE #: (B)(6)
E-MAIL: (B)(6)

NATURE OF COMPLAINT:
MOTHER CALLED CONCERNED ABOUT HER 1 YEAR 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 SEPTEMBER 22 (FEVER 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 OR WAKING (AS OF SEPTEMBER 29TH), BANGING AND HOLDING HER HEAD. ON SEPTEMBER 19TH OR 20TH (PER CUSTOMER) CHILD WAS DIAGNOSED WITH A VIRUS AND GIVEN AMOXICILLIN. SHE VOMITED THAT NIGHT, AND ROLLED HER EYES, WENT STIFF AND STOPPED BREATHING BRIEFLY. THE DOCTOR WHO ONLY SAW THE CHILD SEVERAL DAYS LATER DIAGNOSED IT AS FEVER SEIZURE. THE MOTHER COMMENTED THAT HER OLDER SON HAD SIMILAR SYMPTOMS AND IT WAS DIAGNOSED AS ANGER RELATED. AUGUST 10, 2014 WAS HER LAST IMMUNIZATION. SEPTEMBER 24, 2014 THE CHILD WAS GIVEN MILK FOR THE FIRST TIME.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED:

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT REPORTED ON: 10/03/14
BY: TUTTI GOULD

ADVERSE EVENT SERIOUS: Y / N

SECTION V:

REVIEWED BY MANAGEMENT:

BY: [Signature]
DATE: 10-15-14

cc: QA / QC
Production
Packaging
Shipping / Receiving

Form # V01

OCT 23 2014
DSS
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 (6) and (6) 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 within specification of 50 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 [Signature]

Date 10/14/14

DSS
OCT 24 2014

OCT 28 2014
MOTHER WAS CONCERNED THAT HER 5 MONTH OLD BABY’S SEIZURE WAS ASSOCIATED WITH TAKING TEETHING TABLETS, BEGINNING AUGUST 10, 2014. BABY WAS HOSPITALIZED (b)(6) WITH HIGH FEVER (105.6F), SHALLOW BREATHING, ALTERED STATE OF CONSCIOUSNESS, AND A HEART RATE OF 240. A URINARY TRACT INFECTION WAS DISCOVERED THROUGH A URINE TEST AND THE TREATMENT GIVEN WAS NEURAL TYLENOL AND 3 DIFFERENT ANTIBIOTICS INCLUDING BACTRIM. TWO WEEKS PRIOR, THE MOTHER TOOK THE BABY TO THE HOSPITAL BECAUSE SHE WAS NOT HER USUAL SELF. BABY’S SYMPTOMS INCLUDED DROOLING, NOT SMILING AND A FEVER OF 102.5F.

Revised: OCT 23 2014

CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

FIRST DIAGNOSIS OF "VIRAL SYNDROME" WAS RECEIVED FROM FIRST HOSPITAL VISIT IN (b)(6) WITH A HIGH FEVER (102F). SECOND VISIT ON (b)(6) WAS FOR A HIGH FEVER (105.6F) AND URINARY TRACT INFECTION, AND SEIZURE. MENINGITIS TEST, BRAIN WAVE SCAN, EPILEPSY TEST, AND BLOOD AND URINE TESTS. DIAGNOSIS WAS A URINARY TRACT INFECTION. URINE TEST SHOWED BACTERIA, THE OTHER TESTS WERE NORMAL.

(Continue on page 3)

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

LAST IMMUNIZATION WAS IN AUGUST. BABY IS FORMULA FED.

(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.
### G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
   - Name: Sonya Frackiewicz
   - Address: Hylands, Inc., 154 W. 131st Street, Los Angeles, CA 90061
   - Email Address: Standard@Hylands.com

2. **Phone Number**
   - 310-768-0700

3. **Report Source**
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other:

4. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 10/01/2014

5. **IND #**
   - 351000

6. **Type of Report**
   - 5-day
   - 10-day
   - Initial

7. **Manufacturer Report Number**
   - 54973 AE # 1568

8. **Adverse Event Term(s)**
   - SEIZURE

---

### 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

3. **Device Evaluated by Manufacturer?**
   - Not Returned to Manufacturer
     - Yes
     - Evaluation Summary Attached
     - No

4. **Device Manufacturer Date (mm/dd/yyyy)**

5. **Labeled for Single Use?**
   - 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**
   - 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 380(a), list correction/removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

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:
MOTHER CALLED 911 WHO TOOK HER DAUGHTER TO THE HOSPITAL FOR A HIGH FEVER 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 WAVES, SCANS, 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 RANANAS AS SHE HAD INTRODUCED THEM SHORTLY BEFORE THE SEIZURE EVEN THOUGH THE DOCTOR HAD RULLED 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 THE 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.

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 REACTIONS. 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 $6.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET.
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 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 # 123336 was tested for total Atropine and Scopolamine and the results were with in specification of ≤ 0.04 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 [Signature]

Date 10/8/14

Oct 23 2014

DSS

Oct 24 2014
RSE EVENT DATA FORM

AE #: 1568

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME:

ADDRESS:

CITY: (b)(6)

COUNTRY: USA

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)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: __________________________ DATE: __________

SECTION IV:

REVIEWED BY MANAGEMENT BY: __________________________ DATE: 10-13-14

BY: __________________________ DATE: 10-10-14

QA/QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SA611
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION
1. Patient Identifier
(b) (6)
2. Age at Time of Event:
   Years
   Date of Birth:
   In confidence
3. Sex
   Female
   Male
4. Weight
   lbs
   kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   Death (mm/dd/yyyy)
   Disability or Permanent Damage
   Life-threatening
   Congenital Anomaly/Birth Defect
   Hospitalization - Initial or prolonged
   Other Serious (Important Medical Event)
   Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem
   MOTHER POSTED ON (b) (6) THAT 10 YEAR OLD SON HAS MOTOR FUNCTION DELAYS AFTER USE OF TEETHING TABLETS AS AN INFANT. STRUGGLES WITH SPEECH, OT, READING, ATTENTION SPAN, MEMORY AND IS IN A SPECIAL EDUCATION CLASS.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & milliliter)
   HYLAND'S TEETHING TABLETS
2. Dose, Frequency & Route Used
   #1
   AS DIRECTED ON THE LABEL
2. Therapy Dates (If unknown, give duration) (mm/dd/yyyy) or best estimate
   #1
   #2
4. Diagnosis for Use (Indication)
   PAIN RELIEF OF TEETHING PAIN
   #1
   #2
5. Event Altered After Use (Stop or Dose Reduced?)
   #1
   Experienced (mm/dd/yyyy) or Doesn't Apply
   #2
   Experienced (mm/dd/yyyy) or Doesn't Apply
6. Lot #
7. Exp. Date
   #1
   #2
9. NDOC# or Unique ID
   54973-7504-1
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Lot #
6. Operator of Device
   Health Professional
   Lay User/Patient
   Other:
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Expired, Give Date (mm/dd/yyyy)
9. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   Yes
   No
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)

E. INITIAL REPORTER
1. Name and Address
   DSS
   USA
   2. Phone #
   3. Email Address
   4. Initial Reporter Also Sent Report to FDA
      Yes
      No
      Unk
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, OMB Control Number: FDA 0910-0176. Please do not return this form to the above PRA Staff email address.
COMPLAINT #: 2582  
DATE OF COMPLAINT: 10/04/14

PRODUCT: ATLANTIS TEETHING TABLETS  
ITEM CODE: TET

SIZE: UNKNOWN  
LOT NO.: UNKNOWN

REPORTER:  
ADDRESS:  
CITY:  
STATE:  
COUNTRY: USA  
ZIP CODE:  
PHONE #:  
E-MAIL:  

CUSTOMER POSTED THE FOLLOWING ON (0) (0) I JUST FOUND OUT THAT THESE TABLETS WERE VOLUNTARILY RECALLED BY THE HYLAND'S COMPANY IN 2010 THEN AFTER THEY PUT A CHILD RESISTANT 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 CDN.WIKIPEDIA.ORG/WIKI/TROPIC_BELLADONNA. IT IS THE MOST TOXIC PLANT IN THE NORTHERN HEMISPHERE ANY YET WE HAVE BEEN GIVING THIS TO OUR BABIES!! I DON'T BELIEVE EVERYTHING I SEE ONLINE BUT THIS IS ONE I FOUND I NEEDED TO RESEARCH. MY 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 8 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 OLD DAUGHTER DID NOT TALK UNTIL SHE WAS 3 AND EVEN THEN SHE ONLY HAD AROUND 40 WORDS. 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 INSPECTION: Y [CIRCLE ONE]  
PRODUCT BEING RETURNED FOR INSPECTION: N [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 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

ADVERSE EVENT SERIOUS: Y N  
ADVERSE EVENT REPORTED ON 10/04/14  

SECTION V:

REVIEWED BY MANAGEMENT BY:  
DATE: 10-14-14  

BY:  
DATE: 10-14-14

cc: QA / QC DIRECTION PRODUCTION SHIPPING / RECEIVING
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.
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

DSS

OCT 24 2014

OCT 28 2014
SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 

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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: 

SECTION IV:

REVIEWED BY MANAGEMENT BY: 

DATE: 10-14-14

BY: 

DATE: 10-14-14

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE21

DSS OCT 24 2014
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b) (6) [Redacted]
2. Age at Time of Event or Date of Birth: 14 Months
3. Sex [Female] [Male]
4. Weight [Redacted]

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
   [ ] Death: [Redacted]
   [ ] Disability or Permanent Damage
   [ ] 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) 10/31/2014
4. Date of this Report (mm/dd/yyyy) 11/04/2014
5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on [Redacted]

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   #1 Name: [Redacted]
   Strength: [Redacted]
   Manufacturer: [Redacted]
   #2 Name: [Redacted]
   Strength: [Redacted]
   Manufacturer: [Redacted]

E. SUSPECT MEDICAL DEVICE
1. Brand Name

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

G. REPORTER (See confidentiality section on back)
1. Name and Address
   [Redacted]
   Address:
   City:
   State: -- ZIP:
   Phone #: [Redacted]
   E-mail [Redacted]
2. Health Professional? [ ] Yes [ ] No
3. Occupation [Redacted]
4. Also Reported to:
   [ ] Manufacturer
   [ ] User Facility
   [ ] Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: [ ]
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.
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

10567790.01-00-03

DSS
NOV 5 2014

DOCTOR'S SAW EVIDENCE ON AN EEG THAT CHILD HAD A SEIZURE. NO DIAGNOSIS WAS GIVEN AND A CAUSE FOR THE SEIZURES WERE NOT DETERMINED.
G. ALL MANUFACTURERS

1. Name
   EDITA FRACKIEWICZ

2. Address
   HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

3. Email Address
   STANDARD@HYLANDS.COM

4. Date Received by Manufacturer (mm/dd/yyyy)
   10/21/2014

5. IND #
   PMA #
   510(k) #

6. Type of Report
   (Check all that apply)
   □ 5-day
   □ 30-day
   □ 7-day
   □ Periodic
   □ 10-day
   □ Initial
   □ 15-day
   □ Follow-up #

7. Manufacturer Report Number
   54973 A/E # 1575

8. Adverse Event Term(s)
   SEIZURES, VOMITING

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

10. Additional Manufacturer Narrative

11. Corrected Data

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   □ Death
   □ Serious Injury
   □ Malfunction
   □ Other:

2. If Follow-up, What Type?
   □ Correction
   □ Additional Information
   □ Response to FDA Request
   □ Device Evaluation

3. Device Evaluation by Manufacturer?
   □ No
   □ Evaluation Summary Attached
   □ No (Attach page to explain why not or provide code):

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   □ Yes
   □ No

6. Event Problem and Evaluation Codes (Refer to coding manual)
   Patient
   Device
   Code
   Code

7. If Remedial Action Initiated, Check Type
   □ 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 360(i), list correction/removal reporting number:

DSS
NOV 05 2014

NOV 05 2014

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStatement.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.”
CUSTOMER COMPLAINT RECORD

COMPLAINT #: 2505
DATE OF COMPLAINT: 10/21/14
ITEM CODE: BTET
LOT NO.: UNKNOWN

SECTION I: COMPLAINT

TAKEN BY: (b)(6)
PRODUCT: HYLAN'S BABY TEETHING TABLETS
SIZE: UNKNOWN
REPORTER: (b)(6)
ADDRESS: (b)(6)
CITY: (b)(6)
STATE: (b)(6)
PHONE #: (b)(6)
ZIP CODE: (b)(6)

E-MAIL:

THE REPORTER STATED THAT SHE HAD BEEN GIVING HER SON THE "BABY TEETHING TABLETS" PRODUCT LAST YEAR. SHE STATED THAT HE HAD 3 OR 4 SEIZURES DURING THE TIME THAT HE WAS TAKING THE "TEETHING TABLETS." SHE STATED THAT HER SON WAS ALMOST 2 YEARS OLD AT THE TIME. PER THE REPORTER, HER PARENTS CALLED AN AMBULANCE LAST YEAR WHEN HER SON HAD THE FIRST SEIZURE. SHE STATED THAT HE WAS RUSHED TO THE HOSPITAL AND THAT ALL OF HIS TESTS, INCLUDING AN EEG, WERE NORMAL. PER THE REPORTER, THE CHILD WAS ALSO SEEN BY A SPECIALIST AT THE CHILDREN'S HOSPITAL FOLLOWING THE EMERGENCY ROOM VISIT. PER THIS REPORTER, THE DOCTORS STATED THAT THERE WAS EVIDENCE ON THE EEG THAT HER SON HAD A SEIZURE, BUT THE DOCTORS WERE UNABLE TO DETERMINE A CAUSE FOR THE SEIZURES. PER THE REPORTER, THE CHILD WAS NEVER GIVEN A DIAGNOSIS. THE REPORTER STATED THAT SHE HAD BEEN USING THE CHILD THE "TEETHING TABLETS" ALMOST ON A DAILY BASIS AND THAT SHE HAD USED APPROXIMATELY THREE BOTTLES OF "TEETHING TABLETS" WHILE HER SON WAS TEETHING. SHE STATED THAT SHE GAVE HIM 2-3 TABLETS PER DOSE MAINLY WHEN SYMPTOMS WERE PRESENT. SHE STATED THAT SHE FOLLOWED THE FirmS RECOMMENDED DOSING INSTRUCTIONS ON THE LABEL AND DID NOT GIVE HIM MORE THAN THE RECOMMENDED DOSE. SHE STATED THAT THE SEIZURES DID NOT OCCUR IMMEDIATELY FOLLOWING A DOSE OF "TEETHING TABLETS," BUT THAT THEY OCCURRED DURING THE PERIOD OF TIME THAT THE CHILD WAS TAKING THE "TEETHING TABLETS." SHE STATED THAT HE WAS NOT TAKING ANY OTHER MEDICATIONS OR SUPPLEMENTS AT THE TIME, PER THE REPORTER THE SEIZURES STOPPED WHEN SHE STOPPED GIVING HER SON THE "TEETHING TABLETS." THE REPORTER STATED THAT SHE RECENTLY SAW A POST ONLINE WHICH SUGGESTED THAT THE "BABY TEETHING TABLETS" CAUSE SEIZURES - THIS POST WAS THE REASON THAT SHE CALLED. SHE STATED THAT SHE ALSO SAWS ONLINE THAT THIS PRODUCT HAS BEEN RECALLED BECAUSE IT CAUSES SEIZURES. THE REPORTER STATED THAT IF THESE POSTS ARE TRUE, SHE IS READY TO GET HER ATTORNEY INVOLVED BECAUSE OF ALL OF THE TIME AND MONEY THAT THEY SPENT ON DOCTOR'S VISITS FOR HER SON. THE REPORTER STATED THAT SHE HAD A 1 YEAR OLD DAUGHTER WHO IS HAVING DIFFICULTY TEETHING, BUT SHE IS AFRAID TO GIVE HER DAUGHTER THE "TEETHING TABLETS," AND SHE THREW AWAY THE BOTTLE. SHE ASKED IF WE HAD ANY OTHER PAIN PRODUCTS THAT SHE COULD GIVE TO HER DAUGHTER INSTEAD. THE REPORTER STATED THAT SHE WOULD LIKE A REFUND FOR THE BOTTLE THAT SHE BOUGHT FOR HER DAUGHTER, SHE PAID ABOUT $10.00 FOR EACH BOTTLE. 10/21/14 FOLLOW-UP: SEIZURES OCCURRED DURING THE TIME THAT CHILD WAS TEETHING. THE AMBULANCE TOOK THE CHILD TO THE HOSPITAL. THE DOCTOR CALLED THE MOTHER TO SAY THAT IT WAS A SEIZURE AND NOT A FEVER. THE CHILD HAD 3 MORE SEIZURES AND NOW THEY HAVE RESOLVED. HIS LAST SEIZURE WAS JUNE 2013. NO FAMILY HISTORY OF SEIZURES. WENT TO A SPECIALIST AND THE TESTS WERE NORMAL AND THERE WAS NO SPECIFIC SEIZURE TYPE GIVEN. CHILD WAS 1 1/2 YEARS AT THE TIME OF THE SEIZURES. I TOLD THE MOTHER THAT THERE WAS NO CONCLUSIVE EVIDENCE THAT "BABY TEETHING TABLETS" CAUSE SEIZURES, AND THAT IT IS POSSIBLE THAT HER CHILD COULD HAVE BEEN SENSITIVE OR ALLERGIC TO AN INGREDIENT IN THE TABLETS OR THE SYMPTOMS COULD HAVE BEEN DUE TO SOMETHING ELSE SUCH AS ILLNESS OR OTHER MEDICAL REASON.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:

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:

ADVERSE EVENT REPORTED ON: 10/21/14

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 10-29-14

Review by Management by:

QA / QC DIRECTOR

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1
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 20 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.
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1575
COMPLAINT #: 2585

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: 
E-MAIL: 
STATE: 
ZIP CODE: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:  

DATE: 

SECTION IV:

REVIEWS BY MANAGEMENT BY: Walt  
DATE: 10-29-14

BY: Eric Paul
DATE: 10-29-14

DSS

DISTRIBUTION: FDA  ADVERSE EVENT FILE
A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
   - Age at Time of Event or Date of Birth:
     - 4 Years (b)(6)
   - Sex
     - Female
   - Weight
     - 50 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. Check all that apply:
   - Adverse Event
   - Product Problem (e.g., defects/malfunctions)
   - Product Use Error
   - Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   - Death
   - Disability or Permanent Damage
   - 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)
   - 10/17/2014
4. Date of this Report (mm/dd/yyyy)
   - 11/07/2014

5. Describe Event, Problem or Product Use Error
   - See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
   - See page 3 for complete text.

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.

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
- Yes
- No
- Returned to Manufacturer on:

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - #1: Hylands teething gel and tablets
   - #2: Hylands teething gel and tablets

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #
5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other:
   - Serial #
   - Other #

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Expired, 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

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
2. Health Professional?
3. Occupation
4. Also Reported to:
   - Manufacturer
   - User Facility
   - Distributor/Importer
5. If you DO NOT want your identity disclosed to the manufacturer, place an "X" in this box: [ ]

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.
B.5. Describe Event or Problem (continued)
noticed a possible connection to using Hyland's 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 Children's Hospital for 2 days under observation we were advised not to use those products anymore.
all tests were done on [redacted] at [redacted] Children's Hospital her level seems fine but they said some of those could have been out of her system by the time they took the lab work they also don't check for belladonna toxicity
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
A. PATIENT INFORMATION

1. Patient Identifier (b)(6)
2. Age at Time of Event: ___ Years
   or __________ __________
3. Sex □ Female or □ Male
4. Weight __________ lbs or __________ kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death: ________
   □ Life-threatening: ________
   □ Hospitalization - initial or prolonged: ________
   □ Other Serious (important Medical Events): ________
3. Date of Event (mm/dd/yyyy): 10/06/2014
4. Date of This Report (mm/dd/yyyy): 11/03/2014

5. Describe Event or Problem
   The actual wording of the e-mail was very general. The
   person stated "My son was teething and I bought your
   Hyland's Teething Tablets now he is having trouble
   breathing and his turning pale."

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & miscellaneous)
   #1 HYLAND'S BABY TEETHING TABLETS
   #2

2. Dose, Frequency & Route Used
   #1
   #2

3. Therapy Dates (If unknown, give duration)
   From/to (or best estimate)
   #1
   #2

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:
   □ Catalog #
   □ Expiration Date (mm/dd/yyyy)
   □ 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 □ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
   ________________________________

DSS
NOV 14 2014

E. INITIAL REPORTER

1. Name and Address
   ________________________________
2. Health Professional? □ Yes □ No
3. Occupation NA
4. Initial Reporter Also Sent Report to FDA
   □ 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.

U.S.A
NOV 18 2014

Received
NOV 13 2014

CDE

(Continue on page 3)
Individual Case Safety Report

CaseID: 10584800

AGE 2 OF 5

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

1. Check One
   □ User Facility □ Importer

3. User Facility or Importer Name/Address

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
   □ Initial
   □ Follow-up #

7. Type of Report
   □ Local
   □ Hospital
   □ Home
   □ Other

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

9. Event Problem Codes (Refer to coding manual)
   □ Patient
   □ Device
   □ Code

11. Report Sent to FDA?
   Yes (mm/dd/yyyy)
   □ No

12. Location Where Event Occurred
    □ Inpatient Treatment Facility
    □ Outpatient Treatment Facility
    □ Home
    □ Hospital
    □ Homecare

13. Report Sent to Manufacturer?
   Yes (mm/dd/yyyy)
   □ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   □ Name
   □ Address
   □ Email Address

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

4. Date Received by Manufacturer (mm/dd/yyyy)
   □ 10/19/2014

5. (A)NDA #
   □ IND #
   □ BLA #

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
   □ 5-day
   □ 7-day
   □ 10-day
   □ 15-day

8. Adverse Event Term(s)
   □ TROUBLE BREATHING, PALOR

DEFEAT

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

3. Device Evaluated by Manufacturer?
   □ Not Returned to Manufacturer
   □ Yes (Evaluation Summary Attached)
   □ No (Describe why not)

4. Device Manufacture Date (mm/dd/yyyy)
   □ Yes
   □ No

5. Labeling for Single Use?
   □ Yes
   □ No

6. Event Problem and Evaluation Codes (Refer to coding manual)
   □ Patient
   □ Code
   □ Device
   □ Code

7. If Remediative Action Initiated, Check Type
   □ Recall
   □ Notification
     □ Initial Use of Device
     □ Reuse
     □ Unknown
   □ Repair
     □ Inspection
   □ Replace
     □ Patient Monitoring
     □ Relabeling
     □ Failure
   □ Other

9. If action reported to FDA under 21 USC 360(f), list correct lon/ removal reporting number:

G. ALL MANUFACTURERS

10. Additional Manufacturer Narrative
    □ and/or
    □ 11. Corrected Data

This section applies only to requirements of the Paperwork Reduction Act of 1980.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fas.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.
CUSTOMER SENT THE FOLLOWING E-MAIL ON OCTOBER 16, 2014: MESSAGE: I AM WRITING TO ACTUALLY COMPLAIN ABOUT YOUR PRODUCT. MY SON WAS TEETHING AND I BOUGHT YOUR HYLANDS TEETHING TAB. LETS 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 EMAIL. 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 INSPECTION: 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: ____________________________

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/19/14
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CORRECTIVE ACTION(S) COMPLETED BY: ____________________________ DATE: ____________________________

ADVERSE EVENT REPORTED ON: 10/19/14 BY: EDYTA FRACKIEWICZ

REVIEWED BY MANAGEMENT BY: ____________________________ DATE: 10-29-14

BY: ________________ QA/QC DIRECTOR

cc: QA/QC Packaging Production Shipping/Receiving
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, scopalamine and CBOT testing. The results for C. botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤0 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

NOV 14 2014

NOV 18 2014
AE #: 1576  COMPLAINT #: 2586

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME:  
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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:  
DATE:  

SECTION IV:

REVIEWED BY MANAGEMENT BY:  
DATE: 10-29-14  
BY:  QA / QC DIRECTOR  
DATE: 10-29-14

DSS  
NOV 14 2014

NOV 18 2014
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (D) (E) [In confidence]
2. Age at Time of Event or Date of Birth:
   [ ] Months
   [ ] Years
3. Sex
   [ ] Female
   [ ] Male
4. Weight
   [ ] 20 lb
   [ ] ___ kg

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. Outcome Attributed to Adverse Event
   (Check all that apply)
   [ ] Death: (mm/dd/yyyy)
   [ ] Disability or Permanent Damage
   [ ] 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) 09/26/2014
4. Date of this Report (mm/dd/yyyy) 11/15/2014

5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
   See page 3 for complete text.

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.

CTU
NOV 17 2014

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer or (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:

2. Dose or Amount
   #1 1-2 dissolvable pills a day
   Frequency: Once daily
   Route: Taken under the tongue

   #2

3. Dates of Use (If unknown, give duration) from/to
   (or best estimate)
   #1 09/24/2014 - 11/01/2014
   #2

4. Diagnosis or Reason for Use (Indication)
   #1 teething pain/irritability
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   [ ] Yes [ ] No [ ] Doesn't Apply

6. Event Reappeared After Reintroduction?
   [ ] Yes [ ] No [ ] Doesn't Apply

7. Lot #
   #1
   #2

8. Expired Date (mm/dd/yyyy)
   #1
   #2

9. NDC # or Unique ID
   54973-3127-1

E. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   [ ] Health Professional
   [ ] Lay User/Patient
   [ ] Other

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Implanted, 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 #8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

1. Name and Address
   [ ] Yes [ ] No

2. Health Professional?
   [ ] Yes [ ] No

3. Occupation
   [ ] Other

4. Also Reported to:
   [ ] Manufacturer
   [ ] User Facility
   [ ] Distributor/Importer

5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: [ ]

G. REPORTER (See confidentiality section on back)
1. Name and Address
   [ ] Yes [ ] No

2. Phone #

3. E-mail

4. Fax #

5. All other means:

FILL IN ALL PARTS OF THE FORM.
Case ID: 10589980

Submission of a report does not constitute admission that medical personnel or the product caused or contributed to the event.
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.
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

chest x-rays, blood cultures, CBC, CMP, UA

Individual Case Safety Report

10589980-01-00-03

DSS
NOV 17 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 17 2014
A. PATIENT INFORMATION

1. Patient Identifier
   (b)(6)

2. Age at Time of Event: 12 Months
   or ____________ Date of Birth:
   In confidence

3. Sex
   □ Female
   □ Male
   lbs or ____________ kg

4. Weight

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g. defects/malfunction)

2. Outcomes Attributed to Adverse Event (Check all that apply)
   □ Death: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ 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) 11/01/2014
4. Date of This Report (mm/dd/yyyy) 11/05/2014

5. Describe Event or Problem

THE REPORTER STATED THAT HIS 1 YEAR OLD DAUGHTER HAS BEEN EXPERIENCING SEIZURES WHILE USING THE "HYLAN'S BABY TEETHING TABLETS" PRODUCT. SHE BEGAN USING THE "TEETHING TABLETS" WHEN SHE WAS 6 MONTHS OLD. WHEN SHE WAS 7 MONTHS OLD, SHE HAD 3 SEIZURES IN 1 DAY AND WAS HOSPITALIZED FOR 3.5 DAYS. THE DIAGNOSIS AT THAT TIME WAS: "FEBRILE SEIZURES". THE USE OF THE "TEETHING TABLETS" WAS DISCONTINUED FOR 5 MONTHS. USE BEGAN AGAIN ABOUT 3 WEEKS AGO. ON [b][6] THE CHILD HAD ANOTHER SEIZURE AND WAS HOSPITALIZED OVERNIGHT. PER THE REPORTER, THE DOCTORS COULD NOT DETERMINE A CAUSE FOR THE SEIZURES AT THAT TIME AND ORDERED AN EEG TO BE PERFORMED IN A COUPLE OF WEEKS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & milliliter)
   □ HYLAN'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   □ 3 TIMES A DAY AS NEEDED

3. Therapy Dates (if known, give duration)
   □ 3 TIMES (or best estimate)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model
5. Lot
6. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:

7. If Implanted, Give Data (mm/dd/yyyy)
8. If Explanted, Give Data (mm/dd/yyyy)

9. Is this a Single-use Device that was Reprocessed and Used on a Patient?
   □ Yes
   □ No

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)

DSS
NOV 20 2014

E. INITIAL REPORTER

1. Name and Address
   [b][6]
   [b][6]
   [b][6]

2. Health Professional
   □ Yes
   □ No

3. Occupation
   NA

4. If Initial Reporter Also Sent Report to FDA
   □ Yes
   □ No
   □ Unknown

5. Relevant Tests/Laboratory Data, Including Dates
   CT SCAN -- NORMAL RESULTS
   EEG ORDERED AND WILL BE DONE IN 2 WEEKS.

6. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, 
   rashes, pregnancy, smoking and alcohol use, hepatitis/renal dysfunction, etc.)
   NO FAMILY HISTORY OF SEIZURES. NO KNOWN ALLERGIES.
   CHILD HAS ACID REFLUX.

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.
### 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

3. Device Evaluated by Manufacturer?
   - [ ] Yes
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - [ ] 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
   - [ ] Recall
   - [ ] Notification
   - [ ] Repair
   - [ ] Inspection
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modification
   - [ ] Other: __________________________

8. Usage of Device
   - [ ] Initial Use of Device
   - [ ] Reuse
   - [ ] Unknown

9. If action reported to FDA under 21 USC 366(f), list correction/ removal reporting number:

10. [ ] Additional Manufacturer Narrative and/or

11. [ ] Corrected Data

---

**G. ALL MANUFACTURERS**

1. Contact Office (and Manufacturing Site for Devices)
   - [ ] Name: ERYTA FRACKENICZ
   - Address: HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: STANDARDHYLAND.COM

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply)
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [x] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

4. Data Received by Manufacturer (mm/dd/yyyy)
   - 11/04/2014

5. If IND, Give Protocol #
   - [ ] IND #: ________________________
   - [ ] PMA #: ________________________
   - [ ] BLA #: ________________________

6. AYND #
   - 510(k) #
   - Combination Product
   - Pre-1988
   - OTC Product

7. Type of Report (Check all that apply)
   - [ ] 5-day
   - [ ] 10-day
   - [ ] 15-day
   - [ ] Follow-up #

8. Manufacturer Report Number: 54973 AE # 1577

9. Adverse Event Term(s)
   - SEIZURES

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**DSS NOV 20 2014**

**Nov 19 2014**

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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:
Individual Case Safety Report

COMPLAINT #: 2567                  DATE OF COMPLAINT: 11/04/14

ITEM CODE: BTET-T40                  LOT NO.: A2014

SIZE: 40 TABLETS                      CITY: (b)(6)

REPORTER: (b)(6)                      COUNTRY: USA

ADDRESS:                               ZIP CODE: (b)(6)

E-MAIL:                               PHONE #: (b)(6)


For additional space please use reverse or attach a separate sheet.

ADVERSE EVENT FORWARDED TO PHARMACIST/ NURSE FOR EVALUATION ON: 11/04/14
ADVERSE EVENT FORWARDED TO PHARMACIST/ NURSE FOR EVALUATION BY: [Redacted]

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: [Redacted]

DATE: NOV 20 2014

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y

ADVERSE EVENT REPORTED ON: 11/04/14

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 11/10/14

DATE: 11/07/14

cc: QA/QC

Packing

QA/QC DIRECTOR

20431392-01-00-03

Form #: VD1

DSS

NOV 19 2014
Individual Case Safety Report

Serious 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 89(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 # 121376 was tested for total Atropine and Scopolamine and the results were with in specification of 54 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 bottles 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.

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

Prepared by

Date

11-7-14

DSS

NOV 20 2014

NOV 19 2014

CC-0020-2014
AE-0545-2014
STANDARD

Individual Case Safety Report

10601392-01-00-05

VERSE EVENT DATA FORM

AE #: 1577
COMPLAINT #: 2587

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 PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DSS
DATE: NOV 20 2014

SECTION IV:

REVIEWED BY MANAGEMENT BY: 
DATE: 11-10-14

BY: 
DATE: 11-07-14

DISTRIBUTION: FDA
ADVERSE EVENT FILE
FORM SAE01
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier ID (ID) [YYYY]
2. Age at time of Event or Date of Birth: 14 Months
3. Sex: Male
4. Weight: 22 lb

B. AVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. Adverse Event
2. Product Use Error
3. Product Problem (e.g., defects/malfunctions)
4. Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death:
   □ Disability or Permanent Damage
   □ Life-threatening
   □ Hospitalization - initial or prolonged
   □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Dates of Event (mm/dd/yyyy)
   #1 11/14/2014
   #2 11/26/2014

4. Date of this Report (mm/dd/yyyy)
   #1 [YYYY]
   #2 [YYYY]

5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
   See page 3 for complete text.

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.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: [YYYY]

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   #1 Name: Hyland's Baby Teething Tablets
   Strength: n/a
   Manufacturer: Hylands Inc
   #2 Name: [Blank]
   Strength: [Blank]

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   [CTO]

2. Common Device Name
   [Blank]

3. Manufacturer Name, City and State
   [Blank]

4. Model #
   [Blank]

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:

6. Serial #
   [Blank]

7. Other:
   [Blank]

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
   [Blank]

2. Health Professional? [ ] Yes [ ] No

3. Occupation
   [Blank]

4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: [Blank]

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.
My son who is 14 months old, was taking Hyland's Baby Teething tablets on [0][5] 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
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

EEG - Normal (b)(6) MRI - Normal (b)(6) The Doctor at (b)(6) Children's Hospital could not figure out what had caused my son to have the 3 seizures.

Individual Case Safety Report

10619563-01-00-03

DSS
DEC 01 2014
B.7. Other Relevant History, Inc

Race: White
Medical Conditions: N/A
Allergies: n/a
Important Information: N/A

RX Meds: None

OSC Meds: Children's acetaminophen for fevers.
A. PATIENT INFORMATION
1. Patient Identifier (0 (0)
2. Age at time of Event or Date of Birth: 5 Months (0 (0)
3. Sex □ Female □ Male
4. Weight □ lb □ kg
   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
   □ 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) 11/24/2014
4. Date of this Report (mm/dd/yyyy)
5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

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)
   [ ] Name: Teething tablet
   Strength: Julian teething tablets
   Manufacturer:
2. Name:
   Strength:
   Manufacturer:
   [ ] Name: Teething tablet
   Strength: Julian teething tablets
   Manufacturer:
   [ ] Name: Teething tablet
   Strength: Julian teething tablets
   Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name CTU
2. Common Device Name DEC - 1 2014
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ Other:
   Catalog #
   Expired Date (mm/dd/yyyy)
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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

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
2. Phone #
   (0 (0)
3. E-mail #
   (0 (0)
4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distributor/Importer
   □ Yes □ No
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: □
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

10619580-01-00-02

DSS

DEC 01 2014
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier (mm/dd/yyyy)
   - (00:00)

2. Age at time of Event or Date of Birth
   - 2 Years
   - (00:00)

3. Sex
   - Male

4. Weight
   - 30 lb

   or ___ kg

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
   - 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)
   - 05/01/2014

4. Date of this Report (mm/dd/yyyy)
   - 12/02/2014

5. Describe Event, Problem or Product Use Error
   - See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
   - See page 1 for complete text.

CTU

DEC 03 2014

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   - #1 Name: hyland babb teething tablets
     - Strength:
     - Manufacturer: hylands

   - #2 Name:
     - Strength:
     - Manufacturer:

2. Dose or Amount
   - #1 2
   - #2

3. Frequency
   - #1 Four times daily
   - #2

4. Route
   - Taken by mouth

5. Dates of Use (if unknown, give duration from/to (or best estimate)
   - #1 04/24/2014 - 04/28/2014
   - #2

6. Event Abated After Use
   - Stopped or Dose Reduced?
   - #1 Yes  No  Doesn't Apply
   - #2

7. Diagnosis or Reason for Use (Indication)
   - #1 Teething
   - #2

8. Event Reappeared After
   - Reintroduction?
   - #1 Yes  No  Doesn't Apply
   - #2

9. Lot #
   - #1
   - #2

10. Expiration Date (mm/dd/yyyy)
    - #1
    - #2

11. NDC # or Unique ID
    - 54973-3127-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other:

   - Serial #
   - Other:

6. If Implantated, 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

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
   - (00:00)

2. Phone #
   - (00:00)

3. E-mail
   - (00:00)

4. Also Reported to:
   - Manufacturer
   - User Facility
   - Distributor/Importer

5. If you do NOT want your identity disclosed
to the manufacturer, place an "X" in this box: [ ]
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

10627664-01-00-02

DSS
DEC 03 2014
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

**Individual Case Safety Report**

CaseID: 10627664-01-00-03

DSS
DEC 03 2014
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event or Date of Birth: 18 Months
   □ Female
   □ Male or _______ lb
   □ Male or _______ kg

3. Sex
4. Weight

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: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ 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) 12/02/2014

5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates
   See page 3 for complete text.

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.

CTU
DEC 03 2014

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 tablets
   Strength: Manufacturer: Hyland
   #2 Name: (b)(6)
   Strength: Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Lot #
6. Serial #
7. Other#
8. Operator of Device
□ Health Professional
□ Lay User/Patient
□ Other:
9. If implanted, give date (mm/dd/yyyy)
10. If Explanted, Give Date (mm/dd/yyyy)
11. Is this a single-use device that was Reprocessed and Reused on a Patient?
□ Yes □ No
12. If Yes to Item No. 11, Enter Name and Address of Reprocessor

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
   (b)(6)

Phone # (b)(6)
E-mail (b)(6)

2. Health Professional? □ Yes □ No
3. Occupation
   □ Manufacturer
   □ User Facility
   □ Distributor

4. Also Reported to:
   □ Yes □ No

5. If you DO NOT want your identity disclosed to the manufacturer, place an "X" in this box: □

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.

DEC 03 2014
Hyland teething tablets cause severe tooth decay and seizures.
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

[Redacted]

Individual Case Safety Report

10631888-01-00-03

DSS
DEC 03 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: --
Medical Conditions: none
----------
Allergies: none
----------
Important Information: 
----------
RX Meds: 
----------
OTC Meds: Probiotic and children vitamin

Individual Case Safety Report

10631888-01-00-04

DSS
DEC 08 2014
RECEIVED
DEC 03 2014
CDR

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.
### H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Death</td>
<td>☐ Correction</td>
</tr>
<tr>
<td>☐ Serious Injury</td>
<td>☐ Additional Information</td>
</tr>
<tr>
<td>☐ Malfunction</td>
<td>☐ Response to FDA Request</td>
</tr>
<tr>
<td>☐ Device Evaluation</td>
<td>☐ Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Not Returned to Manufacturer</td>
<td></td>
</tr>
<tr>
<td>☐ Evaluation Summary Attached</td>
<td></td>
</tr>
<tr>
<td>No (Attach page to explain why not) or provide code</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Labeled for Single Use?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Event Problem and Evaluation Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code (-) - (-) - (-) - (-)</td>
</tr>
<tr>
<td>Device Code (-) - (-) - (-) - (-)</td>
</tr>
<tr>
<td>Method (-) - (-) - (-) - (-)</td>
</tr>
<tr>
<td>Results (-) - (-) - (-) - (-)</td>
</tr>
<tr>
<td>Conclusions (-) - (-) - (-) - (-)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type (Check all that apply)</th>
<th>8. Usage of Device</th>
<th>9. If action reported to FDA under 21 USC 360(dd), list correction/removal reporting number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td>Initial Use of Device</td>
<td></td>
</tr>
<tr>
<td>Notification</td>
<td>Repair</td>
<td></td>
</tr>
<tr>
<td>Inspectement</td>
<td>Replace</td>
<td></td>
</tr>
<tr>
<td>Patient Monitoring</td>
<td>Relabeling</td>
<td></td>
</tr>
<tr>
<td>Modification/Adjustment</td>
<td>Other:</td>
<td></td>
</tr>
</tbody>
</table>

| 10. Additional Manufacturer Narrative and/or 11. Corrected Data |

---

### G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - **Name:** EDYTA FRACKIEWICZ
   - **Address:** HYLAND'S, INC.
     154 W. 131ST STREET
     LOS ANGELES, CA 90061
   - **Email Address:** STANDARDHYLANDES.COM

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: PHARMACY
   - ASSISTANT

4. **Date Received by Manufacturer (mm/dd/yyyy):** 11/14/2014

5. **Type of Report** (Check all that apply)
   - ANADA #
   - IND #
   - BLA #
   - PMA/510(k) #
   - Combination Product: Yes
   - Pre-1938: Yes
   - OTC Product: Yes
   - Initial
   - 10-day
   - 15-day
   - Follow-up

6. **Manufacturer Report Number:** 54973 AE # 1579

---

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, and 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."
NATURE OF COMPLAINT: Store reports that a child's attorney reports seizures following use of teething tablets spoke with pharmacy on 11/14/14.

PRODUCT RECEIVED FOR INSPECTION: Y  N  (CIRCLE ONE)  PRODUCT BEING RETURNED FOR INSPECTION: Y  N  (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED: ____________________________

UPS CALL TAG ISSUED: Y  N  (CIRCLE ONE)

DATE PRODUCT RECEIVED: ____________________________

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/14/14

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CORRECTIVE ACTION(S) COMPLETED BY: ____________________________ DATE: ____________________________

ADVERSE EVENT SERIOUS: Y  N

ADVERSE EVENT REPORTED ON: 11/14/14 BY: EDYTA FRACKIEWICZ

REVIEWED BY MANAGEMENT BY: ____________________________ DATE: 11-25-14

BY: ____________________________ DATE: 11-24-14

cc: QA / QC Packaging Production Shipping / Receiving
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.
SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

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 DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

________________________________________________________________________

CORRECTIVE ACTION(S) COMPLETED BY: ____________________________ DATE: ____________________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ____________________________ DATE: 11-25-14

BY: ____________________________ DATE: 11-24-14

QA / QC DIRECTOR
Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier: [redacted]
2. Age at Time of Event or
   Date of Birth: 4 Months
3. Sex: Male
4. Weight: 70 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine
5. Death: (mm/dd/yyyy)
6. Life-Threatening
7. Congenital Anomaly/Birth Defect
8. Hospitalization - initial or prolonged
9. Other Serious (Important Medical Events)
10. Required Intervention to Prevent Permanent Impairment/Damage (Devices)

C. DATE OF EVENT (mm/dd/yyyy)
   08/07/2009

D. DATE OF REPORT (mm/dd/yyyy)
   12/08/2014

E. SUSPECT MEDICAL DEVICE
1. Brand Name: [redacted]

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
   [redacted]
2. Phone # [redacted]
3. E-mail [redacted]
4. Also Reported to:
   [redacted]
5. If you DO NOT want your identity disclosed to the manufacturer, place an "X" in this box: [redacted]

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.
My child took the Hyland Teething Tablets while teething. He was diagnosed with Petit Mal Seizures after taking the tablets.
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.
Race: Black/African American
Medical Conditions: Was diagnosed with Petit Mal Seizures

Allergies: 

Important Information: 

RX Meds: 

OFC Meds: 

Individual Case Safety Report

10642973-01-00-04
### A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at Time of Event or Date of Birth</th>
<th>3. Sex</th>
<th>4. Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>7 Months</td>
<td>Male</td>
<td>20 lb</td>
</tr>
</tbody>
</table>

### B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

- **Check all that apply:**
  - [ ] Adverse Event
  - [ ] Product Problem (e.g., defects/malfunctions)
  - [ ] Product Use Error
  - [ ] Problem with Different Manufacturer of Same Medicine

- **Outcomes Attributed to Adverse Event**
  - [ ] Death: (mm/dd/yyyy)
  - [ ] Disability or Permanent Damage
  - [ ] Life-threatening
  - [ ] Congenital Anomaly/Birth Defect
  - [ ] Hospitalization - initial or prolonged
  - [ ] Other Serious (Important Medical Events)
  - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

- **Date of Event (mm/dd/yyyy):** 10/13/2014
- **Date of this Report (mm/dd/yyyy):** 12/08/2014

### E. SUSPECT MEDICAL DEVICE

1. **Brand Name:**
2. **Common Device Name:**
3. **Manufacturer Name, City and State:**
   - **CTU**

4. **Model #:**
5. **Lot #:**
   - **Sponsor of Device:**
     - [ ] Health Professional
     - [ ] Lay User/Patient
     - [ ] Other
   - **Catalog #:**
   - **Expiration Date: (mm/dd/yyyy):**
   - **Serial #:**
   - **Other #:**

- **If Implanted, Give Date (mm/dd/yyyy):**
- **If Explanted, Give Date (mm/dd/yyyy):**

### 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:**
2. **Phone #:**
3. **E-mail:**
4. **Also Reported to:**
   - [ ] Manufacturer
   - [ ] User Facility
   - [ ] Distributor/Importer

---

**Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**
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 stop breathing and causing him to be very lethargic. He was then hospitalized and after 5 days of intensive testing the Dr diagnosed 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.
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
These lab were done between [dates] He had an EEG, MRI, EKG, blood work, Gastro testing. None of these labs showed anything that could have caused these events.
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 seizures after using this product

Allergies:

Important Information:

RE Meds: He is now taking Keppra medication to prevent any other episodes

OTC Meds:
FORM FDA 3500A (2/13)

Page 1 of 5

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
   #1 HYLAND'S BABY TEETHING TABLETS
   #2
   #3 TASS CRUSHED BY MOUTH

2. Dose, Frequency & Route Used
   #1
   #2

3. Therapy Dates (If unknown, give duration)
   #1 1/17/2014
   #2

4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN
   #2

5. Event Abated After Use
   #1
   #2
   #3

6. Exp. Date
   #1
   #2

9. NDC or Unique ID
   54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
    IBUFFROPEN

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other:

6. If Imprinted, 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

10. Device Available for Evaluation? (Do not send to FDA)
   - Yes
   - No
   - Returned to Manufacturer on:

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

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

2. Health Professional?
   - Yes
   - No

3. Occupation

4. Initial Reporter Also Sent Report to PDA
   - Yes
   - No
   - Unkn.

(Continue on page 3)

Submitted 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)
**H. DEVICE MANUFACTURERS ONLY**

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Type?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Correction</td>
</tr>
<tr>
<td>Serious Injury</td>
<td>Additional Information</td>
</tr>
<tr>
<td>Malfunction</td>
<td>Response to FDA Request</td>
</tr>
<tr>
<td>Device Evaluation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Evaluation Summary Attached</td>
<td></td>
</tr>
<tr>
<td>No (Attach page to explain why not) or provide code:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Labeled for Single Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

| 6. Event Problem and Evaluation Codes (Refer to coding manual) |
|---------------------|-------------------|
| Patient Code | Device Code |
| Method | Results |
| Conclusions | |

<table>
<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td>Initial Use of Device</td>
</tr>
<tr>
<td>Notification</td>
<td>Repair</td>
</tr>
<tr>
<td>Inspection</td>
<td>Replace</td>
</tr>
<tr>
<td>Patient Monitoring</td>
<td>Relabeling</td>
</tr>
<tr>
<td>Relabeling</td>
<td>Modification/Adjustment</td>
</tr>
<tr>
<td>Other:</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

| 9. If action reported to FDA under 21 USC 380, last correction/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:
CUSTOMER SENT THE FOLLOWING E-MAIL ON 11/17/14—"I JUST WANTED TO PASS ALONG THAT MY SON JUST HAD A REACTION TO YOUR TEETHING TABLETS. I AM A FAN OF HYLANDS AND FIGURED MY 11 MONTH BABY COULD BENEFIT FROM THEM. AN HOUR AND A HALF AFTER I GAVE HIM 3 TABLETS, HIS BREATHING BECAME LABORED, HE BECAME LETHARGIC, AND HE SHOT UP TO A 102°F IN A MATTER OF 20 MINUTES. MY WIFE STARTED FREAKING OUT AND THIS WAS THE ONLY THING THAT HE HAD INGESTED. WE GOT HIS FEVER DOWN WITH IBUPROFEN AND HE IMMEDIATELY WENT TO SLEEP. NEEDLESS TO SAY SHE THREW THEM AWAY AND I FEEL THAT YOU NEED TO KNOW ABOUT HIS REACTION. ON 11/24/14 I WAS ABLE TO SPEAK WITH THE CUSTOMER BY PHONE. HE REPORTED THAT THE CHILD HAD SYMPTOMS OF A DRY CONSTANT COUGH—COUGHING EVERY 30 SECONDS. FATHER PURCHASED THE BABY TEETHING TABLETS BECAUSE HE THOUGHT IT WAS A TEETHING COUGH BECAUSE CHILD SOMETIMES COUGHS WHEN HE IS TEETHING DUE TO EXCESS MUCUS. THE FATHER GAVE 3 TABLETS AND THEN ABOUT 1.5 HOURS LATER THE CHILD'S BREATHING WAS FASTER AND LABORED, HE WAS LETHARGIC AND HIS FEVER WENT UP TO 102 DEGREES. THE WIFE GAVE IBUPROFEN AND THIS HELPED THE SYMPTOMS. A COUPLE OF DAYS LATER HIS FEVER CAME BACK 4 DAYS AFTER GIVING THE HYLANDS BABY TEETHING TABLETS. AFTER THE INITIAL EPISODE, THE CHILD WAS TAKEN TO THE DOCTOR AND WAS DIAGNOSED WITH RSV (RESPIRATORY SYNCTYTIAL VIRUS), A DOUBLE EAR INFECTION AND THROAT. HE WAS PRESCRIBED AN UNKNOWN ANTIBIOTIC, NYSTATIN AND ORAL STEROIDS. THE CHILD IS ON THE "UP AND UP" PER THE FATHER. THE WIFE THREW THE BOTTLE AWAY AND THE CUSTOMER DID NOT REQUEST A REFUND OR REPLACEMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 11/17/14

SECTION V: REVIEWED BY MANAGEMENT BY:

QA / QC DIRECTOR

CO: QA / QC
Packaging

Production
Shipping / Receiving

DEC 10 2014

DSS DEC 11 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 0 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.
ISE EVENT DATA FORM

AE #: 1582

COMplaint #: 2592

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (b)(5)

ADDRESS: _________________________________

CITY: ______________________  STATE: (b)(5)

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)

SECTION III: CORRECTIVE ACTION:

DSS

DEC 11 2014

CORRECTIVE ACTION(S) COMPLETED BY: ___________________________ DATE: ___________________________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 12-01-14

BY: QA/QC DIRECTOR ___________________________ DATE: 12-01-14

DISTRIBUTION: FDA  ADVERSE EVENT FILE

FORM SAE01
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION
1. Patient Identifier:
   (ID) [Redacted]
2. Age at Time of Event: 9 Months
   Date of Birth: 
3. Sex: Female
4. Weight: lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event: [Redacted]
   Product (e.g., defects/malfunctions): [Redacted]
2. Outcomes Attributed to Adverse Event:
   - Death (mm/dd/yyyy): [Redacted]
   - Disability or Permanent Damage
   - 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): 11/15/2014
4. Date of This Report (mm/dd/yyyy): 11/19/2014

5. Description of Event or Problem:
   The reporter's 9-month-old daughter has been using the "BABY TEETHING TABLETS" for the past 6 months with no problems. The reporter stated that on 11/13/14 or 11/14/14, she purchased a new bottle of "BABY TEETHING TABLETS" and began giving her daughter doses of the tablets from the new bottle on 11/15/14. The report, on 11/15/14 and on 11/17/14, the child would stop breathing, turn red, and start shaking, and then would become lethargic. The reporter described the child as "going in and out, coherent but not responsive." The reporter, each episode lasted for about 5-7 seconds. The reporter stated that the child has given 1 "TEETHING TABLET" once per day when symptoms were present; sometimes she gave 2 or 3 doses of 1 tablet per day if the child was especially "cranky."

   Since purchasing this last bottle of "BABY TEETHING TABLETS," the reporter gave her daughter 2 tablets on 11/15/14, one in the morning and one in the evening before bed, 2 tablets on 11/16/14 in the morning, and 1 tablet on 11/17/14. The shaking episodes occurred about 5 minutes after the doses of "TEETHING TABLETS" were given on 11/15/14 and 11/17/14, with one episode... (Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates:
   A physical exam of the child was normal. Per the reporter, the doctor could not give a diagnosis because they did not witness the symptoms. Per the reporter, no tests were ordered.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & inactive ingredients):
   #1: HYLAND'S BABY TEETHING TABLETS
   #2: [Redacted]
   #3: Therapy Dates (if unknown, give duration)
   #1: TAB BY MOUTH QD-TID
   #2: [Redacted]

2. Dose, Frequency & Route Used
3. Therapy Dates (if unknown, give duration)
   #1: TAB BY MOUTH QD-TID
   #2: [Redacted]

4. Diagnosis for Use (indication)
   #1: TEMP RELIEF TEETHING PAIN
   #2: [Redacted]

5. Event Aborted After Use Stopped or Dose Reduced?
   Yes No [Redacted]

6. Lot #
7. Exp. Date
8. Event Reappeared After Reintroduction?
   Yes No [Redacted]

9. NDC or Unique ID:
   54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
    ZANTAC (RANITIDINE) FOR ACID-REFUX DISEASE, TYLENOL, AND ANTIBIOTICS

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Catalog #
6. Expiration Date (mm/dd/yyyy)
7. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other:

8. If Implanted, Give Date (mm/dd/yyyy)
9. If Explanted, Give Date (mm/dd/yyyy)
10. Device Available for Evaluation? (Do not send to FDA)
    Yes No [Redacted]

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

E. INITIAL REPORTER
1. Name and Address
2. Health Professional?
   Yes No [Redacted]
3. Occupation
4. Initial Reporter Also Sent Report to FDA
   Yes No [Redacted]

(Continue on page 3)
Individual Case Safety Report

1. Check One
   - User Facility
   - Importer

2. U.S. Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
   - Initial
   - Follow-up #

7. Type of Report
   - Initial
   - Follow-up

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
    - Patient
    - Code

11. Report Sent to FDA?
   - Yes: (mm/dd/yyyy)
   - No: (mm/dd/yyyy)

12. Location Where Event Occurred
    - Hospital
    - Outpatient Diagnostic Facility
    - Home
    - Outpatient Treatment Facility
    - Other: (Specify)

13. Report Sent to Manufacturer?
   - Yes: (mm/dd/yyyy)
   - No: (mm/dd/yyyy)

14. Manufacturer Name/Address

---

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - EDITA FRACKLENWICZ

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:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 11/18/2014

5. Device Manufacturer Name (if different)
   - IND:
   - BLA:

6. Type of Report
   - Initial
   - Follow-up

7. Type of Report
   - Initial
   - Follow-up

8. Adverse Event Term(s)
   - SEIZURE

---

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

3. Device Evaluated by Manufacturer?
   - Yes
   - Evaluation Summary Attached
   - No

4. Device Manufacturer Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - Yes
   - No

6. Event Problem and Evaluation Codes (Refer to coding manual)
   - Patient
   - Code
   - Device
   - Code

7. If Remedial Action Initiated, Check Type
   - 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 380(f), list corrective/
   reporting number:

10. Additional Manufacturer Narrative
    and/or

11. Corrected Date

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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:

Department of Health and Human Services
Office of Information and Regulatory Affairs
Paperwork Reduction Act (PRA) Staff
OIRA Staff Office 8104

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."
### B.5. Describe Event or Problem (continued)

Occurring on each day. The reporter has an appointment to see the doctor regarding these symptoms this afternoon, 11/18/14.

### 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 Doses (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)

### DEC 1 1 2014

### DEC 1 0 2014

### Other Remarks
COMPLAINT RECORD

COMPLAINT #: 2990
DATE OF COMPLAINT: 11/10/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET---T155

SIZE: 135 TABLETS
LOT NO.: A09214

REPORTER: (b)(6)
ADDRESS: (b)(6)

CITY: (b)(6)
STATE: (b)(6)
COUNTRY: USA
ZIP CODE: (b)(6)
PHONE #: (b)(6)
E-MAIL: (b)(6)

THE REPORTER'S 5-MONTH OLD DAUGHTER HAS BEEN USING THE "BABY TEETHING TABLETS" FOR THE PAST 6 MONTHS WITH NO PROBLEMS. THE REPORTER STATED THAT ON 11/13/14 OR 11/14/14, SHE PURCHASED A NEW BOTTLE OF "BABY TEETHING TABLETS" AND BEGAN GIVING HER DAUGHTER DOSES OF THE TABLETS FROM THE NEW BOTTLE ON 11/13/14.


PER THE REPORTER, THE CHILD HAS NOT BEEN SICK, HAS NOT HAD ANY CONCOMITANT SYMPTOMS SUCH AS A RUNNY NOSE OR AN EARRING, AND HAS NOT HAD A FEVER TO THE REPORTER'S KNOWLEDGE. PER THE REPORTER, THERE IS NO FAMILY HISTORY OF SEIZURES, AND THE CHILD HAS NEVER HAD AN EPISODE OR REACTION LIKE THIS BEFORE. THE REPORTER STATED THAT THE CHILD TAKES ZANTAC (RANITIDINE) TWICE PER DAY FOR ACID REFLUX; THIS WAS A PRESCRIPTION, AND THE CHILD HAS BEEN TAKING THIS MEDICATION DAILY SINCE THE AGE OF 2 MONTHS. PER THE REPORTER, THE CHILD HAS NO KNOWN ALLERGIES AND HAS TAKEN TYLENOL AND ANTIBIOTICS IN THE PAST WITH NO ISSUES. THE REPORTER STATED THAT SHE UNDERSTANDS THAT THESE EPISODES MAY BE UNRELATED TO THE "TEETHING TABLETS." SHE STATED THAT SHE DOES NOT WISH TO RETURN THE BOTTLE TO THE COMPANY "IN CASE (SHE) NEEDS IT FOR EVIDENCE IN COURT."

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: N (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 FORWARD TO PHARMACIST / NURSE FOR EVALUATION ON: 11/19/14
ADVERSE EVENT FORWARD TO PHARMACIST / NURSE FOR EVALUATION BY: 

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DSS
DATE: DEC 11 2014

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 11/10/14
BY: (b)(6)

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 12-01-14

DATE: 12-01-14

cc: QA / QC Packaging Production Shipping / Receiving
Form #: 001
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 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 within specification of 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.

Prepared by ___________________________ Date 11/20/14

DSS
DEC 1 1 2014

DEC 1 0 2014
MEDWATCH
FORM FDA 3500A (2/13)

Page 1 of __

A. PATIENT INFORMATION

1. Patient Identifier (b) (b)
2. Age at Time of Event
   or Date of Birth
   18 Months
3. Sex  
   [ ] Female  
   [ ] Male
4. Weight
   or lbs
   or kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [ ] Adverse Event
   or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   [ ] Death: (mm/dd/yyyy)
   [ ] Disability or Permanent Damage
   [ ] 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) 09/09/2014
4. Date of This Report (mm/dd/yyyy) 11/20/2014

5. Describe Event or Problem

MOTHER CALLED ABOUT HER 20 MONTH OLD DAUGHTER WHO HAD A FEBRILE SEIZURE AT 18 MONTHS OLD. SHE WANTED TO KNOW IF HAVING GIVEN HER DAUGHTER BERRY TESTING TABLETS 3 MONTHS PRIOR, COULD BE RELATED TO THE SEIZURE. AT THE TIME OF THE INCIDENT, HER DAUGHTER HAD A FEVER OF 102 FOR 2 - 3 DAYS, OF UNKNOWN CAUSE. THAT MORNING SHE GAVE HER DAUGHTER IBUPROFEN AND 6 HOURS LATER HER DAUGHTER STOOD UP FROM HER BATH AND "PASSED OUT". SHE WAS TAKEN TO THE HOSPITAL WITH A FEVER OF 103.9 AND DIAGNOSED WITH FEBRILE SEIZURE, AND GIVEN IBUPROFEN AND TYLENOL.

C. SUSPECT PRODUCT(S)

1. Name (as label indicates &/or ingredients)
   1) RILAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   1) 1-2 TEABS, 1-2X/DAY

3. Therapy Dates (if unknown, give duration from/to (or best estimate)
   1) #1

4. Diagnosis for Use (Indication)
   1) TEMP RELIEF OF TEETHING PAIN

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #
5. Lot #

E. INITIAL REPORTER

1. Name and Address
   (b) (b)
   (b) USA

2. Health Professional?  [ ] Yes  [ ] No
3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA  [ ] Yes  [ ] No  [ ] Link

Received
DEC 15 2014

CDR

8. Relevant Tests/Laboratory Data, Including Dates

BLOOD TESTS, CATHETER, AND EARS CHECKED.
DIAGNOSED WITH FEBRILE SEIZURE.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, renal/visual dysfunction, etc.)
BORN WITH AN ANUS TOO FAR FORWARD WHICH CAUSES CONSTIPATION. CHILD WAS BORN WITH CHORIOAMNIONITIS AND HAD A HIGH FEVER, TREATED WITH ANTIBIOTICS AT THE MOMENT OF BIRTH. MOTHER ALSO HAD FEVER AT THAT TIME. CHILD HAS SEASONAL ALLERGIES CAN CAUSE EAR INFECTIONS. IT WAS THOUGHT TO BE RROSOLA, BUT THERE WAS NO RASH.

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)

1. Check One
   - [ ] User Facility
   - [ ] Importer

2. User Facility or Importer Name/Address

3. Contact Person

4. Phone Number

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

6. Type of Report
   - [ ] Initial
   - [ ] Follow-up #

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

8. Approximate Age of Device

9. Event Problem Code (Refer to coding manual)
   - Patient Code
   - Device Code

10. Location Wiki Event Occurred
    - Hospital
    - Outpatient Diagnostic Facility
    - Home
    - Ambulatory Surgical Facility
    - Nursing Home
    - Outpatient Treatment Facility
    - Other: [Specify]

11. Report Sent to FDA?
    - [ ] Yes
    - [ ] No

12. Report Sent to Manufacturer?
    - [ ] Yes
    - [ ] No

13. Device Evaluated by Manufacturer?
    - [ ] Yes
    - [ ] No

14. Manufacturer Name/Address

### H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction

2. Follow-up, What Type?
   - [ ] Correction
   - [ ] Additional Information
   - [ ] Response to FDA Request
   - [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
   - [ ] Yes
   - [ ] No

4. Device Manufacturer Code (mm/dd/yyyy)

5. Device Manufacturer Date (mm/dd/yyyy)

6. Event Problem and Evaluation Codes (Refer to coding manual)
   - Patient Code
   - Device Code

7. If Medical Action Initiated, Check Type
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring
   - Relabeling
   - Modifications
   - Other)

8. Usage of Device
   - [ ] Initial Use of Device
   - [ ] Repair
   - [ ] Reuse
   - [ ] Unknown

9. If action reported to FDA, list corrections/ removal reporting number:

10. Additional Manufacturer Narrative

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
Paperswork Reduction Act (PRA) Staff
PRASStaff@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."
MOTHER CALLED ABOUT HER 20 MONTH OLD DAUGHTER WHO HAD A FEBRILE SEIZURE AT 18 MONTHS OLD. SHE WANTED TO KNOW IF HAVING GIVEN HER DAUGHTER BABY TEETHING TABLETS 6 MONTHS PRIOR, COULD BE RELATED TO THE SEIZURE. AT THE TIME OF THE INCIDENT, HER DAUGHTER HAD HAD A FEVER OF 103°F FOR 2 – 3 DAYS, OF UNKNOWN CAUSE. THAT MORNING SHE GAVE HER DAUGHTER IBUPROFEN AND 5 HOURS LATER HER DAUGHTER STOOD UP FROM HER BATH AND PASSED OUT. SHE WAS TAKEN TO THE HOSPITAL WITH A FEVER OF 103.9°F AND DIAGNOSED WITH FEBRILE SEIZURE, AND GIVEN IBUPROFEN AND TYLENOL. THE DAUGHTER AND MOTHER HAVE A HISTORY OF HIGH FEVER DURING DAUGHTER'S BIRTH DUE TO CHORIOAMNIONITIS. DAUGHTER WAS TREATED WITH ANTIBIOTICS IMMEDIATELY AFTER BEING BORN. BABY TEETHING TABLETS WERE USED INTERMITTENTLY AS NEEDED FROM 4 – 12 MONTHS OF AGE. DEPENDING ON WHEN SHE WAS SNAPPING ON HER FINGERS. DURING THAT TIME THE DAUGHTER NEVER HAD A FEVER OVER 100°F. MOTHER DID USE IBUPROFEN FROM TIME TO TIME.

--

**SECTION II:** INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

**SECTION III:** CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:.dec 1 5 2014

**SECTION IV:** ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: \(Y\) \(N\)

ADVERSE EVENT REPORTED ON: 11/2/2014

**SECTION V:**

REVIEWS BY MANAGEMENT BY: dec 1 6 2014

BY: QA/QC DIRECTOR

cc: QA/QC packaging shipping/receiving
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 within specification of ≤4 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.
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1581

COMPLAINT #: 2591

SECTION I: PATIENT INFORMATION (DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 

ADDRESS: 

CITY: 

STATE: (b) (5)

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)

SECTION III: CORRECTIVE ACTION:

DSS

DEC 1 6 2014

CORRECTIVE ACTION(S) COMPLETED BY: __________________________ DATE: ____________

SECTION IV: REVIEWED BY MANAGEMENT BY: __________________________ DATE: ____________

BY: __________________________ DATE: ____________

QA / QC DIRECTOR

DEC 1 5 2014

DISTRIBUTION: FDA

ADVERSE EVENT FILE

FORM EACH
A. PATIENT INFORMATION

1. Patient Identifier (b) (6)
2. Age at Time of Event: 8 Months
3. Sex: □ Female or □ Male
4. Weight: □ lbs or □ kgs

In confidence:

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event or Product Problem (e.g., defects/ malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
   - Death: (mm/dd/yyyy)
   - Disability or Permanent Damage
   - Life-threatening (Congenital Anomaly/Birth Defect)
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
   - Required Intervention to Prevent Permanent Impairment/Damage (Device)

3. Date of Event (mm/dd/yyyy): 11/15 - 30/2014
4. Date of This Report (mm/dd/yyyy): 12/08/2014

5. Describe Event or Problem
   CHILD VOMITED 15 MINUTES AFTER GETTING BABY TEETHING TABLETS AND THEN AGAIN 5 MINUTES LATER. CHILD WAS "OUT OF IT" AT THIS TIME, SEVERELY LETHARGIC. STARTED VOMITING EVERY FEW MINUTES, DRY HEAVING, NOT RESPONDING. CALLED FOR AN AMBULANCE, CHILD LOST CONSCIOUSNESS 3 TIMES IN THE AMBULANCE. WHITE COUNT WAS ELEVATED AND HE WAS SEVERELY DEHYDRATED. DOCTORS THOUGHT IT COULD HAVE BEEN AN INFECTION. TRANSFERRED TO CHILDREN'S HOSPITAL. DID NOT GET AN ANTIBIOTIC ONLY FLUIDS. THE DOCTORS UNSURE OF DIAGNOSIS. AT A LATER DATE SHE GAVE THE BABY TEETHING TABLETS AGAIN AND THE CHILD STARTED VOMITING. MOTHER GAVE PEDIATRICIAN TO THE DOCTOR THE NEXT MORNING. DOCTOR ATTRAFTED SYMPTOM TO BELLADONNA IN BABY TEETHING TABLETS BASED ON THE SYMPTOMS. CHILD HAD USED BABY TEETHING TABLETS IN THE PAST WITH NO PROBLEMS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & refillability)
   #1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 INFANT HS X 1 DOSE

3. Therapy Dates (If unknown, give duration from/to or best estimate)
   #1

4. Diagnosis for Use (indicating)
   #1 TEMP RELIEF TEETHING PAIN

5. Event Abated After Use Stopped or Dose Reduced?
   #1 Yes / No

6. Lot #
   #114193

7. Exp. Date
   #1

8. Event Reappeared After Reactivation?
   #1 Yes / No

9. NDC# or Unique ID
   54973-3127-1

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name & Proceed

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   □ Health Professional
   □ Lay Used/Patient
   □ 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, Enter Name and Address of Reprocessor

DSS

DEC 23 2014

E. INITIAL REPORTER

1. Name and Address
   □ (b) (6)

2. Health Professional?
   □ Yes / No

3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA
   □ Yes / No / Unk.

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TEMPERATURE OF 95.7 - 96.1F RANGE DURING THE FIRST EVENT.
F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One
   - User Facility [ ]
   - Importer [ ]

2. UF/Importer Report Number [ ]

3. User Facility or Importer Name/Address [ ]

4. Contact Person [ ]
   - Phone Number [ ]

5. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) [ ]
   - Initial [ ]
   - Follow-up [ ]

6. Date of Report (mm/dd/yyyy) [ ]

7. Event Problem Codes (Refer to coding manual)
   - Patient Code [ ]
   - Device Code [ ]

8. Date of This Report (mm/dd/yyyy) [ ]

9. Approximate Age of Device [ ]
   - Patient [ ]

10. Event Problem Codes (Refer to coding manual)
    - Device Code [ ]

11. Report Sent to FDA?
    - Yes [ ]
    - No [ ]

12. Location Where Event Occurred
    - Emergency Room [ ]
    - Outpatient Diagnostic Facility [ ]

13. Report Sent to Manufacturer?
    - Yes [ ]
    - No [ ]

14. Manufacturer Name/Address [ ]

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name [ ]
   - Address [ ]

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 [ ]

4. Data Received by Manufacturer (mm/dd/yyyy) [12/01/2014]

5. IND # [ ]

6. MIND, Give Protocol # [ ]

7. Type of Report (Check all that apply)
   - 5-day [ ]
   - 30-day [ ]
   - 7-day [ ]
   - Periodic [ ]
   - 10-day [ ]
   - Initial [ ]
   - Other [ ]

8. Manufacturer Report Number [ ]

9. Adverse Event Term(s)
   - VOMITING, LEATHARGY, DEHYDRATION, LOSS CONSCIOUSNESS, ELEVATED WHITE BLOOD CELL COUNT, HOSPITALIZATION [ ]

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 96 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."
TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABLETS
REPORTER: 
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: 
E-MAIL: 

DATE OF COMPLAINT: 12/01/14
ITEM CODE: RTE0---T135
LOT NO.: 114/13

COMPLAINT #: 2596

NATURE OF COMPLAINT:
I PURCHASED YOUR TEETHING TABLETS ON 2 DIFFERENT OCCASIONS. ONE TO HAVE A BOTTLE AT MY PARENT'S HOUSE IF MY CHILDREN NEEDED SOME AND THEN A BOTTLE TO HAVE AT HOME. I STARTED GIVING MY SON YOUR TEETHING TABLETS WHEN HE WAS APPROXIMATELY 6 MONTHS. I WOULD USUALLY ONLY GIVE IT ONCE A WEEK AND GIVE HIM ONLY 2 TABLETS AT A TIME. I STOPPED GIVING HIM TO HIM AFTER ABOUT 2 WEEKS. AS HE WAS NOT SHOWING SIGNS OF TEETHING, AND DID NOT NEED THEM. AT AROUND 8 MONTHS OLD.

I GAVE MY SON 2 TABLETS AS HE WAS FUSSING AND TEETHING I ENDED UP IN THE HOSPITAL AS HE BECAME SEVERELY LETHARGIC AND DEHYDRATED FROM VOMITING SO MUCH. I HAD NURSED HIM FOR THE HOUR PRIOR. SO THERE WAS NO POSSIBLE WAY HE WAS DEHYDRATED TO BEGIN WITH, AND HE HAD RECEIVED A BOTTLE THE PRIOR FEEDING. HE HAD NOT HAD ANY NEW MEDICATIONS AND NOTHING NEW IN HIS DIET. WE HAD TO CALL AN AMBULANCE TO TAKE US TO THE HOSPITAL, AND HE HAD CONSCIOUSNESS 3 TIMES ON THE WAY TO THE HOSPITAL. THE DOCTORS AND MYSELF THOUGHT IT MAY JUST BE A VIRUS RUNNING THROUGH HIS SYSTEM AND THAT HIS DIET HAD CHANGED, HE WOULD BE FINE. WE WERE DISCHARGED FROM THE HOSPITAL THE NEXT MORNING. ABOUT 2 WEEKS LATER, I GAVE HIM 2 MORE TEETHING TABLETS BEFORE BED, AS HE WAS FUSSY AND I HAD FELT SOME TEETH POSSIBLY POKING THROUGH. WE ENDED UP WITH THE SAME RESULT EXCEPT WE DID NOT END UP AT THE HOSPITAL. I TOOK HIM TO THE DOCTOR THE NEXT MORNING TO HAVE HIM CHECKED OUT. THEY WERE ABLE TO MAKE THE DETERMINATION FROM THE SYMPTOMS BOTH TIMES, THAT THE CAUSE WAS THE BELLADONNA IN THE TEETHING TABLETS. HE HAS NEVER SHOWN A PROBLEM PRIOR TO THE 2 TIMES BEING GIVEN TO HIM, AND NOW, ALL OF A SUDDEN THERE BECAME A PROBLEM. I AM WONDERING IF THIS PRODUCT NEEDS TO BE RE- EVALUATED TO ENSURE THERE ISN'T TOO MUCH BELLADONNA IN EACH DOSE FOR INFANTS / TODDLERS. I DO NOT WANT ANOTHER PARENT TO GO THROUGH WHAT WE HAVE HAD TO ENDURE AND POSSIBLY LOSE THEIR CHILD DUE TO THIS REACTION. I SPOKE WITH THE CUSTOMER ON 12/01/14. CHILD VOMITED 15 MINUTES AFTER GETTING TABLETS. VOMITED UP ABOUT 4 - 6 OUNCES. VOMITED 4 OUNCES ABOUT 5 MINUTES LATER. CHILD WAS "OUT OF IT" AT THIS TIME. WAS VOMITING EVERY FEW MINUTES, DRY HEAVING, NOT RESPONDING. THIS HAPPENED AROUND 12/01/14 CALLED FOR AN AMBULANCE. CHILD LOST CONSCIOUSNESS 3 TIMES IN THE AMBULANCE. WHITE COUNT WAS ELEVATED AND HE WAS SEVERELY DEHYDRATED. DOCTORS THOUGHT IT COULD HAVE BEEN AN INFECTION, TRANSFERRED TO CHILDREN'S HOSPITAL. DID NOT GET AN ANTIBIOTIC, ONLY FLUIDS. THE DOCTORS WERE NOT SURE WHAT IT COULD HAVE BEEN. COUPLE OF NIGHTS LATER SHE GAVE THE BABY TEETHING TABLETS AND CHILD STARTED VOMITING AGAIN. MOTHER GAVE PEDIA-LYTE TO THE DOCTOR THE NEXT MORNING. DOCTOR ATTRIBUTED SYMPTOMS TO BABY TEETHING TABLETS. HE HAS USED BABY TEETHING TABLETS IN THE PAST WITH NO PROBLEMS.

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED: 
UPS CALL TAG: Y (CIRCLE ONE)

DATE PRODUCT RECEIVED: 

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 
EDYTA FRACKIEWICZ

CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

ADVERSE EVENT REPORTS

ADVERSE EVENT REPORTED ON: 
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 
BY: QA / QC DIRECTOR

DATE: 12-18-14
DATE: 12-12-14
cc: QA / QC Production
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 units have been distributed.

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 within specification of ≤10 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.

Prepared by: ___________________________ Date: 12/10/14

CaseID: 10678285

DEC 3 4 2014

DEC 2 3 2014
ERSE EVENT DATA FORM

AE #: 1586
COMPLAINT #: 2596

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: (b) (6)
ADDRESS: ____________________________
CITY: ____________________________ STATE: (b) (9)
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)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ____________________________ DATE: _______________

SECTION IV:

REVIEWED BY MANAGEMENT BY: ____________________________ DATE: 12/15/14
BY: ____________________________ DATE: 12/15/14

QA / QC DIRECTOR
CHILD HAD A SEIZURE IN 2 WEEKS LATER.

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. CHILD WAS INCARCERATED FOR SHAKEN BABY SYNDROME BUT CHILD HAD NO OTHER PHYSICAL SIGNS OF BEING SHAKEN. CHILD ALSO HAD HEMORRHAGING AND EMPOLATION BEHIND THE EYES AND NOW HAS ARCHITECTURAL VISUAL IMPAIRMENT.

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

ALLEGIC TO AMOXICILLIN

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.
COMPLAINT RECORD

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:  ADDRESS:

CITY:  STATE: (b) (6)
COUNTRY: USA  ZIP CODE:
PHONE#: (b) (6)  E-MAIL:

CUSTOMER SENT THE FOLLOWING E-MAIL ON 12/01/2014. MESSAGE: HELLO. FIRST LET ME START OFF BY SAYING I'M NOT INTERESTED IN COLLECTING ANYTHING OR LAWSUITS. I JUST HAVE A QUESTION. I SAW SOMETHING THAT SAID THE HOMEOPATHIC TEETHING TABLETS WERE RECALLED IN 2010. THAT THEY CAUSED BRAIN BLEEDS AND SEIZURES IN CHILDREN. WAS THIS EVER PROVEN? I'M ASKING BECAUSE MY DAUGHTER SUFFERED FROM BOTH. IN 2010, SHE IS NOW BLIND FROM STROKE AND STILL HAS SEIZURES. BUT SOMEONE WAS INCARCERATED BECAUSE THESE SYMPTOMS SEEMED ALMOST IDENTICAL TO SHAKEN BABY SYNDROME. WAS IT TRUE IS ALL I WANT TO KNOW. I CAN'T LIVE WITH THE POSSIBILITY THAT SOMEONE COULD BE FALSELY CONVICTED AND SERVING A JAIL SENTENCE. ON 12/02/2014, CUSTOMER REPORTED CHILD TAKING THE TABLETS IN 2010. INJURY OCCURRED IN (b) (6). WHEN SHE HAD A SEIZURE, 2 WEEKS LATER SHE HAD ANOTHER SEIZURE. RULE OUT DEHYDRATION BY DOCTORS AT THE TIME. A WEEK LATER CHILD HAD A STROKE FROM A BRAIN BLEED - CHILD WAS MOANING AND NERVES WERE GOING OFF. IN THE HOSPITAL THERE WAS A SCAN THAT SHOWED FLUID BETWEEN BRAIN AND SKULL. (b) (6). WAS INCARCERATED FOR SHAKE BABY SYNDROME FOR (b) (6). BUT CHILD HAD NO OTHER PHYSICAL SIGNS OF BEING SHAKE. ALSO HAD HEMORRHAGING AND HEMATOMA BEHIND THE EYES AND NOW HAS CORTICAL VISUAL IMPAIRMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION II:

INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT

SECTION III:

CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:  DATE:

SECTION IV:

ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 12/01/14  BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:  DATE:

DATE: 12-23-14

DATE: 12-12-14

cc: QA / QC  Packaging  Production  Shipping / Receiving  

Form # VD1
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.
Case ID: 10678309-01-00-05

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**ADVERSE EVENT DATA FORM**

**AE #**: 1584  
**COMPLAINT #:** 2594

**SECTION I:  PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)**

**NAME:**

**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 PANELS*

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**SECTION III: CORRECTIVE ACTION:**

**CORRECTIVE ACTION(S) COMPLETED BY:**

**DATE:**

---

**SECTION IV:**

**REVIEWED BY MANAGEMENT BY:**

**DATE:**

**BY:**

**DATE:**

DISTRIBUTION:  FDA  ADVERSE EVENT FILE

FORM SAE31
MEDWatch
FORM FDA 3500A (2/13)

1. Patient Identifier (DO) (SS)
2. Age at Time of Event:
   2 Years
3. Sex
   Male
   Female
4. Weight
   lbs

in confidence

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   Death:
   Disability or Permanent Damage
   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)
   09/06/2014
4. Date of This Report (mm/dd/yyyy)
   12/08/2014
5. Describe Event or Problem

   CHILD TOOK 2 TABLETS IN THE EVENING AND THE NEXT MORNING SHE HAD A SEIZURE SHORTLY AFTER WAKING. WENT TO THE HOSPITAL AND STAYED FOR 3 DAYS. EEG AND MRI WERE NORMAL. AND PEDIATRIC NEUROLOGIST COULDN'T DETERMINE A CAUSE. ONLY HAD THAT ONE SEIZURE. SYMPTOMS WERE FLOPPING AROUND, EYES ROLLING BACK.

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City, and State
4. Model #
5. Operator of Device
   Health Professional
   Lay User/Patient
   Other:
   Catalog #
   Expiration Date (mm/dd/yyyy)
   Serial #
   Unique Identifier (UID) #
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Implanted, 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

E. INITIAL REPORTER
1. Name and Address
2. Health Professional?
   Yes
   No
3. Occupation
   NA
4. Initial Reporter Also Sent 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.
### F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One
   - [ ] User Facility
   - [ ] Importer

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

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

7. Type of Report
   - [ ] Initial
   - [ ] Follow-up

8. Approximate Age of Device

9. Event Problem Codes (Refer to coding manual)
   - [ ] Patient Code
   - [ ] Device Code

10. Event Problem Code (Refer to coding manual)

11. Report Sent to FDA?
   - [ ] Yes
   - [ ] No

12. Location Where Event Occurred
   - [ ] Hospital
   - [ ] Outpatient Diagnostic Facility
   - [ ] Home
   - [ ] Nursing Home
   - [ ] Ambulatory Care Facility
   - [ ] Other

13. Report Sent to Manufacturer?
   - [ ] Yes
   - [ ] No

14. Manufacturer Name/Address

### G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

2. Phone Number

3. Report Source (Check all that apply)
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional

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

5. If IND, Give Protocol #

6. Type of Report (Check all that apply)
   - [ ] 30-day
   - [ ] 60-day
   - [ ] 90-day

7. Manufacturer Report Number

8. Adverse Event Term(s)

9. Additional Manufacturer Narrative

### 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

3. Device Evaluated by Manufacturer?
   - [ ] Yes
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - [ ] 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
   - [ ] 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 360e(f), list correction/ removal reporting number:

10. Additional Manufacturer Narrative

11. Corrected Data
COMPLAINT RECORD

COMPLAINT #: 2595
DATE OF COMPLAINT: 12/04/14

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET-T135

SIZE: 136 TABLETS
LOT NO.: A52214

REPORTER: (b)(6)
ADDRESS: (b)(6)
CITY: (b)(6)
COUNTRY: USA
STATE: (b)(6)
PHONE #: (b)(6)
E-MAIL: (b)(6)

NATURE OF COMPLAINT:
3 MONTHS AGO CHILD TOOK 2 TABLETS FOR THE FIRST TIME EVER IN THE EVENING AND THE NEXT MORNING 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 CONSIDERING SEEING A LAWYER. WANTS TO KNOW WHY FACEBOOK INFORMATION SAYS THAT BABY TEETHING TABLETS CAUSES SEIZURES. CUSTOMER ALSO SENT THE FOLLOWING E-MAIL ON 12/04/14 TO MARY BORNEHAN. THIS IS JUST TO INFORM YOU THAT MY DAUGHTER HAD A SEIZURE ON YOUR TABLETS 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 INSPECTION: 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 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
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 12/04/14
BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: _______________________________
DATE: __________________________

FORM #: V01
cc: QA/QC
Production
Shipping / Receiving
QA / QC DIRECTOR
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 (834) 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 ≤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 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

12/10/14

DEC 24 2014

DEC 23 2014
**RSE EVENT DATA FORM**

**SECTION I:**

**PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)**

**NAME:**  
(b)(6)  

**ADDRESS:**  
________________________  
________________________  
________________________  
________________________  

**CITY:**  
(b)(6)  

**STATE:**  
(b)(6)  

**COUNTRY:** USA  

**ZIP CODE:**  
(b)(6)  

**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)

**SECTION III:**

**CORRECTIVE ACTION:**

________________________  

________________________

**CORRECTIVE ACTION(S) COMPLETED BY:**  
________________________  

**DATE:**  
________________________

**SECTION IV:**

**REVIEWED BY MANAGEMENT BY:**  
________________________  

**DATE:** 12-15-14  

**BY:**  
________________________  

**DATE:** 12-15-14  

**DSS**  
DEC 24 2014  

**DEC 23 2014**  

**DISTRIBUTION:** FDA  
ADVERSE EVENT FILE  

FORM SAE01
Individual Case Safety Report

General Information

Date: 12/29/2014

CEM Report

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier
   (b) (6)

2. Age at Time of Event or Date of Birth:
   11 Months

3. Sex
   Female
   Male

4. Weight
   20 lb
   kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

2. 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)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)
   12/29/2014

4. Date of this Report (mm/dd/yyyy)
   12/29/2014

5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

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 Tablets
      Strength: Hyland Teething Tablets
      Manufacturer:

   #2 Name:
      Strength:
      Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name:

2. Common Device Name
   CTU

3. Manufacturer Name, City and State

4. Model #
5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ 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, Enter Name and Address of Reprocessor

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
   Name: (b) (6)
   Address:
   City:
   State:
   ZIP:
   Phone #
   E-mail

2. Health Professional
   □ Yes
   □ No
3. Occupation

4. Also Reported to:
   □ Manufacturer
   □ User Facility
   □ Distribution/Importer

5. If you DO NOT want your identity disclosed to the manufacturer, place an "X" in this box: √

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.
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

DSS
DEC 30 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:

CPC Meds:

Individual Case Safety Report

10684780-01-00-03

DSS
DEC 30 2014
SON WAS HAVING SEIZURES IN #5 WHILE TAKING
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 MIN. WENT TO THE HOSPITAL. IN THE
HOSPITAL DID BLOODWORK (NORMAL) AND CHILDS HAS AN MRI AND
ECHO SCHEDULED FOR NEXT MONTH. SPECIALIST SAID THE CHILD
LOOKS NORMAL.
Individual Case Safety Report

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)
1. Check One
   [ ] User Facility  [ ] Importer
2. UFI Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report
   [ ] Initial
   [ ] Follow-up #
5. Date of This Report (mm/dd/yyyy)
3. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)
   [ ] Patient
   [ ] Code
   [ ] Device
   [ ] Code
11. Report Sent to FDA?
   [ ] Yes
   [ ] No (mm/dd/yyyy)
12. Location Where Event Occurred
   [ ] Hospital
   [ ] Outpatient Diagnostic Facility
   [ ] Home
   [ ] Ambulatory Surgical Facility
   [ ] Nursing Home
   [ ] Outpatient Treatment Facility
   [ ] Other (Specify)
13. Report Sent to Manufacturer?
   [ ] Yes
   [ ] No (mm/dd/yyyy)
14. Manufacturer Name/Address

G. ALL MANUFACTURERS
1. Contact Office (and Manufacturing Site for Devices)
   Name: EDYTA FRACKIEWICZ
   Address: HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061
   Email Address: STANDARD@HYLANDS.COM
4. Data Received by Manufacturer (mm/dd/yyyy)
   12/08/2014
6. IND or Give Protocol #
3. Report Source (Check all that apply)
   [ ] Foreign
   [ ] Study
   [ ] Literature
   [ ] Consumer
   [ ] Health Professional
   [ ] User Facility
   [ ] Company Representative
   [ ] Distributor
   [ ] Other:
7. Type of Report
   (Check all that apply)
   [ ] 5-day
   [ ] 30-day
   [ ] 7-day
   [ ] Periodic
   [ ] 10-day
   [ ] Initial
   [ ] 15-day
   [ ] Follow-up #
5. (A/NDA #
   IND #
   BLA #
PMA 610(#)
8. Adverse Event Term(s)
   SEIZURES, VOMITING

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
3. Device Evaluated by Manufacturer?
   [ ] Not Returned to Manufacturer
   [ ] Yes
   [ ] Evaluation Summary Attached
   [ ] No (Attach page to explain why not)
   [ ] Provide code:
   5. Labeled for Single Use?
   [ ] Yes
   [ ] No
6. Event Problem and Evaluation Codes (Refer to coding manual)
   [ ] Patient
   [ ] Code
   [ ] Device
   [ ] Code
7. If Remedial Action Initiated, Check Type
   [ ] Recall
   [ ] Notification
   [ ] Inspection
   [ ] Replace
   [ ] Patient Monitoring
   [ ] Relabeling
   [ ] Modification/Adjustment
8. Usage of Device
   [ ] Initial Use of Device
   [ ] Reuse
   [ ] Unknown
   [ ] Other:
   9. If action reported to FDA under 21 USC 351(f)(1), list correction/removal reporting number:
   [ ] JAN 02 2015
10. [ ] Additional Manufacturer Narrative
11. [ ] Corrected Data

This section applies only to requirements of the Paperwork Reduction Act of 1980.
The public reporting burden for this collection of information has been estimated to average 88
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
PRASStaff@fas.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

PRODUCT: HYLAND'S BABY TEETHING TABLETS

SIZE: 135 TABLETS

REPORTER: (b)(6)

ADDRESS: 

CITY: 

COUNTRY: USA

PHONE: (b)(6)

COMPLAINT #: 2597

DATE OF COMPLAINT: 12/08/14

ITEM CODE: BTET---1135

LOT NO.: CAN'T FIND BOTTLE

NATURE OF COMPLAINT:
SON WAS HAVING SEIZURES IN (b)(6) WHILE TAKING BABY TEETHING TABLETS. MOTHER GIVING 1 TABLET AND RUBBING IT ON CHILD'S GUMS EVERY 8 HOURS 3X/WEEK FOR ONE MONTH. ON THE DAY OF THE SEIZURE, CHILD TOOK 1 TABLET IN THE MORNING. THEN CHILD ATE SOME OATMEAL AND WENT INTO THE SWING. MOTHER SAW CHILD IN THE SWING, ARMS OUT, EYES ROLLING IN THE BACK OF THE HEAD, NOT RESPONDING TO MOTHER, SHAKING X 30 SECONDS. WHEN THE SEIZURE STOPPED THE CHILD VOMITTED AND STARTED CRYING. TOOK HIM TO THE BATHROOM TO CLEAN HIM OFF AND HE HAD ANOTHER SEIZURE THAT LASTED 15 SECONDS. WENT TO THE HOSPITAL. IN THE HOSPITAL HAD BLOODWORK (NORMAL) AND CHILD HAS AN MRI AND EKG SCHEDULED FOR NEXT MONTH. SPECIALIST SAID THE CHILD LOOKS NORMAL. NO FAMILY HISTORY OF SEIZURES. FAMILY HISTORY OF AUTISM ON THE FATHER'S SIDE. OFFERED A REFUND AND SHE ACCEPTED -- PAID AROUND $5.00. CALLED MOTHER ON 12/09/14 TO ASK HER IF SHE FOUND THE BOTTLE BECAUSE I WANTED THE LOT #. SHE SAID THAT SHE RECENTLY MOVED AND CAN'T FIND THE BOTTLE AND IT MAY BE SOMEWHERE IN THE GARAGE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) PRODUCT BEING RETURNED FOR INSPECTION: N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/08/14

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 #: 1587

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 12/08/14 BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 

DATE: 12-19-14

DATE: 12-19-14

QA / QC DIRECTOR

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

JAN 0 2 2015
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 CBO testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤0 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  12/17/14

DSS
JAN 05 2015

Page 1 of 1

JAN 02 2015
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier (b)(6)

2. Age at Time of Event: 9 Months
   or
   Date of Birth:

3. Sex
   □ Female
   □ Male

4. Weight
   lbs
   kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event
   □ Product Problem (e.g., defective/malfunctioning)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death

3. Date of Event (mm/dd/yyyy)
   09/07/2014

4. Date of This Report (mm/dd/yyyy)
   12/30/2014

5. Describe Event or Problem
   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 TOOK 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 FEEL A TOOTH COMING IN ON THE BOTTOM.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mL/liter)
   #1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 2 TABLETS CRUSHED IN MOUTH

3. Therapy Dates (If unknown, give duration) (mm/dd/yyyy)
   #1

4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN

5. Event Abated After Use
   ☑ Yes ☐ No

6. Lot #
   #1

7. Exp. Date
   #1 JAN 14 2015

8. NDC# or Unique ID
   54973-3127-3

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ 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. Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
    ☑ Yes ☐ No

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

E. INITIAL REPORTER

1. Name and Address
   JAN 15 2015

2. Health Professional?
   ☑ Yes ☐ No

3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA
   ☑ Yes ☐ No
### 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

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/dd/yyyy)** [ ]

5. **Labeled for Single Use?**
   - [ ] Yes
   - [ ] No

6. **Event Problem and Evaluation Codes (Refer to coding manual)**
   - **Patient Code**
   - **Device Code**
   - **Method**
   - **Results**

7. **If Remediab Action Initiated, Check Type**
   - [ ] Recall
   - [ ] Notification
   - [ ] Inspection
   - [ ] Reuse
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modification/Adjustment
   - [ ] Other:

8. **Usage of Device**
   - [ ] Initial Use of Device
   - [ ] Reuse
   - [ ] Replace
   - [ ] Unknown

9. **If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:** [ ]

10. **Additional Manufacturer Narrative** and/or [ ]

11. **Corrected Data** [ ]

---

**G. ALL MANUFACTURERS**

1. **Contact Office (and Manufacturing Site for Devices):**
   - **Name:** EDITA FRACKIEWICZ
   - **Address:** HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - **Email Address:** STANDARD@HYLANDS.COM

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:

4. **Date Received by Manufacturer (mm/dd/yyyy):** 12/30/2014

5. **(A)NDA #** [ ]
   - **IND #** [ ]
   - **EUA #** [ ]
   - **PMA/510(k) #** [ ]
   - Combination Product [ ]
   - Pre-1938 [ ]
   - OTC Product [ ]

6. **Manufacturer Report Number:** 54973 AE # 1591

7. **Type of Report (Check all that apply):**
   - [ ] 5-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day [ ] Initial
   - [ ] 15-day [ ] Follow-up # [ ]

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

1. **Check One**
   - [ ] User Facility
   - [ ] Importer

2. **UR Importer Report Number** [ ]

3. **User Facility or Importer Name/Address** [ ]

4. **Contact Person** [ ]

5. **Phone Number** [ ]

6. **Date User Facility or Importer Became Aware of Event (mm/dd/yyyy):** [ ]

7. **Type of Report**
   - [ ] Initial
   - [ ] Follow-up # [ ]

8. **Date of This Report (mm/dd/yyyy):** [ ]

9. **Approximate Age of Device** [ ]

10. **Event Problem Codes (Refer to coding manual):**
    - **Patient Code** [ ]
    - **Device Code** [ ]

11. **Report Sent to FDA?**
    - [ ] Yes [ ] (mm/dd/yyyy)
    - [ ] No [ ]

12. **Location Where Event Occurred**
    - [ ] Hospital
    - [ ] Outpatient Diagnostic Facility
    - [ ] Home
    - [ ] Outpatient Surgical Facility
    - [ ] Nursing Home
    - [ ] Other:

13. **Report Sent to Manufacturer?**
    - [ ] Yes [ ] (mm/dd/yyyy)
    - [ ] No [ ]

14. **Manufacturer Name/Address** [ ]

---

**DSS JAN 15 2015**

Department of Health and Human Services
Office of the Secretary
Office of the Assistant Secretary for Planning and Evaluation

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."
TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 12/26/14
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET-T40
SIZE: 40 TABLETS
LOT NO.: THREW AWAY BOTTLE
REPORTER: (b) (6)
ADDRESS: 
CITY: 
STATE: (b) (6)
COUNTRY: USA
ZIP CODE: 
PHONE #: (b) (6)
E-MAIL: 

CUSTOMER SENT THE FOLLOWING E-MAIL MESSAGE: I GAVE MY DAUGHTER THE HYLAND'S TEETHING TABLETS AS SHE PASSED AWAY THAT NIGHT I DON'T THINK THAT MEDICINE SHOULD BE ON THE SHELVES. E. FRACKIEWICZ CALLED THE CUSTOMER ON 12/30/2014 TO OBTAIN MORE INFORMATION. (b) (6) CHILD PASSED AWAY AT THE AGE OF 9 MONTHS WAS HER FIRST TIME USING THE BABY TEETHING TABLETS. 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. DOCTOR RUNNING ALL KINDS OF TESTS FOR CAUSE OF DEATH MOTHER THINKS BABY TEETHING TABLETS CAUSED HER TO HAVE A SEIZURE AND DIE. MOTHER DID NOT CONTACT HYLAND'S SOONER BUT SHE HAS BEEN DOING RESEARCH ON THE INTERNET ABOUT BABY TEETHING TABLETS AND READING THAT BELLADONNA IS CAUSING SEIZURES IN BABIES. SHERIFF IS LOOKING THROUGH MEDICAL FILES AND LOOKING INTO THE BABY TEETHING TABLETS TO DETERMINE A CAUSE OF DEATH. CHILD WAS FOUND WITH A PUDDLE OF VOMIT NEXT TO HER AT THE TIME OF DEATH. SHERIFF, DETECTIVE, AMBULANCE CAME OUT AND TRIED TO REVIVE HER FOR AN HOUR BUT WERE UNSUCCESSFUL. MOTHER DOES NOT HAVE A CAUSE OF DEATH OR DEATH CERTIFICATE. ON THE DAY THIS HAPPENED CHILD WAS "FLUSHING REALLY BAD" AND MOTHER FELT A TOOTH COMING IN ON THE BOTTOM. CHILD WAS 5 WEEKS PREMATURE BUT NO OTHER HEALTH ISSUES. NO NEW FOODS ON THAT DAY, JUST RECEIVED A BOTTLE OF MILK. CUSTOMER DID NOT REQUEST A REFUND OR REPLACEMENT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y  N  (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y  N  (CIRCLE ONE)
DATE REQUESTED PRODUCT BE RETURNED: 
UPS CALL TAG ISSUED: Y  N  (CIRCLE ONE)
DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/26/14
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
ADVERSE EVENT SERIOUS: Y  N
ADVERSE EVENT REPORTED ON: 12/26/2014  BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 
DATE: 01-02-15
DATE: 01-02-14
DATE: 01-07-15

REVIEWED BY MANAGEMENT BY: 
BY: QA/QC DIRECTOR 

DSS JAN 1 5 2015 
JAN 1 4 2015 

cc: QA/QC Packaging Production Shipping/Receiving 
Form # VD1
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 3 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.
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 ON [DATE] AND HE WAS REALLY TIRED PRIOR TO THIS TIME. HE STARTED HAVING 3 - 4 SEIZURES PER DAY, TREATED WITH KEPFRA AND TOPAMAX. CT SCAN WAS NORMAL. EEG WAS ABNORMAL (UNKNOWN RESULTS). CURRENTLY HAVING 1 - 2 SEIZURES PER DAY EVEN WHILE ON ANTI-SEIZURE MEDICATION.

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates
   EEG WAS ABNORMAL (UNKNOWN RESULTS). CT SCAN WAS NORMAL.

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatitis-C 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.
**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

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/dd/yyyy)

5. Labeled for Single Use?
   - Yes
   - No

6. Event Problem and Evaluation Codes (Refer to coding manual)
   - Patient Code
   - Device Code
   - Method
   - Results
   - Conclusions

7. If Remains Action Initiated, Check Type
   - 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 386(f), list correction/removal reporting number:

10. Additional Manufacturer Narrative

11. Corrected Data

---

**G. ALL MANUFACTURERS**

1. Contact Office (and Manufacturing Site for Devices)
   - Name: EDYTA FRACKIEWICZ
   - Address: HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other:

4. Data Received by Manufacturer (mm/dd/yyyy)
   - 01/22/2015

5. (A)nda #

6. If IND, Give Protocol #

7. Type of Report
   - Combination Product
   - BLA #
   - PMA/510(k) #

8. Manufacturer Report Number
   - 54973 AE # 1596

9. Alternate Event Term(s)
   - ATOMIC SEIZURES, LETHARGY

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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 86 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@dshs.texas.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."
SPOKE WITH CUSTOMER ON 01/27/2015. CHILD WAS BORN WITH BLEEDING ON THE BRAIN WHICH PREDISPOSES HIM TO SEIZURES. HAD ASPHYXIA AT BIRTH WITH EMERGENCY C-SECTION. MOTHER WONDERING IF HYLAND'S TEETHING TABLETS COULD HAVE CAUSED CHILD'S ATOMIC EXPLOSIONS. WAS GIVING THE TEETHING TABLETS 2 TABS IN THE CHILD'S FORMULA EVERY OTHER FEEDING X 1 MONTH. CHILD HAD A SEIZURE ON 01/15/15. LAST DOSE OF BABY TEETHING TABLETS WAS ON 01/15/15. STARTED HAVING 3-4 SEIZURES PER DAY. TOOK HIM TO THE ER AND THEN HE WAS TAKEN TO THE HOSPITAL. HE WAS HOSPITALIZED FOR 3 DAYS AND WAS GIVEN AN EKG AND CT SCAN. CT SCAN WAS NORMAL. EEG WAS ABNORMAL (MOTHER DOES NOT KNOW THE RESULTS). CURRENTLY HAVING 1-2 SEIZURES PER DAY EVEN WHILE ON ANTI-SEIZURE MEDICATION. HAS NOT GIVEN BABY TEETHING TABLETS SINCE 01/15/15 AND GIVES TYLENOL FOR TEETHING PAIN. WOULD LIKE A REFUND. PAID $5.99. CUSTOMER SENT THE FOLLOWING E-MAIL MESSAGE: DEAR SIR OR MADAM: I AM WRITING AS A CONCERNED PARENT OF A 3-MO OLD BOY WHO HAS BEEN HAVING SEIZURES FOR A COUPLE OF MONTHS NOW. I INQUIRED FROM SEVERAL PEOPLE ON TEETHING TABLETS AND THEY HAVE WORKED GREAT BUT HERE RECENTLY WITHIN THE LAST 2 WEEKS MY SON HAS BECOME SUPER SLEEPY AND LETHARGIC...WELL THEN CAME SEIZURES. HE HAD SEIZURES 3-4 TIMES A DAY...I WILL NO LONGER USE THIS PRODUCT ON MY CHILD EVEN THOUGH I AM NOT 100% SURE IF THE TEETHING TABLETS ARE THE PROBLEM...MY SON SPENT 3 DAYS IN THE Pediatric NEURO THIS PAST WEEKEND...PLEASE RETEST YOUR PRODUCT.
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 [300] (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 # 118746 was tested for total Atropine and Scopolamine and the results were within 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.

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

Date

DSS
FEB 13 2015

FEB 11 2015
SE EVENT DATA FORM

AE #: 1596
COMPLAINT #: 2606

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM V01)

NAME: 
ADDRESS: 
CITY: 
COUNTRY: USA 
PHONE #: 
E-MAIL: 
STATE: 
ZIP CODE: 

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ______________________________ DATE: __________

DSS
FEB 12 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: ______________________________ DATE: 02-03-15

BY: ______________________________ DATE: 02-02-15

QA / QC DIRECTOR

FEB 11 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01
The FDA safety information and adverse event reporting program

A. PATIENT INFORMATION

1. Patient Identifier
   - Unspecified

2. Age at Time of Event or Date of Birth:
   - 4.5 Months

3. Sex
   - Male

4. Weight
   - 14.5 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event
2. Product Problem (e.g., defects/malfunctions)
3. Product Use Error
4. Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event
   (Check all that apply)

   - Death: __________ (mm/dd/yyyy)
   - Disability or Permanent Damage: __________
   - 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):
   - 02/15/2015

4. Date of this Report (mm/dd/yyyy):
   - 02/15/2015

5. Describe Event, Problem or Product Use Error
   See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

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.

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: __________
     Strength: __________
     Manufacturer: __________

   - #2: Name: __________
     Strength: __________
     Manufacturer: __________

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   - Health Professional
   - Lay User/Patient
   - 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, Enter Name and Address of Reprocessor

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

2. Health Professional?
   - Yes
   - No

3. Occupation

4. Also Reported to:
   - Manufacturer
   - User Facility
   - Distributor/Importer

5. If you DO NOT want your identity disclosed to the manufacturer, place an "X" in this box: 

 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.
B.5. Describe Event or Problem (continued)
Severe constipation in infant Severe agitation

Individual Case Safety Report

10855443-01-00-02

DSS
FEB 18 2015
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Rac: White
Medical Conditions: N/a

Allergies: N/a

Important Information:

SK Meds: Zantac

Gn Meds: Infant Tylenol, polysitol

Individual Case Safety Report

10855443-01-00-03

DSS
FEB 18 2015
4e15
FEDERAL TRADE COMMISSION

CaseID: 10862441

Form Approved:OMB No. 0910-0291, Expires: 08/30/2015
See OMB statement on reverse

A. PATIENT INFORMATION

1. Patient Identifier (b)(6)
2. Age at Time of Event: 7 Months or Date of Birth: 
   ☑ Male
   ☐ Female
   24 lbs or kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defect/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
   ☑ Death: (mm/dd/yyyy)
   ☑ Disability or Permanent Damage:
   ☑ Life-Threatening:
   ☑ Congenital Anomaly/Birth Defect:
   ☐ Hospitalization - Initial or Prolonged:
   ☑ Other Serious (Important Medical Events):
   ☑ Required Intervention to Prevent Permanent Impairment/Damage (Device(s):

3. Date of Event (mm/dd/yyyy): 01/27/2015
4. Date of This Report (mm/dd/yyyy): 01/29/2015

5. Describes Event or Problem

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 STATED 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 TOOK THE CHILD 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

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hypertension, dysphagia, etc.)

FAMILY HISTORY OF ANAESTHETICS TO IBUPROFEN

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.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & ntr/factory):

   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

   1 Tab Daily by Mouth

3. Therapy Dates (If Unknown, Give Duration)

   #1

   #2

4. Diagnosis for Use (Indication)

   TEMP RELIEF TEETHING SYMPTOMS

   #1

   #2

5. Event Abated After Use

   Stopped or Dose Reduced?

   #1 Yes No
   #2 Yes No" Doesn't Apply

6. Lot #

   A22214

7. Expiration Date (mm/dd/yyyy)

   #1
   #2

8. Event Reappeared After Reintroduction?

   #1 Yes No" Doesn't Apply
   #2 Yes No" Doesn't Apply

9. 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

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device

   ☑ Health Professional
   ☐ Lay User/Patient
   ☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Implanted, 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. 9, 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)

   FEB 19 2015

   (Continue on page 3)

E. INITIAL REPORTER

1. Name and Address

   (b)(6)

2. Health Professional?

   Yes ☑ No ☐

3. Occupation

   NA

4. Initial Reporter Also Sent Report to FDA

   Yes ☑ No ☐ Unk.

(Continue on page 3)
### H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfunction

2. **Type of Follow-up**
   - [ ] Correction
   - [ ] Additional Information
   - [ ] Response to FDA Request
   - [ ] Device Evaluation

3. **Device Evaluated by Manufacturer?**
   - [ ] Yes
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why not) or provide code:

4. **Device Manufacturer Date**

5. **Labeled for Single Use?**
   - [ ] 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**
   - [ ] Recall
   - [ ] Notification
   - [ ] Repair
   - [ ] Inspection
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modification/Adjustment
   - [ ] Other:

8. **Usage of Device**
   - [ ] Initial Use of Device
   - [ ] Use
   - [ ] Reuse
   - [ ] Unknown

9. **If action reported to FDA under 21 USC 351(f), list correction/removal reporting number:**

10. **Additional Manufacturer Narrative and or Corrected Data**

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### G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
   - **Name:**
     - EOYTA FRACKثمان
   - **Address:**
     - HYLAND'S, INC.
     - 154 W. 131ST STREET
     - LOS ANGELES, CA 90061
   - **Email Address:**
     - STANDARDBYLANDS.COM
   - **Phone Number:**
     - 310-768-0700

2. **Phone Number**
   - 310-768-0700

3. **Date Received by Manufacturer**
   - 31/27/2015

4. **Report Source (Check all that apply)**
   - [ ] Foreign
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

5. **Adverse Event Term(s)**
   - SEIZURES

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**DSS**

**FEB 20 2015**

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**CaseID:** 10862441

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**OMB Statement:** 
"As 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."
B.5. Describe Event or Problem (continued)


THE CHILD HAS AN APPOINTMENT WITH HIS HEALTHCARE PRACTITIONER ON 2/2/15.

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

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

Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish)

Other Remarks

DSS

FEB 20 2015
COMPLAINT RECORD

COMPLAINT #: 2005
DATE OF COMPLAINT: 01/22/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET---T135

SIZE: 135 TABLETS
LOT NO.: A22214

REPORTER: (b)(6)
ADDRESS: 

CITY: 
STATE: (b)(6)

COUNTRY: USA
ZIP CODE: 
PHONE #: (b)(6)
E-MAIL: 

NATURE OF COMPLAINT:

FOR ADDITIONAL SPACE PLEASE USE 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: 

UPS CALL TAG ISSUED: Y (CIRCLE ONE) DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/27/15
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CATHERINE DOW

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 01/27/15

BY: CATHERINE DOW

SECTION V: REVIEWED BY MANAGEMENT BY: 

BY: 

QA / QC DIRECTOR

cc: QA / QC Packaging Shipping / Receiving

FEB 19 2015
FEB 20 2015

FORM # V01
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 94 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 20 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.
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier
   b(0)6

2. Age at Time of Event or Date of Birth:
   3 Months

3. Sex
   ☐ Female
   ☐ Male

4. Weight
   17.5 lb

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: (mm/dd/yyyy)
   ☐ Life-threatening
   ☐ Disability or Permanent Damage
   ☐ 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)
   02/18/2015

4. Date of this Report (mm/dd/yyyy)
   02/18/2015

5. Describe Event, Problem or Use Error
   See page 2 for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

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.

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 Baby Teething Tablets
   Strength: 135 tab/bottle
   Manufacturer: Hylands Inc.

   #2 Name:
   Strength:
   Manufacturer:

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Lot #

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

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
   (b)(6)

2. Phone #
   (b)(6)

3. E-mail
   (b)(6)

4. Also Reported to:
   ☐ Manufacturer
   ☐ User Facility
   ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:
   ☐

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.
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?
Race: White
Medical Conditions: Was born with addictions to opiates and benzodiazepines. Wordex 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 19 2015
ON AUGUST 6, 2012, DAUGHTER STARTED TAKING THE BABY TEETHING TABLETS. AUGUST 12TH CHILD HAD A SEIZURE LASTING 20 MIN. CHILD NEVER HAD A SEIZURE PRIOR TO USING THE TABLETS. CHILD CONTINUED USING TABLETS AND HAD 4 MORE SEIZURES SOME LASTING OVER AN HOUR. AFTER DISCONTINUING THE BABY TEETHING TABLETS CHILD HAS NOT HAD ANY MORE SEIZURES.
This section applies only to requirements of the Paperwork Reduction Act of 1995.

The public reporting burden for this collection of information is 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 Information Programs and Reports Paperwork Reduction Act (OIRA) Substance Use and Related Disorders Program 5600 Fishers Lane, Room 5724 Rockville, MD 20857-5624 To report violations or for additional information, call 1-800-FDA-1088.
PRODUCT: HYLAND'S BABY TEETHING TABLETS

REPORTER: (b)(6)

ADDRESS: 

CITY: 
STATE: 

COUNTRY: USA
ZIP CODE: 

PHONE #: 

E-MAIL: 

CUSTOMER POSTED THE FOLLOWING MESSAGE ON (b)(6) \(\text{AND DID NOT RESPOND TO TWO NATURE OF COMPLAINT: REQUESTS TO CONTACT HYLAND'S. I STRONGLY SUGGEST YOU FIND ANOTHER SOLUTION. THESE TABLETS ARE NOT JUST SUGAR PILLS. AMONG OTHER THINGS THEY CONTAIN BELLA DONNA (A POISON) WHICH SUPPOSEDLY IS OK IN SMALL DOSES. IN 2010, THE FDA SHOWED HYLAND'S TEETHING TABLETS DID NOT HAVE A CONTROLLED WAY OF ENSURING LOW LEVELS OF THE BELLA DONNA AND ISSUED A RECALL. THE TABLETS HAD INCONSISTENT AMOUNTS OF IT. THEY SAY THEY HAVE CORRECTED THIS BUT WE DON'T FIND THAT TO BE TRUE. SIDE EFFECTS OF B.O. ARE SEIZURES AMONG OTHER THINGS. ON AUGUST 6, 2012, MY DAUGHTER STARTED TAKING THESE. AUGUST 12TH SHE HAD A SEIZURE LASTING 20 MIN. WE DID NOT MAKE A CONNECTION BETWEEN THE TABLETS AND SEIZURE, ALTHOUGH SHE HAD NEVER HAD ONE BEFORE AND THE TABLETS WERE THE ONLY VARIABLE. CONTINUED TAKING THEM, HAD 4 MORE SEIZURES SOME LASTING OVER AN HOUR. SHE HAD NOT HAD A SEIZURE SINCE STOPPING THE TABLETS, OVER A YEAR AND A HALF. HTTP://WWW.FDA.GOV/...PRESSANNOUNCEMENTS/LC/M207691.HTM

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y ☑ N 
(CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y ☑ N 
(CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y ☑ N 
(CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION III: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
01/31/15
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:
EDYTA FRACKIEWICZ

SECTION IV: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: 

SECTION V: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y ☑ N
ADVERSE EVENT REPORTED ON: 01/31/15
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 02-12-15
DATE: 02-10-15

cc: QA / QC
Production
Packaging
Shipping / Receiving

Form # VD1
FEB 24, 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 2ppm.

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.
user-facilities, tors and manufacturers
TORY reporting

FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier
   (b)(6)

2. Age at Time of Event: 3 Years
   Date of Birth:
   In confidence

3. Sex
   □ Female
   Lbs
   □ Male
   Kgs

4. Weight

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. □ Adverse Event and/or
   □ Product Problem (e.g., device/malfunctions)

2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   □ Death: (mm/dd/yyyy)
   □ Disability or Permanent Damage
   □ Life-threatening
   □ Congenital Anomaly/Birth Defect
   □ Hospitalization - Initial or Prolonged
   □ Other Serious (Important Medical Events)
   □ Required Intervention to Prevent Permanent Impairment/Damage (Device(s))

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

4. Date of This Report (mm/dd/yyyy)
   02/09/2015

5. Describe Event or Problem:
   MESSAGE POSTED ON (b)(6)
   REPORTING THAT CHILD HAD A SEIZURE WHILE USING BABY TETTHING TABLETS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
   #1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 UNKNOWN DOSAGE

3. Therapy Dates (If unknown, give duration) (Start to end or best estimate)
   #1
   #2

4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF TEETHING PAIN
   #2

5. Event Related After Use
   Stopped or Dose Reduced?
   #1 Yes
   #2 No
   #3 Doesn't Apply

6. Lot #
   #1
   #2

7. Exp. Date
   #1
   #2

8. NDC# or Unique ID
   #1
   #2

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #

5. Operator of Device
   □ Health Professional
   □ Lay User/Patient
   □ 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, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
    □ Yes
    □ No
    □ Returned to Manufacturer on:

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

E. INITIAL REPORTER

1. Name and Address
   (b)(6)

2. Health Professional?
   □ Yes
   □ No

3. Occupation
   NA

4. Initial Reporter Also Sent Report to FDA
   □ Yes
   □ No
   □ Unc.

(Continue on page 3)

(Continue on page 3)

(Continue on page 3)

(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.
1. Check One
   □ User Facility  □ Importer

2. U/F Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

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

7. Type of Report
   □ Initial
   □ Follow-up #

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)

|--------------|--------------|-------------|-------------|

11. Report Sent to FDA?
   □ Yes (mm/dd/yyyy)
   □ No (mm/dd/yyyy)

12. Location Where Event Occurred
   □ Hospital  □ Outpatient Diagnostic Facility
   □ Home  □ Ambulatory Surgical Facility
   □ Nursing Home  □ Outpatient Treatment Facility
   □ Other: (Specify)

13. Report Sent to Manufacturer?
   □ Yes (mm/dd/yyyy)
   □ No (mm/dd/yyyy)

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)

   EDITA FRACKIEWICZ

   HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061

   Email Address: STANDARDHYLANDS.COM

2. Phone Number

   310-769-0700

3. Report Source (Check all that apply)
   □ Foreign
   □ Study
   □ Literature
   □ Consumer
   □ Health Professional
   □ User Facility
   □ Company Representative
   □ Distributor
   □ Other:

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

   32/05/2015

5. A/NDA #

   IND #
   BLA #

6. If IND, Give Protocol #

7. Type of Report
   (Check all that apply)
   □ 5-day  □ 30-day
   □ 7-day  □ Periodic
   □ 10-day  □ Initial
   □ 15-day  □ Follow-up #

8. Manufacturer Report Number

   54973 AG # 1599

9. Manufacturer Report Number

   SEIZURES

10. Additional Manufacturer Narrative and/or

11. Corrected Data

   DSS

   MAR - 4 2015

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
FRASSStaff@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."
COMPLAINT #: 2609
DATE OF COMPLAINT: 02/05/15

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 TWO MESSAGES ON (b) (6) AND DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT US. I USE THE TEETHING TABLETS AND MY KID WENT INTO SEIZURE BUT MY DAUGHTER DOC TOLD US TRY THEM BECAUSE SHE THREE AND JUSGOT ALL HER TEETH.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y N (CIRCLE ONE)
PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)
DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 02/05/15
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

ADVERSE EVENT SERIOUS: Y N
ADVERSE EVENT REPORTED ON: 02/05/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: 02-18-15
BY: ___________________________ 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 $\leq 0.05$ 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: 2/13/15

DSS
MAR - 4 2015

MAR - 3 2015
**Patient Information**

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<thead>
<tr>
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<tr>
<td>(b)(6)</td>
<td>3 Months</td>
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<th>Date of Birth:</th>
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<td>or</td>
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**Adverse Event or Product Problem**

1. **Adverse Event** and/or **Product Problem** (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event
   - [ ] Death: 
   - [ ] Disability or Permanent Damage
   - [ ] 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: 02/25/2015
4. Date of this Report: 03/03/2015

**Informative Text:**

3 MONTH OLD BABY DEVELOPED DIFFICULTY BREATHING 6 HOURS AFTER RECEIVING ONE TABLET OF BABY TEETHING TABLETS. HE HAS A HISTORY OF ASTHMA AT BIRTH, THAT HAS NOT RECURRENT LATELY AFTER TREATMENT WITH PROAIR ALBUTEROL.

**Adverse Event Description:**

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, nephrocalcinosis, dysfuction, etc.)

ASTHMA AT BIRTH

**Concomitant Medical Products and Therapy Dates** (Exclude treatment of event)

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

PROAIR ALBUTEROL

**Next Page Text:**

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. 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 Evaluation by Manufacturer?
   - Not Returned to Manufacturer
     - Yes
     - Evaluation Summary Attached
     - No (Attach page to explain why not) or provide code.

4. Device Manufacturing Date (mm/dd/yyyy)

5. Labeled for Single Use?
   - 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
   - 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 360(f), list correction/removal reporting number:

10. Additional Manufacturer Narrative
    and/or
11. Corrected Data

12. Location Where Event Occurred
    - Hospital
    - Home
    - Nursing Home
    - Outpatient Diagnostic Facility
    - Outpatient Treatment Facility
    - Ambulatory Surgical Facility
    - Other:

13. Report Sent to Manufacturer?
    - Yes
    - No

14. Manufacturer Name/Address

15. Approximate Age of Device

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

17. Type of Report
    - Initial
    - Follow-up #

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

19. Contact Person
20. Phone Number

21. UF/Importer Report Number

22. User Facility or Importer Name/Address

23. Check One
   - User Facility
   - Importer
**Nature of Complaint:**

3 month old baby developed difficulty breathing 6 hours after receiving one tablet of *Hyland's Baby Teething Tablets*. He has a history of asthma at birth, that has not recurred lately after treatment with ProAir Albuterol. His symptoms occurred early this morning at 4 AM with wheezing, congestion and shortness of breath, "not unlike his asthma symptoms". The mother reported that he needed to be making noises in between breaths in order to facilitate breathing. He was given ProAir at home, but it did not seem to help him as it had previously for his asthma. A doctor was called but not yet reached. I suggested calling the doctor again, or to call 911 if his breathing worsened.

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**FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET**

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**Section II: Investigation**

Investigation: 

Please see attached investigation report.

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**Section III: Corrective Action**

Corrective action(s) completed by: 

Date: 

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**Section IV: Adverse Event Reports**

Adverse event serious: 

Y N  

By: TUTTI GOULD

Date: 02/25/15

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**Section V:**

Reviewed by management by: 

Date: 03-04-15

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**QA / QC Director:**

E. Brant

---

cc: QA / QC Packaging Production Shipping / Receiving
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 (00) 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 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 # 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.

Prepared by

Date

03-03-15

DSS  
MAR 19 2015  
MAR 18 2015
AE #: 1601
COMPLAINT #: 2611

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: 
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 PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: 
REVIEWED BY MANAGEMENT BY: 
DATE: 
BY: 
DATE: 

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01
A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event: ____________
   or ____________ Date of Birth: ____________
3. Sex: ☐ Female or ☐ Male
4. Weight: lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. ☑ 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
   ☐ 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): 05/00/2014 -- 03/12/2015
4. Date of This Report (mm/dd/yyyy): 03/12/2015
5. Describe Event or Problem
   MOTHER INITIALLY HAD POSTED ON (b)(6) THAT HER DAUGHTER HAD A SEVERE ALLERGIC REACTION. THEN OVER A MONTH LATER SAW AN UPDATE AND PRODUCT CLARIFICATION VIA E-MAIL. CHILD WAS GIVEN HYLAND'S BABY TEETHING TABLETS AND IN MAY 2014 DEVELOPED SEVERE BLISTERING FROM HER MOUTH THROUGH HER ENTIRE DIGESTIVE TRACT TO HER ANUS. BLISTERING CAUSED BLEEDING INSIDE OF HER MOUTH. SHE HAD BLOOD IN HER STOOL AS WELL AS BLISTERS THAT POPPED ON HER BUTTOKS. CHILD REFUSED TO EVACUATE DUE TO PAIN AND IT TOOK HER OVER A MONTH FOR THE BLISTERS TO HEAL. CHILD CONTINUES TO HAVE HEMORRHOIDS INSIDE OF THE ANUS AND HAS DIFFICULTY HAVING BOWEL MOVEMENTS. CHILD ON SPECIAL DIET, STOOL SOFTENERS AND MIRALAX.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & lot/serial number)
   HYLAND'S BABY TEETHING TABLETS
   #2
2. Dose, Frequency & Route Used
   #1
   #2
3. Therapy Dates (If unknown, give duration)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1
   #2
5. Event Abated After Use
   #1 Yes No Doesn't Apply
   #2
6. Event Reappeared After Reintroduction
   #1 Yes No Doesn't Apply

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
5. Operator of Device
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ Other
6. Catalog #
7. Expiration Date (mm/dd/yyyy)
8. Serial #
9. Unique identifier (UDI) #
10. If implanted, Give Date (mm/dd/yyyy)
11. If Explanted, Give Date (mm/dd/yyyy)

E. INITIAL REPORTER
1. Name and Address
2. Health Professional? Yes No
3. Occupation 
4. Initial Reporter Also Sent Report to FDA Yes No
1. Check One
   - User Facility
   - Importer

2. UFI/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report
   - Initial
   - Follow-up #

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

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
    - Patient Code
    - Device Code

11. Report Sent to FDA?
    - Yes
    - No (mm/dd/yyyy)

12. Location Where Event Occurred
    - Hospital
    - Outpatient Diagnostic Facility
    - Home
    - Nursing Home
    - Ambulatory Surgical Facility
    - Outpatient Treatment Facility
    - Other: (Specify)

13. Report Sent to Manufacturer?
    - Yes
    - No (mm/dd/yyyy)

14. Manufacturer Name/Address

**ALL MANUFACTURERS**

1. Contact Office (and Manufacturing Site for Devices)
2. Phone Number
3. Report Source (Check all that apply)
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company
   - Representative
   - Distributor
   - Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 33/10/2015
5. Type of Report (Check all that apply)
   - 5-day
   - 30-day
   - Initial
   - Follow-up #

6. Type of Adverse Event (Check all that apply)
   - ALLERGIC REACTION
   - GI BLISTERS
   - MOUTH BLISTERS
   - HEMORRHOIDS

7. If remedial action initiated, check type
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Relabel
   - Patient Monitoring
   - Other:

8. Usage of Device
   - Initial Use of Device
   - Reuse
   - Unknown

9. If action reported to FDA under 21 USC 3506(f)(4), list corrective/removal reporting number:

10. Additional Manufacturer Narrative
11. Corrected Data

**OSHA 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 POSTED THE FOLLOWING COMMENT REGARDING BABY CALMING TABLETS ON 1/11/15: THESE ARE NOT JUST SUGAR PILLS, MY DAUGHTER HAD A SEVERE ALLERGIC REACTION TO THESE PILLS. CUSTOMER DID NOT RESPOND TO HYLANDS REQUEST TO CONTACT US. ON 3/10/15 CUSTOMER SENT THE FOLLOWING E-MAIL WHICH PROVIDED CLARIFICATION THAT THE PRODUCT IN QUESTION WAS BABY TEETHING TABLETS AND THE ADVERSE EVENT WAS DETERMINED TO BE AN SE. CUSTOMER DID NOT RESPOND TO HYLANDS REGARDING TO CONTACT COMPANY BY PHONE. HI,  I WAS CONTACTED BY CHRISTINE PHILLIPS VL,(B) (G) REGARDING THE ALLERGIC REACTION THAT MY DAUGHTER HAD TO YOUR PRODUCTS. IT HAPPENED IN MAY OF LAST YEAR AND WE ARE STILL DEALING WITH THE AFTER EFFECTS OF IT. SHE WAS GIVEN THE TEETHING TABLETS AND IT CAUSED SEVERE BLISTERING FROM HER MOUTH THROUGH HER ENTIRE DIGESTIVE TRACT TO HER ANUS. THE BLISTERING WAS SO SEVERE THAT SHE WAS BLEEDING INSIDE HER MOUTH, SHE HAD BLOOD IN HER STOOL AS WELL AS BLISTERS THAT POPPED ON HER BUTT SO SHE REFUSED TO HAVE HER DIAPER CHANGED. BECAUSE SHE WAS IN SO MUCH PAIN SHE THEN REFUSED TO GO TO THE BATHROOM AT ALL. IT TOOK OVER A MONTH FOR THE BLISTERS TO HEAL. SHE STILL HAS HEMORRHOIDS INSIDE OF HER ANUS. SHE STILL REFUSES TO TAKE A BOWL MOVEMENT ON A REGULAR BASIS BECAUSE SHE THINKS ITS GOING TO HURT. HER PEDIATRICIAN HAS BEEN WORKING WITH US TO GET HER BACK TO NORMAL SINCE WE GAVE HER THE TEETHING TABLETS. SHE HAS BEEN TO THE DOCTOR NUMEROUS TIMES BECAUSE OF THIS ISSUE AND HAS BEEN PLACED ON A SPECIAL DIET TO KEEP HER STOOLS SOFT SO THAT IT WILL BE LESS PAINFUL FOR HER TO GO TO THE BATHROOM. SHE ALSO HAS BEEN ON MIRLAX TO TRY AND MAKE IT EASIER FOR HER DUE TO THE HEMORRHOIDS. THIS HAS BEEN HORRIBLE FOR HER AND FOR US. IT IS VERY TRAUMATIC TO HAVE TO WATCH YOUR CHILD BE IN SUCH PAIN ON A REGULAR BASIS. THE PAIN OF HAVING TO GIVE HER SUPPOSITORIES AND ENEMAS IS TOO MUCH TO EVEN DESCRIBE. I JUST WONDER HOW MANY CHILDREN HAVE THE SAME ISSUE AND YOUR COMPANY IS AWARE OF IT AND DOES NOTHING ABOUT IT?

DATE OF COMPLAINT: 03/10/2015
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: UNKNOWN
REPORTE: (b)(6)
ADDRESS: 
CITY: 
STATE: 
COUNTRY: USA 
ZIP CODE: 
PHONE #: (b)(6) 
E-MAIL: 

NATURE OF COMPLAINT: 1/11/15: THESE ARE NOT JUST SUGAR PILLS. MY DAUGHTER HAD A SEVERE ALLERGIC REACTION TO THESE PILLS. CUSTOMER DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT US. ON 3/10/15 CUSTOMER SENT THE FOLLOWING E-MAIL WHICH PROVIDED CLARIFICATION THAT THE PRODUCT IN QUESTION WAS BABY TEETHING TABLETS AND THE ADVERSE EVENT WAS DETERMINED TO BE AN SE. CUSTOMER DID NOT RESPOND TO HYLAND'S REGARDING TO CONTACT COMPANY BY PHONE.

PRODUCT RECEIVED FOR INSPECTION: 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: 

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 FRACKIEWICZ

CORRECTIVE ACTION:
CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 03/10/15
BY: EDYTA FRACKIEWICZ

REVIEWS BY MANAGEMENT BY: 
DATE: 03-19-15
DATE: 03-16-15

cc: QA/QC Packaging Production Shipping/Receiving

Form # V01
Serious Adverse Event
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, scopalamine 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 ≤ 0.1 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 ___________________________
Date 3/15/15

DSS
APR - 2 2015

APR - 1 2015
EVENT DATA FORM

AE #: 1602

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)

NAME: [Redacted]
ADDRESS: [Redacted]
CITY: [Redacted]
COUNTRY: USA
PHONE #: [Redacted]
E-MAIL: [Redacted]

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: [Redacted] DATE: [Redacted]

SECTION IV:

REVIEWED BY MANAGEMENT BY: [Redacted] DATE: 03-19-15

BY: [Redacted] DATE: 03-16-15

DSS APR - 2 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01
The FDA safety information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier [ ]
2. Age at Time of Event or Date of Birth: [ ]
   10 Months
3. Sex [ ] Female [ ] Male
4. Weight ___ lb ___ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. □ Adverse Event [ ] Product Problem (ex. 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
   [ ] 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) 04/02/2015
4. Date of this Report (mm/dd/yyyy) 04/03/2015
5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: [ ]

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   #1 Name: Oragel Nighttime Formula
      Strength: 
      Manufacturer: Oragel

   #2 Name: 
      Strength: 
      Manufacturer:

C. PRODUCT AVAILABILITY

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.
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 enamil