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.

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<th>Esub Case ID(s) Printed:</th>
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Run by: STEPPERH
Date - Time: 04-NOV-2016 08:49 AM
Total number of cases (Esub): 27
Case ID: 11775061

Case Information:

Case Type: EXPEDITED (15-DAY)  eSub: Y  HP: Country: USA  Event Date:  Outcomes: OT

FDA Rcvd Date: 24-Nov-2015  Mfr Rcvd Date: 11-Nov-2015  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1044595  Application Type: NDA  Application #: 999999

FDA - Adverse Event Reporting System (FAERS)

Patient Information:

Age:  Sex: Male  Weight:

Suspect Products:

<table>
<thead>
<tr>
<th>#</th>
<th>Product Name</th>
<th>Compounded Drug?</th>
<th>Dose/Frequency</th>
<th>Route</th>
<th>Dosage Text</th>
<th>Indications(s)</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Baby Teething</td>
<td></td>
<td>1 DF/</td>
<td>Oral</td>
<td></td>
<td></td>
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<table>
<thead>
<tr>
<th>#</th>
<th>Product Name</th>
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Event Information:

Preferred Term (MedDRA® Version: 18.1):

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<th>Preferred Term</th>
<th>18.1</th>
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</thead>
<tbody>
<tr>
<td>Pyrexia</td>
<td></td>
</tr>
<tr>
<td>Screaming</td>
<td></td>
</tr>
<tr>
<td>Seizure</td>
<td></td>
</tr>
</tbody>
</table>

Event/Problem Narrative:

MOTHER POSTED ON THAT SHE GAVE HER SON A TEETHING TABLET AND PUT HIM TO BED AND SHORTLY AFTER HE WOKE UP SCREAMING AND HAD A HIGH FEVER. SHE GAVE THE CHILD TYLENOL FOR THE FEVER AND WHILE LAYING HIM DOWN TO SLEEP HE HAD A MINI SEIZURE. CHILD WAS PUT IN A COLD BATH TO GET THE FEVER DOWN. SYMPTOMS RESOLVED AND HAVE NOT REOCCURRED.
### Relevant Medical History:

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

<table>
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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:

<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>
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### Reporter Source:

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

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Print Time: 04-NOV-2016 08:49 AM

If a field is blank, there is no data for that field
Case ID: 11778980

Case Information:

**Case Type:** EXPEDITED (15-DAY)  
**Case Information:**  
**eSub:** Y  
**HP:**  
**Country:** USA  
**Event Date:** 15-Nov-2015  
**Outcomes:** OT  
**FDA Rcvd Date:** 25-Nov-2015  
**Mfr Rcvd Date:** 15-Nov-2015  
**Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1044659  
**Application Type:** NDA  
**Application #:** 999999

**Patient Information:**  
**Age:** 213 DAY  
**Sex:** Male  
**Weight:**

**Suspect Products:**  
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<th>#</th>
<th>Product Name</th>
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<th>Dose/Frequency</th>
<th>Route</th>
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<th>ReC</th>
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<th>NDC #</th>
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<tr>
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**Event Information:**  
**Preferred Term (MedDRA® Version: 18.1)**  
Dyskinesia  
Dyspnoea  
Muscle twitching  
Seizure  
Tremor  

Print Time: 04-NOV-2016 08:49 AM  
If a field is blank, there is no data for that field.
Case ID: 11778980

Event/Problem Narrative:
THE CUSTOMER REPORTS THAT HIS 7 MONTH OLD SON BEGAN TAKING BABY TEETHING TABLETS 3 DAYS AGO. APPROXIMATELY 24 HOURS AGO, THE CHILD BEGAN HAVING EPISODES OF SHAKING, TWITCHING AND MAKING ABNORMAL FACES. THE CUSTOMER ALSO REPORTS THAT HIS SON'S BREATHING HAS ALSO BEEN HEAVIER. THE LAST DOSE OF MEDICINE WAS GIVEN THIS MORNING AND THE CHILD EXPERIENCED ANOTHER EPISODE OF SHAKING ONE HOUR LATER. THERE ARE NO OTHER SYMPTOMS AT THIS TIME.

Relevant Medical History:

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

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

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Case Information:

Case Type: EXPEDITED (15-DAY)  
eSub: Y  HP:  
Country: USA  Event Date: 2015  Outcomes: OT  
Application Type: NDA

FDA Rcvd Date: 25-Nov-2015  Mfr Rcvd Date: 15-Nov-2015  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1044662  
Application #: 999999

Patient Information:

Age:  Sex: Male  Weight:

Suspect Products:

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<th>End Date</th>
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<tr>
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Event Information:

Preferred Term (MedDRA® Version: 18.1)  ReC

Tremor  NA

Event/Problem Narrative:

REPORTER SENT AN E-MAIL STATING THAT HER SON HAS RECENTLY STARTED HAVING UNCONTROLLABLE SHAKING WHICH HAS OCCURRED AROUND THE TIME OF STARTING THE HYLAND'S BABY TEETHING TABLETS. HE IS SCHEDULED TO SEE A PEDIATRIC NEUROLOGIST IN THREE WEEKS.
Case ID: 11779071

Relevant Medical History:

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Relevant Laboratory Data:

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<th>Result</th>
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Concomitant Products:

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<th>Start Date</th>
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<th>Interval 1st Dose to Event</th>
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Reporter Source:

Study Report?: No  Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:
Case ID: 11792162

Case Information:
- Case Type: EXPEDITED (15-DAY)
- eSub: Y
- HP: USA
- Event Date: Jan-2015
- Outcomes: OT
- Application Type: NDA
- FDA Rcvd Date: 01-Dec-2015
- Mfr Rcvd Date: 13-Nov-2015
- Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1044881
- Application #: 999999

Patient Information:
- Age: 182 DAY
- Sex: Male
- Weight:

Suspect Products:
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<th>#</th>
<th>Product Name</th>
<th>Compounded Drug?</th>
<th>Dose/Frequency</th>
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<th>Dosage Text</th>
<th>Indications(s)</th>
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<th>End Date</th>
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<tbody>
<tr>
<td>1</td>
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<th>MFR/Labeler</th>
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Event Information:
- Preferred Term (MedDRA® Version: 18.1)

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<th>Term</th>
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<tr>
<td>Ear disorder</td>
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<td>Febrile convulsion</td>
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<td>Seizure</td>
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Event/Problem Narrative:
CHILD HAD HIS FIRST SEIZURE AT THE AGE OF 6 MONTHS WHILE USING THE BABY TEETHING TABLETS AND ALSO HAD A SLIGHT FEVER AT THE TIME. HE WAS DIAGNOSED WITH A FEBRILE SEIZURE BUT CHILD DOES NOT GET HIGH TEMPERATURES BECAUSE THEY ARE AROUND 100 DEG. FAHRENHEIT. WHEN HE HAS THE SEIZURE HE STARTS SHAKING, TWITCHING, JERKING, DROOLING IN THE MOUTH, EARS TURN PURPLE. SOMETIMES HE HAS SEIZURES WITHOUT A FEVER. CHILD IS NOW 16 MONTHS OLD AND ON KEPPRA. CHILD ALSO USES THE BABY GAS DROPS.
Case ID: 11792162

Relevant Medical History:

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<tr>
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<th>End Date</th>
<th>Indications</th>
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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>
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Concomitant Products:

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<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>
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Reporter Source:

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<td>Sender Organization:</td>
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| Literature Text: | |
|-----------------| |
### Case Information:

- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **Country:** USA
- **Event Date:** 25-Nov-2015
- **Outcomes:** LT
- **Application Type:** NDA
- **FDA Rcvd Date:** 04-Dec-2015
- **Mfr Rcvd Date:** 25-Nov-2015
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1045081
- **Application #:** 999999

### Patient Information:

- **Age:** 91 DAY
- **Sex:** Male
- **Weight:**

### Suspect Products:

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<th>#</th>
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<tr>
<td>1</td>
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<td>PAIN</td>
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<th>#</th>
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<tbody>
<tr>
<td>1</td>
<td>Baby Teething</td>
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### Event Information:

- **Preferred Term (MedDRA® Version):** 18.1

<table>
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<th>Preferred Term</th>
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<tbody>
<tr>
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<tr>
<td>Cyanosis</td>
<td>NA</td>
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<tr>
<td>Respiratory arrest</td>
<td>NA</td>
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<tr>
<td>Unresponsive to stimuli</td>
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</table>
Event/Problem Narrative:
MOTHER GAVE THE CHILD 2 BABY TEETHING TABLETS ON (b) (6) FOR THE FIRST TIME AND LAID HIM DOWN IN THE BOUNCER SEAT AND (b) (6) LATER CHILD WAS NOT BREATHING AND UNRESPONSIVE. MOTHER JOSTLED HIM AND HE WOULD NOT WAKE UP. GAVE HIM CPR AND CALLED AN AMBULANCE. CHILD HAD ANOTHER EPISODE IN THE HOSPITAL WHERE HE TURNED BLUE AND AGAIN STOPPED BREATHING. CHILD WAS GIVEN A BARIUM SWALLOW TEST TO RULE OUT REFLUX, EKG, URINALYSIS, HEART ECHO AND ALL TESTS ARE NORMAL. DOCTORS BELIEVE SYMPTOMS RELATED TO USE OF BABY TEETHING TABLETS BECAUSE THEY CANNOT DETERMINE ANOTHER CAUSE ALTHOUGH THERE IS A SLIGHT POSSIBILITY THAT SYMPTOMS COULD BE DUE TO REFLUX.

Relevant Medical History:
BORN AT 36 WEEKS - SLIGHTLY PREMATURE. NO FAMILY HISTORY OF SEIZURES.

<table>
<thead>
<tr>
<th>Disease/Surgical Procedure</th>
<th>Start Date</th>
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<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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</tbody>
</table>

Relevant Laboratory Data:
Test Name | Result | Unit | Normal Low Range | Normal High Range | Info Avail
---|---|---|---|---|---

Concomitant Products:
| # | Product Name | Dose/ Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event |
|---|---|---|---|---|---|---|---|---|---|

Print Time: 04-NOV-2016 08:49 AM
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### Case ID: 11803222

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<td><strong>503B Compounding Outsourcing Facility?:</strong></td>
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**Literature Text:**
FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 11823505

Case Information:
- Case Type: EXPEDITED (15-DAY)
- eSub: Y
- HP: Country: USA
- Event Date: Jul-2015
- Outcomes: HO
- Application Type: NDA

FDA Rcvd Date: 10-Dec-2015
Mfr Rcvd Date: 03-Dec-2015
Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1045316
Application #: 999999

Patient Information:
- Age: 152 DAY
- Sex: Male
- Weight:

Suspect Products:

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<th>Dose/Frequency</th>
<th>Route</th>
<th>Dosage Text</th>
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<th>End Date</th>
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<tr>
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Event Information:

Preferred Term (MedDRA® Version: 18.1)

Hypopnoea
NA
Seizure
NA

Event/Problem Narrative:
THE REPORTER'S 10-MONTH-OLD SON HAS BEEN USING THE "BABY TEETHING TABLETS" SINCE JULY. THE REPORTER STATED THAT THE CHILD HAS BEEN EXPERIENCING SEIZURES SINCE BEGINNING USE OF THE TABLETS. THE REPORTER STATED THAT THE CHILD HAD HIS FIRST SEIZURE "A COUPLE OF WEEKS" AFTER HIS FIRST DOSE OF THE "BABY TEETHING TABLETS." SHE STATED THAT SINCE THEN, HE HAS BEEN HOSPITALIZED 5 OR 6 TIMES WITH SEIZURES AND THAT THEY HAVE BEEN FORCED TO CALL AN AMBULANCE FOR HIM MULTIPLE TIMES. SHE STATED THAT SHE WOULD GIVE HIM AT MOST 2-3 TABLETS AT ONE TIME WHEN TEETHING SYMPTOMS WERE PRESENT AND THAT SHE WOULD DOSE HIM 1-2 TIMES PER DAY, DEPENDING ON THE SEVERITY OF THE SYMPTOMS. THE REPORTER STATED THAT HER SON WOULD BECOME FUSSY WITH TEETHING SYMPTOMS, SHE WOULD GIVE HIM A DOSE OF "BABY TEETHING TABLETS," AND THEN HE WOULD NURSE AND FALL ASLEEP. SHE STATED THAT ABOUT 30-45 MINUTES LATER, THE CHILD WOULD WAKE UP WITH A SEIZURE. SHE STATED THAT HE WOULD TENSE UP IN HIS SLEEP, AND THEN "HIS ENTIRE BODY WOULD SHAKE OR TREMOR REALLY..."
VIOLENTLY." SHE STATED THAT HIS MOUTH WOULD QUIVER AND HIS EYES WOULD ROLL UP TO THE LEFT OR RIGHT. SHE DESCRIBED HOW HE WOULD MAKE NOISES THAT SOUNDED AS IF HE WAS GASPING FOR BREATH AND THAT "A COUPLE OF TIMES HE STOPPED BREATHING AND WOULD TURN BLUE." SHE STATED THAT THE SEIZURES WOULD TYPICALLY LAST FOR ABOUT 2-3 MINUTES AND THAT SHE HAS THE SEIZURES ON VIDEO FOR MEDICAL PURPOSES. THE REPORTER DISCONTINUED USING THE "BABY TEETHING TABLETS" WITH HER SON ABOUT ONE MONTH AGO; HE HAS NOT HAS A SEIZURE SINCE DISCONTINUING USE OF THE PRODUCT. THE REPORTER STATED THAT THE CHILD'S BREATHING WOULD SLOW DOWN WHILE HE WAS SLEEPING, AS WELL. SHE STATED THAT IT WOULD SLOW TO THE POINT THAT IT APPEARED AS THOUGH HE WASN'T BREATHING FOR A FEW MINUTES, AND THEN HE WOULD "KIND OF GASP AND BE FINE." SHE STATED THAT THIS SYMPTOM HAS ALSO DISSIPATED SINCE DISCONTINUING USE OF THE "BABY TEETHING TABLETS." PER THE REPORTER, THE DOCTORS, INCLUDING NEUROLOGY SPECIALISTS, CANNOT FIND ANYTHING INDICATING A CAUSE FOR THE SEIZURES.

Relevant Medical History:
NO PRE-EXISTING CONDITIONS. THE CHILD IS EXCLUSIVELY BREAST-FED, AND THE MOTHER IS ON A STRICT DIET DUE TO BREAST-FEEDING. THE CHILD CURRENTLY HAS PRESCRIPTIONS FOR DIASTAT AND KLONOPIN; HE HAS NOT BEEN GIVEN THE DIASTAT AT HOME, BUT HE HAS BEEN GIVEN THE KLONOPIN TWICE. HE IS CURRENTLY TAKING NO OTHER MEDICATIONS.

### Disease/Surgical Procedure
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Case ID: 11823505

Reporter Source:  
Study Report?: No  
Sender Organization: STANDARD HOMEOPATHIC  
503B Compounding Outsourcing Facility?: 

Literature Text:
FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11840826

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Event Date: 2015 Outcomes: OT, Application Type: NDA

FDA Rcvd Date: 16-Dec-2015 Mfr Rcvd Date: 07-Dec-2015 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1045556 Application #: 999999

Patient Information:

Age: 1 YR Sex: Female Weight:

Suspect Products:

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Event Information:

Preferred Term (MedDRA® Version: 18.1) ReC

Renal failure NA

Event/Problem Narrative:

A HEALTH FOOD STORE EMPLOYEE REPORTED WHAT A CUSTOMER TOLD HER ON 12/04/15 WHILE IN THE STORE, THE CUSTOMER SAID HER 15 MONTH OLD DAUGHTER WAS DIAGNOSED WITH KIDNEY FAILURE AND WAS AT HOME PRESENTLY WAITING FOR A BED AT HOSPITAL. SHE SAID THE DOCTORS RELATED IT TO THE TEETHING TABLETS. WE DO NOT PRESENTLY HAVE THE NAME OR CONTACT INFORMATION OF THE MOTHER OR HER DAUGHTER.
Case ID: 11840826

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Print Time: 04-NOV-2016 08:49 AM
FDA - Adverse Event Reporting System (FAERS)  
FOIA Case Report Information

Case ID: 11867472

Case Information:
- Case Type: EXPEDITED (15-DAY)
- eSub: Y
- HP: Country: USA  
- Event Date: 12-Dec-2015  
- Outcomes: HO
- Application Type: NDA
- FDA Rcvd Date: 24-Dec-2015
- Mfr Rcvd Date: 16-Dec-2015
- Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1045885
- Application #: 999999

Patient Information:
- Age: 1 YR
- Sex: Male
- Weight:

Suspect Products:

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Event Information:
- Preferred Term (MedDRA & Version: 18.1)
  - Dehydration
  - Febrile convulsion

Event/Problem Narrative:
MOTHER CALLED WANTING A REFUND OF $5 FOR BABY TEETHING TABLETS. SHE SAID HER 15 MONTH OLD SON HAD BEEN IN HOSPITAL FOR SEVERAL DAYS WITH SEIZURES, AND SHE HAD READ ON LINE THAT TEETHING TABLETS CAUSED THEM.
12/10/15 11 AM, HE RECEIVED 2 VACCINES: HEPATITIS A AND PNEUMOCOCCAL (NEW FOR HIM).
12/11/15 8:45 AM HE STARTED A FEVER IN THE MORNING AND MOTHER BROUGHT HIM TO THE DOCTOR WHO SAID HE WAS FINE AND RECOMMENDED TYLENOL.
12/11/15 AT 9 PM, HE HAD HIS FIRST AND ONLY DOSE OF 2 TABLETS OF BABY TEETHING TABLETS.
MOTHER CHECKED ON HIM AND FOUND HE WAS HAVING SEIZURES IN HIS SLEEP, WITH DIFFICULTY BREATHING, AND FACE TURNING BLUE. HIS FEVER WAS 104.8. HE WAS GIVEN MOUTH TO MOUTH RECUSCITATION AND TAKEN TO THE HOSPITAL.
IN HOSPITAL, HE HAD A SECOND SEIZURE AT 3:30 PM.
HE CONTINUED TO HAVE FEVERS WITH SPIKES UP TO 105.8 WHILE IN THE HOSPITAL.
HE WAS TESTED WITH CHEST X-RAY AND CAT SCAN (ALL NORMAL), AND WAS GIVEN IV FOR DEHYDRATION. DIAGNOSIS WAS: FEBRILE SEIZURES, CAUSE UNKNOWN. HE WAS RELEASED FROM HOSPITAL AT NIGHT AFTER 24 HOURS WITH NO FEVER.

Relevant Medical History:

THERE IS NO FAMILY HISTORY OF SEIZURES; HE HAS NO PRE-EXISTING CONDITIONS OR ALLERGIES.
12/10/15 11 AM, HE RECEIVED 2 VACCINES: HEPATITIS A AND PNEUMOCOCCAL.
HE HAD FEVER STARTING IN THE MORNING OF 12/11/15; IT CONTINUED UNTIL , IT RANGED FROM 102 F TO SPIKES UP TO 105.8 F.

Relevant Laboratory Data:

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Disease/Surgical Procedure

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Medical History Product(s)

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### Reporter Source:

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

**Literature Text:**
Case ID: 11911253

Case Information:
Case Type: EXPEDITED (15-DAY)  eSub: Y  Country: USA  Event Date: 30-Dec-2015  Outcomes: OT  Application Type: NDA
FDA Rcvd Date: 12-Jan-2016  Mfr Rcvd Date: 05-Jan-2016  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1046405  Application #: 999999

Patient Information:
Age: 152 DAY  Sex: Female  Weight:

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Event Information:
Preferred Term (MedDRA® Version: 18.1)  ReC
Seizure  NA

Event/Problem Narrative:
CUSTOMER CALLED TO REPORT THAT HER GRANDDAUGHTER HAS BEEN EXPERIENCING SHAKING AND TWITCHING WHICH APPEARS TO BE A SEIZURE. SHE IS GOING TO A NEUROLOGIST THIS WEEK FOR A DIAGNOSIS AND EVALUATION. WHILE THESE SYMPTOMS ARE OCCURRING THE CHILD MOVES HER HEAD AND ARMS A LOT. SOMETIMES SHE ACTS LIKE SHE IS LOST IN SPACE AND NOT RESPONDING. THE SYMPTOMS HAVE BEEN OCCURRING X 1 WEEK AND SHE HAD 3 EPISODES YESTERDAY.
Case ID: 11911253

**Relevant Medical History:**
NO RECENT IMMUNIZATIONS, NO FAMILY HISTORY OF SEIZURES, WAS NOT BORN PREMATURE.

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**Reporter Source:**

- **Study Report?:** No
- **Sender Organization:** STANDARD HOMEOPATHIC

**Literature Text:**
Case ID: 12127275

Case Information:

Case Type: EXPEDITED (15-DAY)  
Country: USA  
Event Date: 15-Feb-2016  
Outcomes: HO, OT  
Application Type: NDA

FDA Rcvd Date: 29-Feb-2016  
Mfr Rcvd Date: 15-Feb-2016  
Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1048482  
Application #: 999999

Patient Information:

Age:  
Sex: Male  
Weight:

Suspect Products:

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Event Information:

Preferred Term (MedDRA® Version: 18.1)  
ReC

Seizure  
NA

Event/Problem Narrative:

FATHER REPORTED ON THAT HIS SON HAS HAD TWO SEIZURES FOLLOWING THE USE OF BABY TEETHING TABLETS AND IS CURRENTLY HOSPITALIZED.
# Case ID: 12127275

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## Reporter Source:

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

- **Literature Text:**
**Case ID: 12224038**

**Case Information:**
- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **HP:** Country: USA  Event Date: 10-Sep-2015  Outcomes: OT
- **FDA Rcvd Date:** 30-Mar-2016
- **Mfr Rcvd Date:** 23-Mar-2016
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1049998
- **Application Type:** NDA
- **Application #:** 999999

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

**Suspect Products:**
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**Event Information:**
- **Preferred Term (MedDRA® Version):** 18.1
- **Seizure**

**Event/Problem Narrative:**
HYLAND'S RECEIVED WRITTEN CORRESPONDENCE THAT A CHILD EXPERIENCED A SEIZURE AFTER INGESTION OF A TABLET.
### Relevant Medical History:

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### Reporter Source:

- **Study Report?**: No
- **Sender Organization**: STANDARD HOMEOPATHIC
- **503B Compounding Outsourcing Facility?**
**Case Information:**

- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **HP:** Country: USA
- **Event Date:**
- **Outcomes:** OT
- **Application Type:** NDA
- **FDA Rcvd Date:** 15-Apr-2016
- **Mfr Rcvd Date:** 04-Apr-2016
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1050623
- **Application #:** 999999

**Patient Information:**

- **Age:** 1 YR
- **Sex:** Male
- **Weight:**

**Suspect Products:**

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**Event Information:**

- **Preferred Term (MedDRA® Version):** 18.1
- **Preferred Term:**
  - Drug withdrawal syndrome: NA
  - Petit mal epilepsy: NA
  - Seizure: NA

Print Time: 04-NOV-2016 08:49 AM

If a field is blank, there is no data for that field
Event/Problem Narrative:
MOTHER SENT AN E-MAIL AND POSTED ONLINE THAT HER SON EXPERIENCED SEIZURES AFTER DISCONTINUING THE PRODUCTS. MOTHER REPORTED THAT CHILD WAS HAVING STARING SPELLS WHILE TAKING THE PRODUCT(S) AND AFTER SHE STOPPED GIVING THE PRODUCT(S) TO THE CHILD, HE WENT THROUGH A WITHDRAWAL AND STARTING HAVING SEIZURES THAT CAME ON MASSIVELY AT 50 TO 100 PER DAY FOR 3 WEEKS UNTIL THE CHILD'S DOCTOR'S APPOINTMENT AND THEN THEY SLOWED DOWN TO 20 TO 30 PER DAY.

Relevant Medical History:

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### Case Information:

- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **HP:** Country: USA
- **Event Date:** 06-Apr-2016
- **Outcomes:** LT,
- **Application Type:** NDA
- **FDA Rcvd Date:** 18-Apr-2016
- **Mfr Rcvd Date:** 06-Apr-2016
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1050690
- **Application #:** 999999

### Patient Information:

- **Age:** 2 YR
- **Sex:** Male
- **Weight:**

### Suspect Products:

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### Event Information:

- **Preferred Term (MedDRA® Version):** 18.1
- **Preferred Term:**
  - Aspiration: NA
  - Choking: NA
  - Crying: NA
  - Dyspnoea: NA
  - Screaming: NA
Case ID: 12278506

Event/Problem Narrative:
MOTHER GAVE A TABLET AND CHILD STARTED TO CHoke ON IT AND WAS COUGHING AND VISIBLY CHOKING. MOTHER HIT HIM ON THE BACK AND HE SCREAMED AND CRIED FOR A LONG TIME AND WAS BREATHING HARD. MOTHER IS NOT SURE IF THE CHILD SWALLOWED THE TABLET OR IF HE COULD HAVE ASPIRATED IT INTO HIS LUNGS. AT THE TIME OF THE CALL THE CHILD WAS SLEEPING VERY SOUNDLY AND BREATHING NORMALLY.

Relevant Medical History:

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Concomitant Products:

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

Case ID: 12281261

Case Information:
Case Type: EXPEDITED (15-DAY)  
eSub: Y  
HP: Country: USA  
Event Date:  
Outcomes: OT

FDA Rcvd Date: 19-Apr-2016  
Mfr Rcvd Date: 07-Apr-2016  
Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1050701

Application Type: NDA  
Application #: 999999

Patient Information:
Age:  
Sex: Female  
Weight:

Suspect Products:

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Event Information:

Preferred Term (MedDRA® Version: 18.1)  
ReC

Status epilepticus  
NA

Event/Problem Narrative:

FATHER REPORTED VIA E-MAIL THAT HE HAD BEEN GIVING THE BABY TEETHING TABLETS TO HIS DAUGHTER AND SHE WAS DIAGNOSED WITH NON-CONVULSIVE EPILEPSY.
Case ID: 12281261

Relevant Medical History:

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Reporter Source:

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Literature Text:
**Case ID:** 12306511

### Case Information:

- **Case Type:** EXPEDITED (15-DAY)
- **Case Information:**
  - HP: USA
  - Event Date: 10-Apr-2016
  - Outcomes: HO, OT
  - Application Type: NDA
- **FDA Rcvd Date:** 26-Apr-2016
- **Mfr Rcvd Date:** 11-Apr-2016
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051026
- **Application #:** 999999

### Patient Information:

- **Age:** 213 DAY
- **Sex:** Male
- **Weight:**

### Suspect Products:

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### Event Information:

- **Preferred Term (MedDRA ® Version):** 18.1 Seizure
- **Preferred Term:** Seizure

### Event/Problem Narrative:

A BABY WAS GIVEN BABY TEETHING TABLETS, DEVELOPED SEIZURES AND HAS BEEN HOSPITALIZED SINCE APPROXIMATELY THE BABY WAS SEDATED IN THE HOSPITAL WITH MEDICATION TO CALM THE BABY DOWN. THE BABY REMAINS HOSPITALIZED.
## Relevant Medical History:

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## Reporter Source:

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

**Literature Text:**
FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 12306848

Case Information:
Case Type: EXPEDITED (15-DAY)
Case Information: 
eSub: Y  HP: Country: USA  Event Date: 09-Apr-2016  Outcomes: HO  Application Type: NDA
FDA Rcvd Date: 26-Apr-2016  Mfr Rcvd Date: 14-Apr-2016  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1051032  Application #: 999999

Patient Information:
Age: 213 DAY  Sex: Male  Weight: 

Suspect Products:
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<tbody>
<tr>
<td>1</td>
<td>Baby Teething</td>
<td>Unk</td>
<td>Unk</td>
<td>B38415</td>
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Event Information:
Preferred Term (MedDRA® Version: 18.1 )
Cerebral haemorrhage  ReC

Event/Problem Narrative:
The Reporter stated that her son was recently hospitalized after using the "Baby Teething Tablets." Reporter states she has been administering 2 tablets of BTET twice daily since the middle of last month (approx. 3/15/16). Early in the morning of she noticed that the child's head looked swollen. She also felt a soft knot on the child's head. She took him to a local hospital. Child was transferred to a hospital in where the doctors diagnosed child's condition as "bleeding on his brain." Child was discharged on and child is at home now. Swelling is yet to go down.
### Relevant Medical History:

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

<table>
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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>
<th>Info Avail</th>
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### Concomitant Products:

<table>
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<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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</thead>
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### Reporter Source:

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

**Literature Text:**
**Case Information:**

- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **HP:** Country: USA
- **Event Date:** 19-Mar-2016
- **Outcomes:** HO, OT
- **Application Type:** NDA

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<th>Mfr Control #</th>
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<tr>
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<td>18-Apr-2016</td>
<td>US-STANDARD HOMEOPATHIC COMPANY-1051095</td>
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| Application #: | 999999 |

### Patient Information:

- **Age:** 1 YR
- **Sex:** Female
- **Weight:**

### Suspect Products:

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<th>Dose/Frequency</th>
<th>Route</th>
<th>Dosage Text</th>
<th>Indications(s)</th>
<th>Start Date</th>
<th>End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Baby Teething</td>
<td></td>
<td>1 DF/</td>
<td>Oral</td>
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<td>TEETHING PAIN, BODY TEMPERATURE INCREASED</td>
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<tr>
<td>2</td>
<td>HYLAND'S BABY TINY COLD TABLETS</td>
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### Event Information:

- **Preferred Term (MedDRA® Version):** 18.1
- **Preferred Term:** Seizure
- **ReC:** NA
Event/Problem Narrative:
CHILD WAS HOSPITALIZED FOR SEIZURES. CUSTOMER STATED THAT CHILD STARTED HAVING SEIZURES A MONTH AGO. LAST USE OF TEETHING TABLETS AND TINY COLD TABLETS PRIOR TO THE FIRST SEIZURE OCCURRED WAS 2-3 WEEKS. SEIZURES LOOKED LIKE STARING SPELLS WITH UPPER BODY CONVULSIONS LASTING 10 SECONDS AND TAKING ABOUT 20 MINUTES FOR CHILD TO RETURN TO NORMAL. CHILD HAS HAD A TOTAL OF THREE SEIZURES AND THE CHILD WAS HOSPITALIZED AFTER THE THIRD SEIZURE. DOCTORS UNABLE TO DETERMINE A CAUSE FOR THE SEIZURES.

Relevant Medical History:
DOCTORS OFFERED MEDICINE BUT MOTHER DECLINED. MOTHER IS TAKING THE CHILD BACK TO THE DOCTOR AND FOR A FOLLOW-UP VISIT WITH A NEUROLOGIST.

Disease/Surgical Procedure | Start Date | End Date | Continuing?
--- | --- | --- | ---
Medical History Product(s) | Start Date | End Date | Indications | Events

Relevant Laboratory Data:
Test Name | Result | Unit | Normal Low Range | Normal High Range | Info Avail
--- | --- | --- | --- | --- | ---

Concomitant Products:
# | Product Name | Dose/Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event
--- | --- | --- | --- | --- | --- | --- | --- | ---

Print Time: 04-NOV-2016 08:49 AM
Case ID: 12311125

Reporter Source:  
Study Report?: No  
Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:
**Case ID: 12341669**

**Case Information:**
- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **HP:** Country: USA
- **Event Date:** 20-Apr-2016
- **Outcomes:** OT
- **FDA Rcvd Date:** 06-May-2016
- **Mfr Rcvd Date:** 24-Apr-2016
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1051563
- **Application Type:** NDA
- **Application #:** 999999

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

**Suspect Products:**

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<th>Dose/Frequency</th>
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<th>End Date</th>
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<th>Lot#</th>
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<th>NDC #</th>
<th>MFR/Labeler</th>
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**Event Information:**
- **Preferred Term (MedDRA® Version):** 19.0

**Event/Problem Narrative:**
MOTHER POSTED ON THAT HER SON HAD A SEIZURE AFTER TAKING THE TABLETS.
Case ID: 12341669

Relevant Medical History:

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Reporter Source:

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Literature Text:
FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 12341756

Case Information:

Case Type: EXPEDITED (15-DAY)  eSub: Y  HP: Country: USA  Event Date:  Outcomes: OT  Application Type: NDA

FDA Rcvd Date: 06-May-2016  Mfr Rcvd Date: 26-Apr-2016  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1051565  Application #: 999999

Patient Information:

Age:  Sex: Male  Weight:

Suspect Products:

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<th>End Date</th>
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<tbody>
<tr>
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<td>TEETHING PAIN</td>
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<tr>
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<td>Baby Teething</td>
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Event Information:

Preferred Term (MedDRA® Version: 19.0)  ReC

Generalised tonic-clonic seizure  NA

Event/Problem Narrative:

MOTHER POSTED ON THAT CHILD EXPERIENCED GRAND MAL SEIZURES THAT WERE TRACED BACK TO THE TEETHING TABLETS. AS PROOF PARENTS GAVE HIM ONE TABLET AND IN THE MATTER OF 15 MINUTES HE HAD A SEIZURE.
### Case ID: 12341756

#### Relevant Medical History:

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#### Relevant Laboratory Data:

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#### Concomitant Products:

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<th>Dose/Frequency</th>
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<th>Indications(s)</th>
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#### Reporter Source:

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Literature Text:

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Print Time: 04-NOV-2016 08:49 AM If a field is blank, there is no data for that field
### Case Information:

- **Case ID:** 12388846
- **Case Type:** EXPEDITED (15-DAY)  
- **eSub:** Y  
- **Country:** USA  
- **Event Date:**  
- **Outcomes:** HO, OT  
- **Application Type:** NDA
- **FDA Rcvd Date:** 20-May-2016  
- **Mfr Rcvd Date:** 06-May-2016  
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1052532  
- **Application #:** 999999

### Patient Information:

- **Age:** 1 YR  
- **Sex:** Male  
- **Weight:**

### Suspect Products:

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<tbody>
<tr>
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<td>1 DF/</td>
<td>Oral</td>
<td>NA</td>
<td>TEETHING PAIN, FEVER</td>
<td>April-2016</td>
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<tr>
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### Event Information:

- **Preferred Term (MedDRA® Version):** 19.0
- **ReC:**
  - Pyrexia: NA
  - Rash: NA
  - Seizure: NA
  - Vomiting: NA
**Event/Problem Narrative:**
CHILD WAS IN THE HOSPITAL FOR SEIZURES ABOUT A MONTH AGO WHEN MOTHER FIRST STARTED USING THE BABY TEETHING TABLETS. AT THE TIME OF THE HOSPITALIZATION THE CHILD HAD A FEVER OF 102.3 DEGREES. THE CHILD ALSO HAD A FEVER OF 101.2 DEGREES WITH RASH 2 DAYS AGO AND VOMITED YESTERDAY.

---

**Relevant Medical History:**
FATHER HAD SEIZURES WHEN HE WAS LITTLE.

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<th>Continuing?</th>
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**Relevant Laboratory Data:**

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**Concomitant Products:**

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<th>Product Name</th>
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<table>
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<td>Literature Text:</td>
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**Case ID: 12389148**

**Case Information:**
- **Case Type:** EXPEDITED (15-DAY)
- **eSub:** Y
- **Country:** USA
- **Event Date:** 2016
- **Outcomes:** HO
- **Application Type:** NDA
- **FDA Rcvd Date:** 20-May-2016
- **Mfr Rcvd Date:** 09-May-2016
- **Mfr Control #:** US-STANDARD HOMEOPATHIC COMPANY-1052539
- **Application #:** 999999

**FDA - Adverse Event Reporting System (FAERS)**

**FOIA Case Report Information**

**Patient Information:**
- **Age:** 167 DAY
- **Sex:** Male
- **Weight:**

**Suspect Products:**

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<tbody>
<tr>
<td>1</td>
<td>BABY TEETHING GEL (HYLAND HOMEOPATHIC)</td>
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<td>TEETHING PAIN</td>
<td>2016</td>
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**Event Information:**
- **Preferred Term (MedDRA® Version):** 19.0
- **Preferred Term:** Seizure

**Event/Problem Narrative:**

**Print Time:** 04-NOV-2016 08:49 AM
TOLD HER THAT THEY WERE "GOING TO LOOK FOR A CAUSE" OF THE SEIZURES. THE CHILD'S LAST SEIZURE OCCURRED ON 6/28/2021. THE REPORTER STATED THAT THEY WENT TO THE HOSPITAL ON THIS DATE AND THAT THEY DISCONTINUED USING THE PRODUCT ON THIS DATE.

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FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12389148

Reporter Source:

Study Report?: No

Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:
Case Information:

Case ID: 12412557

Case Type: NON-EXPEDITED  eSub: Y  HP: Y  Country: USA  Event Date: 2009  Outcomes: OT

FDA Rcvd Date: 08-Jun-2016  Mfr Rcvd Date: 11-Apr-2016  Mfr Control #: 54973 AE#1611

Patient Information:

Age: 152 DAY  Sex: Female  Weight:

Suspect Products:

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Event Information:

Preferred Term (MedDRA® Version: 19.0)  ReC
Seizure

Event/Problem Narrative:

2009/2010 CHILD HAD FIVE SEIZURES ON SEPARATE OCCASIONS WHILE USING THE TEETHING TABLETS. FOUR OF THE SEIZURES WERE FEBRILE SEIZURES AND ONE WAS AN UNPROVOKED SEIZURE. CHILD'S FEVERS OCCURRED RAPIDLY. MOTHER BELIEVES THAT THE BELLADONNA MAY HAVE LOWERED THE CHILD'S SEIZURE THRESHOLD AND CONTRIBUTED TO HER SEIZURES. CHILD OUTGREW THE SEIZURES.
### Relevant Medical History:
FAMILY HISTORY OF SEIZURES - TWO HALF-SIBLINGS FROM FATHER'S SIDE HAD FEBRILE SEIZURES AS INFANTS. CHILD HAD A FEVER FOR FOUR OF THE FIVE SEIZURES.

### Disease/Surgical Procedure
<table>
<thead>
<tr>
<th>Disease/Surgical Procedure</th>
<th>Start Date</th>
<th>End Date</th>
<th>Continuing?</th>
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### Medical History Product(s)
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<tr>
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<th>Start Date</th>
<th>End Date</th>
<th>Indications</th>
<th>Events</th>
</tr>
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</table>

### Relevant Laboratory Data:
<table>
<thead>
<tr>
<th>Test Name</th>
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### Concomitant Products:

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<tr>
<th>#</th>
<th>Product Name</th>
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<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:

- **Study Report?**: No
- **Sender Organization**: STANDARD HOMEOPATHIC
- **503B Compounding Outsourcing Facility?**
Case ID: 12424787

Case Information:
- Case Type: EXPEDITED (15-DAY)
- eSub: Y
- HP: USA
- Event Date: 2016
- Outcomes: OT
- Application Type: NDA
- FDA Rcvd Date: 01-Jun-2016
- Mfr Rcvd Date: 17-May-2016
- Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1053003
- Application #: 999999

Patient Information:
- Age:
- Sex: Male
- Weight:

Suspect Products:
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<th>Indications(s)</th>
<th>Start Date</th>
<th>End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Baby Teething</td>
<td></td>
<td>1 DF/</td>
<td>Oral</td>
<td></td>
<td>TEETHING PAIN</td>
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<th>ReC</th>
<th>Lot#</th>
<th>Exp Date</th>
<th>NDC #</th>
<th>MFR/Labeler</th>
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<tr>
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Event Information:
- Preferred Term (MedDRA® Version): 19.0
- Seizure

Seizure: NA

Event/Problem Narrative:
TARGET STORE REPORTED BY E-MAIL THAT CUSTOMER'S SON SUFFERED A SEIZURE AFTER TAKING A BABY TEETHING TABLET.
### Case ID: 12424787

#### Relevant Medical History:

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**Literature Text:**
Case ID: 12429653

Case Information:

Case Type: EXPEDITED (15-DAY)  eSub: Y  HP:  Country: USA  Event Date: 20-May-2016  Outcomes: OT

FDA Rcvd Date: 02-Jun-2016  Mfr Rcvd Date: 22-May-2016  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1053119  Application Type: NDA  Application #: 999999

Patient Information:

Age: 304 DAY  Sex: Male  Weight:

Suspect Products:

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<td>Oral</td>
<td>TEETHING PAIN</td>
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Event Information:

Preferred Term (MedDRA® Version: 19.0 )

- Body temperature abnormal
- Flushing
- Muscle twitching
- Staring
- Unresponsive to stimuli

ReC
Event/Problem Narrative:
MOTHER GAVE CHILD A DOSE AT 2:45 PM FOR TEETHING PAIN. AT 4:30 PM CHILD SEEMED OUT OF IT, STARING OFF BLANKLY INTO THE ROOF, TWITCHING, AND UNRESPONSIVE TO MOTHER TALKING TO HIM, BRIGHT RED FLUSHED CHEEKS AND A TEMPERATURE. MOTHER WAS GOING TO TAKE CHILD TO THE HOSPITAL, HOWEVER SYMPTOMS RESOLVED AND CHILD ONLY REMAINED TIRED AND FLUSHED. SYMPTOMS OCCURRED ONCE AGAIN THE FOLLOWING DAY AFTER TAKING 2 TABLETS AND SUBSEQUENTLY RESOLVED.

Relevant Medical History:

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**Case ID:** 12460888

**Case Information:**

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**Patient Information:**

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**Suspect Products:**

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<th>Route</th>
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<th>Indications(s)</th>
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<th>End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>1 DF/</td>
<td>Oral</td>
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<td>TEMPERATURE INCREASED, TEETHING PAIN</td>
<td>Mar-2016</td>
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<thead>
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<tbody>
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</tbody>
</table>

**Event Information:**

Preferred Term (MedDRA Version: 19.0 )

Seizure

**Event/Problem Narrative:**

CUSTOMER'S SON WAS DIAGNOSED WITH SEIZURES 1 MONTH AGO WHILE TAKING BABY TEETHING TABLETS. HE HAS SINCE DISCONTINUED THE TABLETS AND CONTINUES TO HAVE SEIZURES AND IS TAKING KEPPRA. HE WAS HOSPITALIZED FOR 1 WEEK DUE TO THE SEIZURES AND IN THE HOSPITAL HE WAS HOOKED UP TO AN EEG MACHINE WHICH FOUND SEIZURES ON ONE SIDE OF HIS BRAIN. DOCTORS UNSURE WHAT IS CAUSING THE SEIZURES.
### Relevant Medical History:

- **NOT BORN PREMATURE, NO FAMILY HISTORY OF SEIZURES.**

### Disease/Surgical Procedure

<table>
<thead>
<tr>
<th>Description</th>
<th>Start Date</th>
<th>End Date</th>
<th>Continuing?</th>
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### Medical History Product(s)

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### Relevant Laboratory Data:

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<th>Test Name</th>
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### Concomitant Products:

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### Reporter Source:

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

**Literature Text:**

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*Print Time: 04-NOV-2016 08:49 AM*

*If a field is blank, there is no data for that field*
FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 12726345

Case Information:

Case Type: EXPEDITED (15-DAY)  eSub: Y  HP: Country: USA  Event Date: Jun-2016  Outcomes: OT  Application Type: NDA

FDA Rcvd Date: 08-Sep-2016  Mfr Rcvd Date: 26-Aug-2016  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1057183  Application #: 999999

Patient Information:

Age: 182 DAY  Sex: Female  Weight: 

Suspect Products:

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<th>#</th>
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<tbody>
<tr>
<td>1</td>
<td>Baby Teething</td>
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<td>1 DF/</td>
<td>Oral</td>
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<td>BODY TEMPERATURE INCREASED, TEETHING PAIN</td>
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<tbody>
<tr>
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Relevant Medical History:
WENT TO CHILDREN'S HOSPITAL ER FOR EVALUATION. DOCTOR CAME UP WITH A DIAGNOSIS OF SEIZURES BY QUESTIONING BECAUSE IT WAS TOO LATE TO DO AN EEG AS CHILD WAS NOT EXPERIENCING SEIZURES WHILE IN THE HOSPITAL. ACID REFLUX ON OCCASION. NO FAMILY HISTORY OF SEIZURES.

<table>
<thead>
<tr>
<th>Disease/Surgical Procedure</th>
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<th>Continuing?</th>
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Relevant Laboratory Data:

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<th>Test Name</th>
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Concomitant Products:

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Literature Text:
FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 12756114

Case Information:
Case Type: EXPEDITED (15-DAY)  eSub: Y  Country: USA  Event Date: 05-Sep-2016  Outcomes: LT  Application Type: NDA
FDA Rcvd Date: 16-Sep-2016  Mfr Rcvd Date: 05-Sep-2016  Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1057400  Application #: 999999

Patient Information:
Age: 152 DAY  Sex: Female

Suspect Products:

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<td>1</td>
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<tbody>
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Event Information:
Preferred Term (MedDRA® Version: 19.0)
Choking
Dysphagia

Print Time: 04-NOV-2016 08:49 AM  If a field is blank, there is no data for that field
Event/Problem Narrative:
CUSTOMER REPORTED ON [9] AND BY E-MAIL THAT CHILD WAS GIVEN BABY TEETHING TABLETS AND SHORTLY THEREAFTER WAS GIVEN GRIPE WATER AND SHE CHOKED ON THE GRIPE WATER. CHILD'S FACE TURNED COLORS AND SHE COULD NOT CATCH HER BREATH. PARENTS CALLED 911 FOR ASSISTANCE. PARENTS BELIEVE THAT BABY TEETHING TABLETS NUMBED THE CHILD'S THROAT AND CAUSED DIFFICULTY SWALLOWING.

Relevant Medical History:
CHILD WAS ALSO ADMINISTERED UNKNOWN BRAND OF GRIPE WATER (NO PRIOR REACTIONS TO GRIPE WATER).

Disease/Surgical Procedure | Start Date | End Date | Continuing?
--- | --- | --- | ---

Medical History Product(s) | Start Date | End Date | Indications | Events
--- | --- | --- | --- | ---

Relevant Laboratory Data:
Test Name | Result | Unit | Normal Low Range | Normal High Range | Info Avail
--- | --- | --- | --- | --- | ---

Concomitant Products:
# | Product Name | Dose/Frequency | Route | Dosage Text | Indications(s) | Start Date | End Date | Interval 1st Dose to Event
--- | --- | --- | --- | --- | --- | --- | --- | ---

Print Time: 04-NOV-2016 08:49 AM
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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:
11008869 11012660 11061630 11088037 11090548 11145186 11173807 11176579
11179757 11179760 11179773 11179851 11188555 11254142 11258215
11275465 11275478 11279245 11301071 11364562 11374329 11395428 11415807
11419862 11468448 11473233 11500192 11513415 11516350 11516352
11516354 11516357 11516369 11516392 11516404 11516539 11516540 11516601
11536908 11544456 11603023 11614940 11628084 11639546
11658849 11683168 11699938 11700316 11788548 11788578 11878433 11999660
12009242 12079943 12197698 12470569 12480346 12491395 12606520
12654615 12689440 12693124 12720370 12721292

Failed Case Id's for Images:

Total Failed Cases: 0
A. PATIENT INFORMATION
1. Patient Identifier (0-6):
2. Age at Time of Event: 2 Months
3. Sex: Female
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
   - 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):
3. Date of Event (mm/dd/yyyy): 03/13/2015
4. Date of This Report (mm/dd/yyyy): 03/26/2015

5. Describe Event or Problem
   CHILD HAD A SEIZURE THE MORNING OF 03/13/15. NO PAST HISTORY OF SEIZURE. CHILD'S FIRST TIME USING THE TABLETS. MOTHER GAVE 2 TABS ON 03/10 AND 03/11 IN THE AM AND 1 TAB 03/12 IN THE AM. SEIZURE OCCURRED IN THE BATHROOM AND GRANDMOTHER DESCRIBED IT AS CHILD LOBBING BALANCE, EYES STARTED ROLLING IN THE BACK OF THE HEAD, DIFFICULTY BREATHING. SEIZURE LASTED ABOUT 5 - 7 MINUTES. FAMILY CALLED 911 AND SUBSEQUENTLY THE CHILD WAS FINE. CHILD WILL FOLLOW-UP WITH THE NEUROLOGIST.

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.)
   GRANDFATHER’S BROTHER AND COUSIN HAVE HISTORY OF SEIZURES.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer):
   HYLAND'S BABY TEETHING TABLETS
2. Date, Frequency & Route Used:
   2 TABLETS 3X/10X3/11X TABLET
3. Therapy Started:
   APR 08 2015
4. Diagnosis for Use (Indication):
   #1 TEMP RELIEF
5. Event Altered After Use Stopped or Dose Reduced:
   #1 Yes #2 No #3 Doesn't Apply
6. Lot #:
   #1 A03815
7. Exp Date:
   APR 08 2015
8. Event Reappeared After Reproduction?
   #1 Yes #2 No #3 Doesn't Apply
9. NDC or Unique ID:
   54973-5127-1

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 Data (mm/dd/yyyy):
7. If Explanted, Give Data (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:
   DSS
   APR - 9 2015
2. Health Professional?
   - Yes
   - No
3. Occupation
   - NA
4. Initial Reporter Also Sent Report to FDA
   - Yes
   - No
**Individual Case Safety Report**

**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 Remediative Action Initiated, Check Type**
   - [ ] Recall
   - [ ] Repair
   - [ ] Replace
   - [ ] Recall Device
   - [ ] Medical Action
   - [ ] Other

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

9. **If action reported to FDA under 21 USC 360(i), list corrections/ removal reporting number:**

   DSS
   APR: 09 2015

**G. ALL MANUFACTURERS**

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

2. **Phone Number**
   - 310-769-0700

3. **Report Source**
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [X] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

4. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 03/23/2015

5. **(A)NDA #**
   - IND #
   - BLA #
   - PMA/ 510(k) #
   - Combination Product
   - Pre-1938
   - OTC Product
   - Yes

6. **Type of Report**
   - [ ] 6-day
   - [ ] 30-day
   - [ ] 7-day
   - [ ] Periodic
   - [ ] 10-day
   - [X] Initial
   - [ ] 15-day
   - [ ] Follow-up

7. **Manufacturer Report Number**
   - 54973 AE # 1604

8. **Adverse Event Term(s)**
   - SERIZORE

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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
PRAS Staff@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

PRODUCT: HYLAND'S BABY TEETHING TABLETS

SIZE: 135 TABLETS

REPORTER: (b)(6)

ADDRESS:

CITY: STATE: (b)(6)

COUNTRY: USA ZIP CODE:

PHONE #: (b)(6)

E-MAIL:

NATURE OF COMPLAINT: CHILD HAD A SEIZURE THE MORNING OF MARCH 13. HAS NOT HAD A SEIZURE IN THE PAST. THIS WAS THE CHILD'S FIRST TIME USING THE TABLETS. MOTHER GAVE 2 TABLETS ON MARCH 10 AND 1 IN THE MORNING AND 1 TABLET ON MARCH 12 IN THE MORNING. SEIZURE OCCURRED IN THE BATHTUB AND GRANDMOTHER DESCRIBED IT AS CHILD LOSING BALANCE, EYES STARTED ROLLING IN THE BACK OF THE HEAD. DIFFICULTY BREATHING. THIS LASTED ABOUT 5-7 MINUTES. THEY CALLED 911 AND THE CHILD WAS FINE. FOLLOWED UP WITH THE DOCTOR AND CHILD HAS AN APPOINTMENT WITH THE NEUROLOGIST. GRANDFATHER'S BROTHER AND COUSIN HAVE HISTORY OF SEIZURES.

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: ____________________________ DATE: ____________________

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT REPORTED ON: 03/23/15

ADVERSE EVENT REPORTED BY: EDYTA FRACKIEWICZ

ADVERSE EVENT SERIOUS: Y N

AE #: 1604

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 03-30-15

DATE: 03-27-15

QA / QC DIRECTOR

cc: QA / QC Packaging Production Shipping / Receiving
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A08815, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A08815 associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A08815. The Baby Teething bulk lot # 124034 was tested for total Atropine and Scopolamine and the results were with in specification of (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 has been received for Hyland's Baby Teething Tablets lot # A08815. The other complaint was also an SAE (SAE-0010-2015). The complaints were reviewed and although both complaints did indicate that the patient "had trouble breathing" they appear to be isolated and do not represent a trend. 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.
SERIOUS ADVERSE EVENT DATA FORM

AE #: 1604
COMPLAINT #: 2614

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: 03-30-15
BY: __________________________ DATE: 03-27-15

DSS APR - 9 2015

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SASH
Individual Case Safety Report

A. PATIENT INFORMATION
1. Patient Identifier (ID) #
2. Age at Time of Event: 5 Months
3. Sex: Male
4. Weight: ___ lbs
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: (name/yy)
   - 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): 03/19/2015
4. Date of This Report (mm/dd/yyyy): 03/24/2015
5. Describe Event or Problem:
   MOTHER POSTED ON (03/16) THAT HYLAND'S BABY TEETHING TABLETS DID NOT DISSOLVE, CHILD WAS CHOKING ON THEM, AND MOTHER HAD TO PERFORM THE HEIMLICH MANEUVER.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer's ORY reporting #)
   #1 HYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used
   #1 UNKNOWN
3. Therapy Days (If unknown, give duration) #1
4. Diagnosis for Use (Indicating)
   #1 TEMP RELIEF OF TEETHING PAIN
5. Event Aborted After Use
   Stopped or Does Reduced?
   #1 Yes  #2 No  #3 Doesn't Apply

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 No. 9, Enter Name and Address of Reprocessor
    DSS APR 10 2015

E. INITIAL REPORTER
1. Name and Address
   USA 2015
2. Health Professional?
   Yes  No
3. Occupation
   NA
4. Initial Reporter Also Sent Report to FDA
   Yes  No  Unk.
### E. ALL MANUFACTURERS

<table>
<thead>
<tr>
<th>1. Contact Office (and Manufacturing Site for Devices)</th>
<th>2. Phone Number</th>
</tr>
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<tbody>
<tr>
<td>EDDY PAURO BICGI</td>
<td>(310) 768-0070</td>
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<th>3. Report Source (Check all that apply)</th>
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<td>User Facility</td>
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<td>Company Representative</td>
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<td>Distributor</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. (AJNDA #)</th>
<th>IND #</th>
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<th>6. FDA Advisory Council for Devices (PMA #)</th>
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<th>7. Type of Report (Check all that apply)</th>
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<td>5-day</td>
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<td>7-day</td>
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<td>10-day</td>
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<tr>
<td>15-day</td>
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<th>8. Manufacturer Report Number</th>
<th>54973 AE # 1603</th>
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<tr>
<th>9. Manufacturer Name and Address</th>
<th>10. Additional Manufacturer Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYLAND'S, INC.</td>
<td></td>
</tr>
<tr>
<td>154 W. 131ST STREET</td>
<td></td>
</tr>
<tr>
<td>LOS ANGELES, CA 90061</td>
<td></td>
</tr>
<tr>
<td>STANDARDSHYLANDS.COM</td>
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</tbody>
</table>

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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

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CUSTOMER COMPLAINT RECORD

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: NOT PROVIDED
REPORTER: (D)(B)
ADDRESS:

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

DATE OF COMPLAINT: 03/19/15
ITEM CODE: 8TET
LOT NO.: NOT PROVIDED

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (D)(B) ABOUT BABY TEETHING TABLETS AND DID NOT CONTACT HYLAND'S WITH MORE INFORMATION. THEY WERE NOT QUICK MELTING AT ALL. HAD TO GIVE MY 5 MONTH OLD THE HEMIUCHI! SHE WAS CHOKING ON THEM. FURIOUS!

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:

UPS CALL TAG ISSUED: Y
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:

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y
ADVERSE EVENT REPORTED ON: 03/19/15
BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 03-31-15
DATE: 03-30-15

Individual Case Safety Report

cc: QA/QC Packaging

11012660-01-00-03
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. Although a lot number was not provided all BTET lots are tested for disintegration and typically disintegrate in less than 20 seconds.

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 six (46) 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 Clostridium botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of 240 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 #: 1603
COMPLAINT #: 2613

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: APR 10 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: [Redacted]
DATE: 03-31-15

BY: [Redacted]
DATE: 03-30-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR - 9 2015
MOTHER AND AUNT POSTED ON (5) THAT SHORTLY AFTER RECEIVING HYLAND'S BABY TEETHING TABLETS, CHILD HAD A SEIZURE AND HAD TO BE ADMINISTERED CPR.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

3. Therapy Dates (If unknown, give duration)

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

5. Event Avoided After Use

6. Lot #

7. Exp. Date

8. Event Reproduced After
   Reproduction?

9. NDC# or Unique ID
   54073-3127-1

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

6. If Implanted, Give Date

7. If Expiration, Give Date

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

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?
   - Initial Report
   - Follow-up #
   - No

3. Device Evaluated by 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
   - Device
   - Code

7. If Remediai Action Initiated, Check Type
   - Recall
   - Notification
   - Repair
   - Inspection
   - Replace
   - Patient Monitoring

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

9. If action reported to FDA under 21 USC 380(k), list correction/removal reporting number:

10. Additional Manufacturer Narrative and/or Corrected Data

G. ALL MANUFACTURERS

1. Contact Office and Manufacturing Site for Devices
   - Name: EDYTA FRACKIADNIAZ
   - Address: HYLAND'S, INC.
     154 W. 1111 STREET
     LOS ANGELES, CA 90061
     Email Address: STANDARDHYLANDS.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)
   - 03/03/2015

5. FDA
   - (A) IND #
   - BLA #
   - 510(k) #
   - Combination Product
   - Yes
   - Pre-1938
   - Yes
   - OTC Product
   - Yes

6. Manufacturer Report Number
   - 54973 AE 1605

7. Adverse Event Term(s)
   - SEIZURE

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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
PRASSubmit this Cov
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 POSTED THE FOLLOWING COMMENT ON HYLAND'S BABY TEETHING FACEBOOK PAGE: THIS PRODUCT MADE MY KID GET A SEIZURE LOOK INTO IT PLEASE!! AUNT POSTED THE FOLLOWING COMMENT ON MY 1 YEAR OLD NEPHEW HAD A SEIZURE RIGHT AFTER HE WAS GIVEN THESE TABLETS. ONE OF THE SYMPTOMS OF USING THIS PRODUCT, WAS UNAWARE UNTIL WE DID A SYMPTOM RESEARCH!!! PLEASE STOP THE USE, IT WAS THE SCARIEST THING EVER IN OUR LIVES!!! THANK GOD HE WAS AND IS OK. AND WITHOUT KNOWING IT WAS A SEIZURE, THAT MY MOM WAS THERE TO GIVE HIM CPR!!! PLEASE DO NOT USE!!! WAS UNABLE TO SPEAK TO MOTHER OVER THE PHONE. BECAUSE SHE DID NOT CALL OR PROVIDE A NUMBER WHERE SHE COULD BE REACHED. 04/15/15 FOLLOW-UP:

EDYTA FRACKIEWICZ SPOKE WITH MOTHER AND CHILD IS CURRENTLY DOING WELL. ON THE DAY OF THE SEIZURE THEY CALLED PARAMEDICS AND WENT TO THE ER. DOCTOR'S NOT SURE WHY THE CHILD HAD A SEIZURE AND THEY WILL DO FOLLOW-UP TESTS. NO FEVER OR ILLNESS AT THE TIME OF THE SEIZURE AND NO FAMILY HISTORY OF SEIZURES. CHILD BECAME STIFF AND STOPPED BREATHING FOR 3 MINUTES DURING THE SEIZURE. OFFERED A REFUND AND CUSTOMER DECLINED. SHE REQUESTED THAT HYLAND'S BABY TEETHING TABLETS BE REMOVED FROM THE MARKET.

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: 04/03/15
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: 04/03/15 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT: DATE: 04-16-15
BY: QA / QC DIRECTOR DATE: 04-16-15
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A41614, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (632) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A41614 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 # A41614. The Baby Teething bulk lot # 123302 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 one other complaint (CC-0846-2014) has been received for Hyland's Baby Teething Tablets lot # A41614. The complaints were reviewed but 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 # A41614.

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

Prepared by

Date

DSS

APR 23 2015

APR 22 2015
CUSTOMER SENT AN E-MAIL STATING THAT TEETHING TABLETS AND TEETHING GEL THICKENED THE SALIVA OF HER BABY AND MADE HIM CHOKED.

04/16/15 FOLLOW-UP: MOTHER REPORTED THAT CHILD HAD DIFFICULTY SWALLOWING AND THICK SALIVA WHICH CAUSED SEVERE CHOKING AND DIFFICULT BREATHING. MOTHER Laid THE CHILD ON HIS SIDE ON THE FLOOR IN ORDER TO OPEN HIS AIRWAY AND ALMOST HAD TO PERFORM CPR.
CaseID: 11088037

1. Device Manufacturers Only
   - 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?
     - [ ] 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
     - [ ] Device
     - [ ] 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:

G. All Manufacturers
   - 1. Contact Office (and Manufacturing Site for Devices)
     - Name: EDYTA 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 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)
     - 34/11/2015
   - 5. (AINDA #) IND #
   - 6. If IND, Give Protocol #
   - 7. Type of Report (Check all that apply)
     - [ ] 5-day
     - [ ] 30-day
     - [ ] Initial
     - [ ] Follow-up #
   - 8. Adverse Event Terms
     - [ ] INFLAMMATION
     - [ ] CHEST PAIN
   - 9. Manufacturer Report Number
     - 54973 AE # 1606
   - 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 95 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 SENT THE FOLLOWING E-MAIL: I BOUGHT THE TEETHING GEL AND THE TEETHING TABLETS, BOTH YOUR BRANDS, AND I HAVE TO SAY THEY ARE DANGEROUS. THEY THICKENED THE SALIVA OF MY BABY AND MADE HIM CHOKED! THESE SHOULD COME WITH A WARNING ON THEM! 04/11/16 FOLLOW-UP: SPOKE WITH CUSTOMER AND SHE INFORMED ME THAT CHILD HAD TROUBLE SWALLOWING AFTER USING BOTH TEETHING GEL AND BABY TEETHING TABLETS DUE TO THICK SALIVA WHICH HE STARTED CHOKING ON BOTH TIMES. CHOKE WAS SEVERE. SHE HAD TO LAY HIM ON HIS SIDE ON THE FLOOR AND OPEN HIS AIRWAY DUE TO DIFFICULTY BREATHING. ALMOST HAD TO PERFORM CPR. WILL RETURN THE PRODUCT TO THE STORE. NO MEDICAL ISSUES, NOT PREMATURE, NO KNOWN ALLERGIES, NO ILLNESS, NO FEVER. HAS AN APPOINTMENT TO SEE THE DOCTOR NEXT WEEK.

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: [signature]

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: [Y/N]
ADVERSE EVENT REPORTED ON: 04/11/15
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: [signature]
BY: [signature]

[Signature]
QA/QC DIRECTOR

OC: QA/QC
Production
Shipping/Receiving

DSS
MAY 1 2015

04-23-15
04-23-15

APR 30 2015
The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) & Hyland's Baby Teething Gel (TGEL) but no lot numbers, 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 two-hundred seventeen (217) Adverse Events (AE) which also included fifty-one (51) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). There were nine (9) Adverse Events (AE) and only one (1) of them as elevated to an SAE for they Hyland's Teething Gel. 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 and TGEL lot numbers cannot be determined Standard Homeopathic Company does submit all Baby Teething 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 500 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 _______ 4/16/15

DSS
MAY 1 2015
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

SECTION III: CORRECTIVE ACTION:

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

SECTION IV:

REVIEWED BY MANAGEMENT BY: \\
DATE: 04-23-15 \\
BY: QA/DC DIRECTOR \\
DATE: 04-23-15
**Individual Case Safety Report**

**Product Name:** CTU

**Manufacturer Name:** May - 4 2015

**Date of Event:** 05/01/2015

**Event Described:**

- **Brand Name:** CTU
- **Common Device Name:**
- **Manufacturer Name, City and State:**

**Model #**

**Lot #**

**Operator of Device**

- **Health Professional**
- **Lay User/Patient**
- **Other:**

**If Implanted, Give Date:**

**If Expiplanted, Give Date:**

**Is this a Single-use Device that was Reprocessed and Reused on a Patient?**

- **Yes**
- **No**

**Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)**

**Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)**

**Adverse Event, Product Problem or Error**

- **Outcome Attributed to Adverse Event:**
  - Death
  - Life-threatening
  - Disability or Permanent Damage
  - Congenital Anomaly/Birth Defect
  - Other Serious (Important Medical Event)
  - Required Intervention to Prevent Permanent Impairment/Damage (Devices)

**Date of Event:** 05/01/2015

**Date of this Report:** 05/01/2015

**Product Name and Therapy Dates (Excluding treatment of event)**

**Other (Concomitant) Medical Products**

**Reporter**

**Name and Address:**

**State:**

**ZIP:**

**Health Professional?**

- **Yes**
- **No**

**Also Reported To:**

- **Manufacturer**
- **User Facility**
- **Distributor/Importer**

**Dose or Amount**

- **#1** 2-3 tablets 4x a day
- **#2**

**Frequency**

- **Three times daily**

**Route**

- Taken by mouth

**Event Abated After Use Stopped or Dose Reduced?**

- **Yes**
- **No**
- **Doesn't Apply**

**Diagnosis or Reason for Use (Indication)**

- **#1** Teaching

**Lot #**

- **#1** A24314
- **#2**

**Expiration Date**

- **#1**

**NDC # or Unique ID**

- **A24314**

**PLEASE TYPE OR USE BLACK INK**

**Form FDA 3500 (1/09)**
8.5. Describe Event or Problem (continued)

Hylands teething tablets. Noticed irritability, constipation, flushing from belladonna ingredient.
Race: White

Medical Conditions:

Allergies: Pollen

Important Information:
Gave baby Hyland's Teething Tablets and he seemed to have side effects (slowed breathing, seizure-like shaking, and would stare off into space for a little bit). Only used them as needed (probably gave him about 10-16 tablets total). Ever since I stopped giving him the tablets, the symptoms subsided.

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

n/a

E.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: n/a

Allergies: n/a

Important Information: n/a

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

RX Meds: n/a

OTC Meds: n/a
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION

1. Patient Identifier (on back)
   - Age at Time of Event: 1 1/2 Years
   - Sex: Female
   - 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) 04/06/2014
4. Date of This Report (mm/dd/yyyy) 05/21/2015

5. Describe Event or Problem
   -Mother reported that child had been using the product for a couple of days. On the day of the seizure, the child was given 1 tab couple of hours prior to seizure. Then 1 1/2 - 1 hour prior to the seizure gave second tablet. The seizure lasted 15 minutes and he was transported to children's hospital. He fell over during the seizure, stopped breathing, also vomited and aspirated during the seizure, hit his head when he fell, and eyes rolled back. Child had no fever, but seizure was labeled by doctors as pedi-er seizure.

C. SUSPECT PRODUCT(S)

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

2. Dose, Frequency & Route Used
   - #2 TABS SL BD PRT K2x2DAYS

3. Therapy Dates (if unknown, give duration) (months or best estimate)
   - #1

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

5. Lot #
   - #1
   - #2

6. Exp. Date
   - #1
   - #2

7. Event Abated After Use Stopped or Dose Reduced?
   - Yes
   - No

8. Event Reappeared After Reintroduction?
   - Yes
   - No

9. NDC or Unique ID
   - 54973-2127-3

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 #

5. Operator of Device
   - Health Professional
   - Lay User/Participant
   - 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

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

3. Occupation

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

5. Phone #

6. Email Address

7. Fax #

8. 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.

JUN 05 2015

CDR

JUN 8 2015

JUN 5 2015
## H. DEVICE MANUFACTURERS ONLY

<table>
<thead>
<tr>
<th>1. Type of Reportable Event</th>
<th>2. If Follow-up, What Types?</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></td>
<td>Device Evaluation</td>
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</tbody>
</table>

<table>
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<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 (Attach page to explain why not)</td>
</tr>
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<tr>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
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<tr>
<th>5. Labeled for Single Use?</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
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<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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
</tr>
<tr>
<td>Notification</td>
</tr>
<tr>
<td>Repair</td>
</tr>
<tr>
<td>Inspection</td>
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<tr>
<td>Replace</td>
</tr>
<tr>
<td>Patient Monitoring</td>
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</tbody>
</table>

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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>
</tr>
<tr>
<td>Unknown</td>
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<tr>
<th>9. If action reported to FDA under 21 USC 351(f), list correction/removal reporting number:</th>
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<table>
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<tr>
<th>10. Additional Manufacturer Narrative</th>
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<tr>
<th>11. Corrected Data</th>
</tr>
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</table>

## 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</td>
<td>310-768-0700</td>
</tr>
<tr>
<td>EDYTA FRACKIEWICZ</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Report Source (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign</td>
</tr>
<tr>
<td>Study</td>
</tr>
<tr>
<td>Literature</td>
</tr>
<tr>
<td>Consumer</td>
</tr>
<tr>
<td>Health Professionals</td>
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<tr>
<td>User Facility</td>
</tr>
<tr>
<td>Company Representative</td>
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<tr>
<td>Distributor</td>
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<tr>
<td>Other</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>
<tr>
<td>05/21/2015</td>
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</table>

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<tr>
<th>5. Type of Report (Check all that apply)</th>
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<tbody>
<tr>
<td>5-day</td>
</tr>
<tr>
<td>30-day</td>
</tr>
<tr>
<td>7-day</td>
</tr>
<tr>
<td>Periodic</td>
</tr>
<tr>
<td>10-day</td>
</tr>
<tr>
<td>Initiate</td>
</tr>
<tr>
<td>15-day</td>
</tr>
<tr>
<td>Follow-up #</td>
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<tr>
<th>6. Type of Protocol</th>
</tr>
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<tbody>
<tr>
<td>IND #</td>
</tr>
<tr>
<td>BLA #</td>
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<tr>
<th>7. Type of Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMA/310(k) #</td>
</tr>
<tr>
<td>Combination Product</td>
</tr>
<tr>
<td>Product</td>
</tr>
<tr>
<td>Pre-1938</td>
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<tr>
<td>OTC Product</td>
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</table>

<table>
<thead>
<tr>
<th>8. Manufacturer Report Number</th>
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</thead>
<tbody>
<tr>
<td>54973 AE # 1508</td>
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</tbody>
</table>

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<tr>
<th>9. Adverse Event Term(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEIZURE</td>
</tr>
</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 Office of Management and Budget, Privacy Act and Information Collection Division, Room 1309, 445 Park Avenue, Suite 560, Washington, DC 20503.

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."
CaseID: 1173807

Product: 
Lot No.: NOT PROVIDED

Size: NOT PROVIDED

Reporter: 
Address: N/A
City: N/A
Country: USA
Phone #: N/A
E-mail: N/A

Nature of Complaint:
Mother posted the following comments on Facebook: "DO NOT USE THESE. THESE CAN CAUSE SEIZURES. My son had a seizure while using these and had never had one before he used them. He hasn't had one since he stopped using them. He had only had two tablets that day. No, I can't say for certain that this was the only cause, but I strongly believe it was a contributing factor. We haven't seen the recall on these for several weeks after his seizure but didn't take too long to connect the dots. That was in 2014. The most tablets he had in a day was 4. By the way, I'm very cautious about meds with my children. I spoke with mother on 5/21/15. She reported that she threw away the bottle in 2014. Son never had a seizure in the past, and then had a seizure in April of 2014. Child had no fever, but was labeled by doctors as febrile seizure. Several weeks later she found information about the recall. She had just started using BTET a couple days prior (was using Braheb before then). Brought a new bottle for the child. The seizure lasted 15 minutes and he was transported to children's hospital. He fell over during the seizure, stopped breathing, also vomited and aspirated, hit his head when he fell, and even rolled back. Was given 1 tab couple of hours prior to seizure. Then 1/2 to 1 hour prior to the seizure. Customer did not want a refund.

Product received for inspection: N
Product being returned for inspection: N

Section II: Investigation

Section III: Corrective Action

Corrective Action(s) completed by: 

Section IV: Adverse Event Reports

Adverse Event Serious: Y

Section V:
Reviewed by management by: 
headed by: 

cc: QA/QC, Production, Packaging, Shipping/Receiving
Serious Adverse Event  
SAE-0017-2015

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 forty-three (143) Adverse Events (AE) which also included fifty-two (52) 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 5 ppm.

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

Prepared by

Date 5/26/15
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event
   INFANT
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:
   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)
   05/08/2015
4. Date of This Report (mm/dd/yyyy)
   05/19/2015

5. Describe Event or Problem
   MOTHER SENT AN E-MAIL THAT HER CHILD DEVELOPED BELLADONNA TOXICITY AFTER TAKING 2 TABLETS AND EXHIBITED SYMPTOMS OF WEARING, ALTERED STATE, CRYING, DILATED PUPILS, CONFUSION, STAGGERED WALK WHEN CRAWLING, UNSTEADY WHEN TRYING TO STAND.

Re: receipt
JUN 08 2015

CDR

8. Relevant Tests/Laboratory Data, Including Dates

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

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. UfImporter 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

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: EDYTA FRACKIEWICZ
   - Address: HYLAND'S, INC.
     154 W. 131ST STREET
     LOS ANGELES, CA 90061
   - Email Address: STANDARD@HYLAND.COM

2. Phone Number
   - 310-768-3700

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)
   - 05/18/2015

5. A/INDA #

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. Adverse Event Term(s)
   - BELLADONNA TOX, WRITHING, ALTERED STATE, CRYING, DILATED PUPILS, CONFUSION, STAGGERING, UNSTABILITY

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

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

If action reported to FDA under 21 URS 3804(f), list correction/ removal reporting number:

### DSS

JUN - 9 2015

JUN - 8 2015

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

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

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

PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: NOT PROVIDED
REPORTER: N/A
ADDRESS: N/A
CITY: N/A
STATE: N/A
COUNTRY: USA
ZIP CODE: N/A
PHONE #: NOT PROVIDED
E-MAIL: CUSTOMER SENT THE FOLLOWING E-MAIL: MY BABY SHOWED SYMPTOMS OF BELADONNA TOXICITY AFTER USING TWO OF YOUR TEETHING TABLETS. SHE WAS WRITHING FOR HOURS, IN AN ALTERED STATE, CRYING (WHICH SHE NEVER DOES FOR MORE THAN A FEW SECONDS OR HALF A MINUTE, BUT NOT HOURS), DILATED PUPILS, CONFUSED, STAGGERED PACE WHEN TRYING TO DRAW, AND COULD BARELY HOLD HERSELF UP WHEN TRYING TO STAND. I AM LIVID AND NOW VERY FRIGHTENED THIS COULD HAVE DONE LASTING DAMAGE TO HER. I EXPECT A RESPONSE IMMEDIATELY AND I WILL PURSUE THIS BY OTHER MEANS AS WELL. NO BABY OR CHILD SHOULD GO THROUGH THIS. EVER. THIS SHOULD NOT BE ON THE MARKET AND THIS COMPANY SHOULD BE BANNED FROM PRODUCING ANYTHING.

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: 
UPS CALL TAG ISSUED: Y
DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/18/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDEYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: 
DATE: 

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y
ADVERSE EVENT REPORTED ON: 05/18/2015
ADVERSE EVENT REPORTED BY: EDEYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: 
DATE: 05-21-15
BY: 
DATE: 05-21-15

cc: QA / QC Packaging Production Shipping / Receiving

DSS
JUN - 9 2015
AE #: 1607

JUN - 8 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 forty-two (142) Adverse Events (AE) which also included fifty-one (51) 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 Clostridium botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of 500 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**

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at Time of Event: 4 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date of Birth:</td>
</tr>
</tbody>
</table>

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. Adverse Event yes  
   Product Problem (e.g., defects, malfunctions) no

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 (check other serious)
   - Other Serious (check significant medical events)
   - Required intervention to prevent permanent impairment/damage (check other)

3. Date of Event (mm/dd/yyyy): 05/21/2015
4. Date of this Report (mm/dd/yyyy):

5. Describe Event or Problem
   MOTHER POSTED (06/02/2015) THAT SON HAD A FEW SEIZURES WITHIN A 24 HOUR PERIOD AFTER USING THE TABLETS. SEIZURES RESOLVED AFTER TABLETS WERE DISCONTINUED.

---

**C. SUSPECT PRODUCT(S)**

1. Name (Give tablet strength & manufacturer):
   - MYLAND’S BABY TEETHING TABLETS

2. Dosage, Frequency & Route Used:
   - Unknown

3. Therapy Dates (If unknown, give duration):
   - 06/02/2015

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

---

**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):

---

**E. INITIAL REPORTER**

1. Name and Address:
2. Health Professional? Yes  
   Occupation: NA
3. Initial Reporter Also Sent Report to FDA: 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.

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**USA JUN 10**

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**JUN - 9 2015**
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 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:

   [ ] Additional Manufacturer Narrative
   [ ] Corrected Data

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   Name: EDOYA FRANKIEWICZ
   Address: HYLAND'S, INC.
   154 W. 131ST STREET
   LOS ANGELES, CA 90061
   Email Address: STANDARDS@HYLANDS.COM

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)
   05/21/2015

5. (A)NDA #
   IND #
   BLA #
   PMA/510(k) #

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 # 1609

9. Adverse Event Term(s)
   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 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
PRAStart@OIRA.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.

JUN 10 2015
COMPANY: HOMEOPATHIC
MADE IN THE USA SINCE 1983

SECTION II: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 05/21/2015
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET
SIZE: N/A
LOT NO.: N/A
REPORTER: N/A

Individual Case Safety Report

PHONE #: N/A
E-MAIL: N/A

STATE: N/A
ZIP CODE: N/A

NATURAL COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON (3) (5) AND DID NOT RESPOND TO REQUEST TO CONTACT HYLAND'S. RIGHT AFTER I USED THESE TABLETS MY SON HAD A SEIZURE HE WAS ONLY 4 MONTHS OLD STOPS THEM AND HE WAS FINE DON'T USE THESE WARNING, NOT SHUR WHAT I CAN REALLY SAY ALL I KNOW IS MY SON WAS TEETHING I PICKED UP THE TEETHING TABLETS AND MY SON HAD A FEW SEIZURES OF THE NEXT 24 HRS.

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: 05/21/2015
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) BY: EDYTA FRACKIEWICZ
ADVERSE EVENT REPORTED ON: 05/21/2015

SECTION V: REVIEWED BY MANAGEMENT BY: 
DATE: 06-01-15
BY: QA / QC DIRECTOR
DATE: 05-29-15

cc: QA / QC Production
Packaging 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 in the last twelve months that there have been one hundred forty-three (143) Adverse Events (AE) which also included fifty-two (52) 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 ≤ 0.000 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.
RSE EVENT DATA FORM

AE #: 1609
COMPLAINT #: 2619

SECTION I: PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VO1)

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: [Signature]
DATE: 06-01-15

BY: [Signature] QA/QC DIRECTOR
DATE: 05-29-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUN - 9 2015
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event:
   or
   11 Months
3. Sex
   □ Female
   □ Male
4. Weight
   lbs
   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)
   05/25/2015
4. Date of This Report (mm/dd/yyyy)
   05/27/2015

5. Describe Event or Problem
   PHARMACIST REPORTS THEY HAVE AN 11 MONTH OLD FEMALE PATIENT THAT IS PRESENTING TO ER WITH BRUISES AND RED SPOTS ON SKIN.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer)
   1. HYLAND'S BABY TEETHING TABLETS
   2. ☐
2. Dose, Frequency & Route Used
   1. UNKNOWN
   2. ☐
3. Therapy Dates (if unknown, give duration)
   1. ☐
   2. ☐

D. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Model #
4. Lot #
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
   ☐
10. Device Available for Evaluation? (Do not send to FDA)
    Yes ☐ No ☑
11. Returned to Manufacturer on: (mm/dd/yyyy)
12. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER
1. Name and 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.
### G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices)**
   - **Name**: BODTA 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. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 05/25/2015

5. **Report in Device**
   - A/NDA #
   - IND #
   - BLA #
   - PMA
   - 510(k) #
   - Combination Product
   - Pre-1938
   - OTC Product

6. **Common Event Term(s)**
   - BRUISES AND RED SPOTS ON SKIN

7. **Device Manufacturers Only**
   1. **Type of Reportable Event**
      - [ ] Death
      - [ ] Serious Injury
      - [ ] Malfunction
      - [ ] Other:
   2. **Device Evaluate by Manufacturer?**
      - [ ] Yes
      - [ ] No
      - [ ] Other:
   3. **Device Manufacture Date**
      - [ ] (mm/dd/yyyy)

8. **Device Problem and Evaluation Codes**
   - Patient Code
   - Device Code
   - Method
   - Results
   - Conclusion
   - If Remedial Action Initiated, Check Type
     - [ ] Recall
     - [ ] Notification
     - [ ] Repair
     - [ ] Inspection
     - [ ] Replace
     - [ ] Patient Monitoring
     - [ ] Relabeling
     - [ ] Modification/Adjustment
     - [ ] Other:

9. **If action reported to FDA under 21 USC 380(f), list collection/removal reporting number:**

### DSS

**JUN 10 2015**

**JUN 9 2015**

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAAffirmations@hsd.gov
Please DO NOT RETURN this form to the above PRA Staff email address.
SECTION I: COMPLAINT

COMPLAINT #: 2622
TAKEN BY: (0 (0)
DATE OF COMPLAINT: 05/25/2015
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET
SIZE: NOT PROVIDED
LOT NO.: NOT PROVIDED
REPORTER:
ADDRESS:
CITY: (? (0)
STATE: (0 (0)
COUNTRY: USA
PHONE #: (0 (0)
E-MAIL: N/A

REPORTER IS A PHARMACIST CALLING FROM THE ER DEPT AT (0 (0)
HE REPORTS THEY HAVE AN 11 MONTH OLD FEMALE PATIENT THAT HAS BEEN USING BABY
TEETHING TABS. SHE IS PRESENTING TO ER WITH BRUISING AND RED SPOTS ON SKIN. REPORTER WOULD LIKE TO KNOW IF THERE ARE ANY
INGREDIENTS IN THE PRODUCT ASSOCIATED WITH HEMOLYTIC ANEMIA OR SOME SORT OF THROMBOCYTOPENIA. REPORTER WOULD NOT
PROVIDE ANY FURTHER INFORMATION REGARDING THE CHILD’S SYMPTOMS, HISTORY, OR USE OF THE PRODUCT. HE WILL ASK THE FAMILY TO
CALL BACK TO PROVIDE ADDITIONAL INFORMATION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

SECTION III: CORRECTIVE ACTION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/25/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS Y / N
ADVERSE EVENT REPORTED ON: 05/25/2015
BY: (0 (0)

SECTION V:

REVIEWED BY MANAGEMENT BY: Eric Baum
BY: QA/QC DIRECTOR

oc: QA/QC
Packaging
Production
Shipping / Receiving

JUN - 9 2015

DSS JUN 10 2015
AE #: 1612

DATE: 06-01-15
DATE: 05-29-15
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 forty-seven (147) Adverse Events (AE) which also included fifty-six (56) 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 ≤0.0 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.
AE #: 1612  COMPLAINT #: 2622

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

NAME: UNKNOWN
ADDRESS: 
CITY: 
COUNTRY: USA
PHONE #: (b)(6)
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: 06-01-15
BY: QA/QC DIRECTOR
DATE: 05-29-15

FORM SA031
JUN - 9 2015
A. PATIENT INFORMATION

1. Patient Identifier [ Please Type or use black ink ]
2. Age at Time of Event: 5 Months
3. Sex: Female
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/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): 00/00/0000
4. Date of This Report (mm/dd/yyyy): 05/25/2015

5. Describe Event or Problem
   CHILD DEVELOPED INFANT BOTULISM AND WAS HOSPITALIZED FOR 3 MONTHS.

C. SUSPECT PRODUCT(S)

1. Name (give labeled strength & manufacturer)
   - #1 HYLAND'S BABY TEETHING TABLETS
   - #2 HYLAND'S BABY NIGHTTIME TEETHING TABLETS

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

3. Therapy Dates (if known, give duration)
   - #1 TEMP RELIEF TEETHING PAIN
   - #2 TEMP RELIEF TEETHING

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

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

6. Lot #
   - #1
   - #2

7. Exp. Date
   - #1
   - #2

8. NDC# or Unique ID
   - 54973-3127-3, 54973-3197-1

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. 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. If Yes to Item No. 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
   - [ Please Type or use black ink ]

2. Health Professional
   - Yes
   - No

3. Occupation
   - [ Please Type or use black ink ]

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

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

4. Devices Manufactured 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 386(h), fill correction/removal reporting number:

10. Additional Manufacturer Narrative
    and/or

11. Correct 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: 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)
   - 05/21/2013

5. If IND, Give Protocol #
   - IND #
   - BLA #
   - PMA/610K #

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 # 1611

8. Adverse Event Term(s)
   - INFANT BOTULISM

---

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
databases, 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.”

JUN 9 2015
NATURE OF COMPLAINT:
MOTHER POSTED THE FOLLOWING COMMENTS REGARDING PRODUCT AND IT'S NOT CLEAR WHETHER SHE WAS REFERRING TO THE BABY TEETHING TABLETS OR BABY NIGHTTIME TEETHING TABLETS. SHE DID NOT CONTACT HYLAND'S TO PROVIDE MORE INFORMATION. THEY MADE MY DAUGHTER SICK WITH INFANT BOTULISM AT 5 MONTHS OLD. SHE WAS HOSPITALIZED FOR ALMOST 3 MONTHS. I ALMOST LOST HER. I NO LONGER TRUST THIS BRAND.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) & Hyland's Nighttime Baby Teething Tablets (BTNT) but no lot numbers, 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 forty-seven (147) Adverse Events (AE) which also included fifty-six (56) 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. There have been no other Adverse Events (AE) or Serious Adverse Events reported for the Hyland's Nighttime Baby Teething Tablet lots (BTNT).

Although, the BTET or BTNT lot numbers cannot be determined Standard Homeopathic Company does submit all Baby Teething Tablet and Nighttime Baby Teething Tablets lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been “negative” and the total Atropine and Scopalamine 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.
A. PATIENT INFORMATION
1. Patient Identifier (b) (6)
2. Age at Time of Event: 1 Years
3. Sex:
   - Female
   - Male
4. Weight:
   - lbs
   - kg

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event
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): 05/23/2015
4. Date of This Report (mm/dd/yyyy): 05/26/2015

5. Describe Event or Problem
   THE REPORTER STATED THAT CHILD WAS GIVEN A 2 TABLET DOSE AND THEN WAS GIVEN A SECOND 2 TABLET DOSE "A COUPLE OF HOURS LATER" THEN ABOUT 10 MINUTES AFTER THE SECOND DOSE, THE CHILD BEGAN TO EXHIBIT CONVULSIONS, TURNED BLUE, AND HER EYES WERE ROLLING BACK IN HER HEAD. THE REPORTER STATED THAT THIS "SEIZURE" LASTED FOR ABOUT 30 SECONDS. FOLLOWING THIS EPISODE, THE REPORTER TOOK THE CHILD'S TEMPERATURE AND FOUND THAT SHE HAD A FEVER OF 103 DEGREES FAHRENHEIT. SOME TIME LATER, THE CHILD EXPERIENCED ANOTHER EPISODE SIMILAR TO THE FIRST, THAT LASTED FOR ABOUT ONE MINUTE. CHILD TAKEN TO ER.

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, dysfunction, etc.)
   TEMPERATURE OF 103 DEGREES FAHRENHEIT FOLLOWING 1ST SEIZURE. F/U 05/24/15: FEVER HAS NOT EXCEEDED 101 DEGREES FAHRENHEIT.

C. SUSPECT PRODUCT(S)
1. Name (Give brand name & manufacturer):
   • HYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used
   • 2 TABS EVERY TWO HRS X2
3. Therapy Dates (If unknown, give duration)
   • From/to (for best estimate)
   •
4. Diagnosis for Use (Indication)
   • TEMP RELIEF TEETHING PAIN
5. Event Altered After Use Stopped or Dose Reduced?
   • Yes
6. Lot #
7. Expiration Date

CDR
JUN 09 2015

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
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 (Exclude treatment of event)

DSS
JUN 10 2015

E. INITIAL REPORTER
1. Name and Address
2. Health Professional?
   • Yes
3. Occupation
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.
Individual Case Safety Report

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 Evaluation 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 Remedial Action Initiated, Check Type
   - Recall
   - Notification
   - Inspection
   - Replacement
   - Monitoring
   - Other:

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

9. If action reported to FDA under 21 USC 380(k), list correction/removal reporting number:

DSS
JUN 10 2015

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
   - (Check all that apply)
     - Foreign
     - Study
     - Literature
     - Consumer
     - Health Professional
     - User Facility
     - Company Representative
     - Distributor
     - Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 05/23/2015

5. Type of Protocol
   - Combination Product
   - Pre-1935
   - OTC Product

6. Manufacturer Number
   - 54973 AE # 1610

7. Adverse Event Term(s)
   - SEIZURE, FEVER

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 45 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@fdasc.fda.gov

OMR 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

COMPLAINT #: 2802

TAKEN BY: LILIANA GLUBISZ

DATE OF COMPLAINT: 05/23/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: 123

LOT NO.: 123053

REPORTER: N/A

ADDRESS: N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A


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: N

DATE: 05/23/2015

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: LILIANA GLUBISZ

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/23/2015

SECTION V: REVIEWED BY MANAGEMENT BY:

BY: QA / QC DIRECTOR

DATE: 06-01-15

DATE: 05-29-15

JUN 10 2015
THE REPORTER STATED THAT THE CHILD HAS NEVER EXPERIENCED ANYTHING LIKE THIS BEFORE. HE STATED THAT SHE HAS NO KNOWN ALLERGIES.

THE REPORTER ASKED WHAT THE HALF LIFE WAS FOR BELLADONNA. HE STATED THAT HE WANTED TO KNOW THE MANUFACTURING DATE OF HIS LOT NUMBER TO MAKE SURE THAT THE TABLETS WERE NOT RECALLED. WHEN ASKED, HE STATED THAT THE CALCAREA CARBONICA ACTIVE INGREDIENT WAS LISTED AS A 6X POTENCY. HE STATED THAT IT WOULD BE OKAY TO CONTACT HIM TOMORROW.

E/A 05/24/2015 WITH THE REPORTER'S WIFE. SHE STATED THAT THE CHILD IS IMPROVING TODAY AND THAT HER FEVER HAS NOT GONE HIGHER THAN 101 DEGREES FAHRENHEIT TODAY. SHE STATED THAT THE ER DOCTOR DID NOT RECOMMEND TRANSFERRING THE CHILD TO A CHILDREN'S HOSPITAL AS THE CHILDREN'S FACILITY WAS LOCATED AN HOUR AWAY AND THE DOCTOR FELT THAT THE SITUATION WAS NO LONGER EMERGENT AS THE SEIZURES HAD ALREADY OCCURRED. SHE STATED THAT THE CHILD WAS NOT ADMITTED TO THE HOSPITAL. SHE STATED THAT THE CHILD'S FEVER YESTERDAY WAS ASSOCIATED WITH TEETHING. SHE STATED THAT THERE WAS SPECULATION BY THE ER DOCTOR THAT THE "BABY TEETHING TABLETS" COULD HAVE CAUSED THE LOW-GRADE FEVER TO SPIKE, WHICH MAY HAVE PROMPTED THE SEIZURES. SHE STATED THAT THE ER DOCTOR VERIFIED THAT THE CHILD EXPERIENCED TWO SEIZURES AND STATED THAT THEY COULD BE FEBRILE SEIZURES. I RECOMMENDED THAT THEY DISCONTINUE USING THE "BABY TEETHING TABLETS" AT THIS TIME AND THAT THEY CONTACT ME OR THE COMPANY IF THEY HAVE ANY OTHER QUESTIONS. I ALSO OFFERED HER A REFUND, WHICH SHE SAID WOULD NOT BE NECESSARY.

Individual Case Safety Report

11178851-01-00-04

DSS
JUN 10 2015

JUN - 9 2015
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET) packets, lot # 123037, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (0) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # 123037 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 # 123037. The Baby Teething bulk lot # 123037 was tested for total Atropine and Scopolamine and the results were within specification of (10) ppm.

Retention Samples:

Retention samples of packets are not kept therefore an inspection of the packet retain 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 complaints have been received for Hyland's Baby Teething Tablets packets lot # 123037. A review of complaints associated with lots manufactured using the same bulk (123037) was conducted and four complaints (CC-0847-2014, CC-0847-2014, CC-0814-2014 & CC-0045-2015) were found. The complaints were reviewed but they do not appear to be 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 # 123037.

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

Prepared by

Date

DSS
JUN 10 2015

CC-0422-2015
AE-0233-2015

JUN 9 2015
RSE EVENT DATA FORM

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

NAME: ________________________________
ADDRESS: ________________________________
CITY: __________________ STATE: (6)(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:

________________________________________________________________________
________________________________________________________________________

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

SECTION IV:

REVIEWED BY MANAGEMENT BY: ________________________________ DATE: ____________
BY: ________________________________ DATE: ____________

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE
FORM FDA 3500A (2/13)

A. PATIENT INFORMATION
1. Patient Identifier (ID): (Assurance and confidentiality)
2. Age at Time of Event: 7 Months
3. Sex: Male
4. Weight: lbs or kg: 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 (Device)

3. Date of Event (mm/dd/yyyy): 05/14/2015
4. Date of This Report (mm/dd/yyyy): 05/28/2015

5. Describe Event or Problem
   CHILD EXPERIENCING SEIZURES WHICH STARTED 2 WEEKS AGO AND HAPPEN EVERY OTHER DAY. DISCONTINUED BABY TEETHING TABLETS 5/27/15 PM. CHILD HAD A SEIZURE 5/28/15 AFTER HE DISCONTINUED THE BABY TEETHING TABLETS.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & form/identifier):
   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used:
   #1: TAB PO BID X 1 MONTH
   #2: TAB PO QID X 1 MONTH

3. Therapy Dates (if known, give duration) (mm/dd/yyyy) or (best estimate):
   #1: 05/01/2015
   #2: 05/01/2015

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

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

6. Lot #:
   #1: A36714
   #2: NA

7. Exp. Date:
   #1: 05/01/2015
   #2: 05/01/2015

8. Multiple Lot Numbers?
   [ ] Yes [ ] No

9. NADC or Unique ID:
   54973-3127-3

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

D. SUSPECT MEDICAL DEVICE
1. Brand Name:
2. Common Device Name:
3. Model Number:
4. Catalog #,
5. Operator of Device:
   [ ] Health Professional
   [ ] Lay User/Patient
   [ ] Other:

6. Serial #,
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):

E. INITIAL REPORTER
1. Name and Address:
   (Assurance and confidentiality)

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.

Received
JUN 11 2015
CDR

(Continue on page 3)

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, pain, pregnancy, smoking and alcohol use, hemorrhage, dysfunctions, etc.):
   FATHER HAS SEIZURE DISORDER AND CONRADICTION. CHILD HAS BEEN HAVING FEVERS NOT EXCEEDING 101 DEGREES FAHR.
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>□ Malfunction</td>
<td>□ Device Evaluation</td>
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<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacture Data (mm/dd/yyyy)</th>
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<tbody>
<tr>
<td>□ Not Returned to Manufacturer</td>
<td></td>
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<tr>
<td>□ Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>No</td>
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<tr>
<td>□ Evaluation Summary Attached</td>
<td>□ Evaluation Summary Attached</td>
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<th>5. Labeled 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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<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
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<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>
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<tr>
<td>□ Relabeling</td>
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<tr>
<td>□ Modifications/Adjustment</td>
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<tr>
<th>8. Usage of Device</th>
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<tbody>
<tr>
<td>□ Initial Use of Device</td>
<td>Calculate/Remove reporting number:</td>
</tr>
<tr>
<td>□ Repair</td>
<td></td>
</tr>
<tr>
<td>□ Replace</td>
<td></td>
</tr>
<tr>
<td>□ Unknown</td>
<td></td>
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</tbody>
</table>

| 9. If action reported to FDA under 21 USC 360(i), list correction/repair 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:

Department of Health and Human Services
Office of Information Management
Paperwork Reduction Act (PRA) Staff
OMB Control Number: 0910-0166
PRAStaff@hs.dhhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

DSS
JUN 12 2015

JUN 11 2015
PRODUCT: BABY TEETHING TABLETS
SIZE: 40 TABS
REPORTER: ((NA))
ADDRESS: ((NA))
CITY: USA
COUNTRY: USA
PHONE #: ((NA))
E-MAIL: N/A

NATURE OF COMPLAINT: GIVES 1 TAB BID X 1 MONTH. SEIZURES STARTED 2 WEEKS AGO AND HAPPEN EVERY OTHER DAY. STOPPED TEETHING TABLETS YESTERDAY. CHILD HAD A SEIZURE TODAY EVEN AFTER HE STOPPED THE TEETHING TABLETS. FATHER HAS SEIZURE DISORDER AND IS ON MEDICATION. FATHER CANNOT DESCRIBE SEIZURES BECAUSE HE IS NOT HOME WHEN THEY HAPPEN AND HAS NOT SEEN ONE AND ONLY HIS WIFE HAS SEEN THEM.

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: N (CIRCLE ONE)
DATE PRODUCT RECEIVED: 

SECTION II: INVESTIGATION
INVESTIGATION: 
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 05/29/2015
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) N
ADVERSE EVENT REPORTED ON: 05/29/2015
BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWS BY MANAGEMENT BY: 
DATE: 06-03-15
BY: QA / QC DIRECTOR
DATE: 06-03-15

cc: QA / QC
Packaging
Production
Shipping / Receiving
Adverse Event
SAE-0023-2015

Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A36714, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (616) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A36714 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 # A36714. The Baby Teething bulk lot # 123037 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. Of the units manufactured one other complaint (CC-0854-2014) has been received for Hyland's Baby Teething Tablets lot # A36714. A search of complaints of products manufactured using the same bulk lot (123037) was also conducted and revealed four complaints (CC-0847-2014, CC-0814-2014, CC-0045-2015 & CC-0422-2015). The complaints were reviewed and although CC-0422-2015 does indicate a similar reaction as indicated in this instance they do not appear to be related are both isolated incidents. 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 # A36714.

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

Prepared by

Date

DSS
JUN 12 2015
AE #: 1614  
COMPLAINT #: 2624

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: 06-03-15

BY: QA/GC DIRECTOR  
DATE: 06-03-15

DISTRIBUTION: FDA  
ADVERSE EVENT FILE

JUN 1 2 2015
likely brief seizure

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)

healthy infant with no other predisposing factors

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

none
Individual Case Safety Report

A. PATIENT INFORMATION
1. [Patient Identifier (10)]
2. Age at Time of Event: [Month]
3. Sex [Female or Male]
4. Weight [lbs or kgs]

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Adverse Event [Check all that apply]
   - Death
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Hospitalization
   - Other Serious (Include Date of Event)

2. Outcomes Attributed to Adverse Event
   - [Death]
   - [Disability or Permanent Damage]
   - [Life-threatening]
   - [Congenital Anomaly/Birth Defect]
   - [Hospitalization]
   - [Other Serious]

3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem
   - [Mother reports on [6/16/2015] that she gave tablets to her baby and baby had seizures that were attributed to fever.

C. SUSPECT PRODUCT(S)
1. Name [Give labeled strength & mfg/product]
   - HYLAND'S BABY TEETHING TABLETS
   - HYLAND'S TEETHING COLD
2. Dose, Frequency & Route Used
   - [UNKNOWN]
3. Therapy Dates (If unknown, give duration)
   - [TEMP RELIEF PAIN]

4. Diagnosis for Use (Indication)
   - [TEMP RELIEF PAIN]
5. Event Abated After Use
   - [Yes] No [NDC or Unique ID]
   - [54973-3127-3; 54973-7504-1]
6. Lot #
7. Exp. Date
8. NDC or Unique ID
   - [54973-3127-3; 54973-7504-1]
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. Lot #
6. Operator of Device
   - [Health Professional]
7. If Implanted, Give Date (mm/dd/yyyy)
8. If Explanted, Give Date (mm/dd/yyyy)
9. Single-use Device that was Reprocessed and Reused on a Patient
   - [Yes] [No]
10. If Yes to Item No. 9, Enter Name and Address of Reprocessor
11. Device Available for Evaluation?
   - [Yes] [No]
   - [Returned to Manufacturer on]
   - [mm/dd/yyyy]
   - [Concomitant Medical Products and Therapy Dates]

E. INITIAL REPORTER
1. Name and Address
   - [Mother reports on [6/16/2015] that she gave tablets to her baby and baby had seizures that were attributed to fever.
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.
**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 Manufacturer Data**
   - [mm/dd/yyyy]
   - [ ] Yes
   - [ ] No

5. **Event Problem and Evaluation Codes**
   - [ ] Patient Code
   - [ ] Device Code
   - [ ] Method
   - [ ] Results
   - [ ] Conclusions

6. **DSS**
   - JUL 9 2015

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(h), list correction/ removal reporting number:**

   - [ ]

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

**G. ALL MANUFACTURERS**

1. **Contact Office (and Manufacturing Site for Devices)**
   - [ ]

2. **Phone Number**
   - [ ]

3. **Report Source**
   - [ ]

4. **Date Received by Manufacturer**
   - [ ]

5. **IND #**
   - [ ]

6. **BLA #**
   - [ ]

7. **Type of Report**
   - [ ]

8. **Manufacturer Report Number**
   - [ ]

9. **Adverse Event Term(s)**
   - [ ]

---

**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**

**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

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING COMMENT ON (8/6) OF HYLAND'S BABY TEETHING TABLETS. I WISH I WOULD HAVE KNOWN ABOUT THE RECALL WHEN IT ACTUALLY HAPPENED, SINCE I GAVE THESE TO MY BABY AND SHE HAD SEIZURES THAT WE ATTRIBUTED TO FEVER.

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: ____________________________

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/18/2015

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

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: EDYTA FRACKIEWICZ DATE: 06/18/2015

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON: ____________________________

SECTION V: REVIEWED BY MANAGEMENT BY:

REVIEWED BY MANAGEMENT BY: ____________________________

FORM # VD1

JUL 9 2015

DSS

QA / QC DIRECTOR

QA / QC

Packaging

Shipping / Receiving

DATE: 06-29-15

DATE: 06-26-15

JUL - 8 2015
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Teething Tablets (BTET) & Hyland's Teething Tablets (TEET) but no lot numbers, 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 fifty-two (152) Adverse Events (AE) which also included fifty-seven (57) Serious Adverse Events (SAE) reported for Hyland's Baby Teething Tablets (BTET). There were ten (10) Adverse Events (AE) and nine (9) of them as elevated to an SAE for they 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.

Although the BTET lot number cannot be determined Standard Homeopathic Company does submit all Baby Teething 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 <10 ppm.

Conclusion:

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

Prepared by

Date 6/26/2015
EVENT DATA FORM

AE #: 1616
COMPLAINT #: 2626

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

NAME: ________________________________
ADDRESS: ____________________________________________
CITY: __________________ 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: 06-29-15
BY: ____________________________ DATE: 06-26-15
QA/QC DIRECTOR
VENT DATA FORM

AE #: 1616
COMPLAINT #: 2626

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

NAME: 
ADDRESS: 
CITY: 
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: __________________________

BY: __________________________ DATE: 06-26-15
QA / QC DIRECTOR

DSS JUL 9 2
A. PATIENT INFORMATION

1. Patient Identifier

2. Age at Time of Event:

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

3. Therapy Dates

4. Diagnosis for Use (Indication)

5. Event Aborted After Use Stopped or Dose Reduced?

6. Lot #

7. Exp. Date

8. NDC# or Unique ID

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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength and manufacturer)

2. Dose, Frequency, Route Used

3. Therapeutic Class

4. Diagnosis for Use (Indication)

5. Event Aborted After Use Stopped or Dose Reduced?

6. Lot #

7. Exp. Date

8. NDC# or Unique ID

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

6. If Implanted, Give Date

7. If Explanted, Give Date

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

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

10. Device Available for Evaluation? (Do not send to FDA)

11. 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

---

CHILD HAD HIGH FEVER OF 103-104 AND DEVELOPED SEIZURES (DESCRIBED AS JERKING, EYES ROLLING BACK, UNABLE TO CRY OR MAKE SOUNDS) 2 HOURS AFTER TAKING OTC TABLETS. HE ALSO HAD SEIZURES THE NEXT NIGHT, AFTER TABLETS WERE STOPPED.

CHILD WAS PRESCRIBED ANTIBIOTICS, MOTIN & TYLENOL BY DOCTOR.

Received

JUL 14 2015

CDR
### DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - [ ] Death
   - [ ] Serious Injury
   - [ ] Malfuction

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 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(k), list correction/ removal reporting number:**

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

11. **Corrected Data**

### 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 (Check all that apply)**
   - [ ] Foreign
   - [ ] Study
   - [ ] Literature
   - [ ] Consumer
   - [ ] Health Professional
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other

4. **Date Received by Manufacturer** (mm/dd/yyyy)
   - 06/22/2015

5. **(A)NDA #**
   - IND #
   - BLA #
   - PMA/510(k) #

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

7. **Manufacturer Report Number**
   - 54973 AE # 1613

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

---

**DSS**

**JUL 15 2015**

**JUL 14 2015**

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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 95 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@gdas.fda.gov

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

SECTION I: COMPLAINT

TAKEN BY: TUTTI GOULD
DATE OF COMPLAINT: 08/22/2015
PRODUCT: BABY TEETHING TABLETS
ITEM CODE: BTET-T49
SIZE: 40 TABS
LOT NO.: B21541
REPORTER: N/A
ADDRESS: N/A
CITY: N/A
STATE: N/A
COUNTRY: USA
ZIP CODE: N/A
PHONE #: (516) 543-5434
E-MAIL: N/A

NATURE OF COMPLAINT: 9 MONTH OLD HAD SEIZURES ON 08/22/2015. HE HAD A FEVER OF 104, AND WAS GIVEN ONE DOSE ONCE OF 2 TABLETS OF BABY TEETHING TABLETS AT 6 PM. AT 8 PM HE EXPERIENCED BACK TO BACK SEIZURES, JERKING AND EYES ROLLING BACK, UNABLE TO CRY OR MAKE SOUNDS. MOTHER TOOK HIM TO THE HOSPITAL AND WHILE DRIVING THERE HE HAD A 5 MINUTE SEIZURE IN THE CAR. AT THE HOSPITAL, SHE DOES NOT REMEMBER IF THEY DID ANY TESTS, BUT HE DID SEE 2 DOCTORS WHO DIAGNOSED IT AS FEBRILE SEIZURES AND PRESCRIBED ANTIBIOTICS, MOTRIN AND TYLENOL. THE NEXT DAY, 08/23/2015, HE AGAIN DEVELOPED SEIZURES IN THE EVENING, HAD A FEVER OF 103-104, AND MOTHER TOOK HIM TO THE HOSPITAL WHERE THEY RECOMMENDED THE SAME TREATMENT: ANTIBIOTICS, MOTRIN AND TYLENOL. THEY SAID IF HE HAS SEIZURES AGAIN, TO TAKE HIM TO THE CHILDREN'S HOSPITAL AS OF YET, THE CHILD HAS NO TEETH, BUT HAS SYMPTOMS OF TEETHING: RUBBING HIS GUMS AND INCREASED SALIVATION. MOTHER HAD GIVEN HIM MOTRIN AND TYLENOL PRIOR TO THIS EVENT WITH NO REACTION.

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: TUTTI GOULD
DATE: JUL 16 2015

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y
ADVERSE EVENT REPORTED ON: 08/22/2015
BY: TUTTI GOULD

SECTION V: REVIEWED BY MANAGEMENT BY:

DATE: 07-01-15

BY: QA/QC DIRECTOR

cc: QA/QC
Packaging
Shipping/Receiving

Form # VD1
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # B21514, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (0) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B21514 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 # B21514. The Baby Teething bulk lot # 123902 was tested for total Atropine and Scopolamine and the results were with in specification of ≤0.05 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-0490-2015) has been received for Hyland's Baby Teething Tablets lot # B21514. 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 # B21514.

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

Prepared by

Date

6/30/2015
AE #: 1618

COMPLAINT #: 2628

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:

DSS

CORRECTIVE ACTION(S) COMPLETED BY: 

DATE: JUL 15 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: 

DATE: 07-01-15

BY: QA/QC DIRECTOR 

DATE: 07-01-15

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SADH
### A. PATIENT INFORMATION

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>(0) (0)</td>
<td>7 Months</td>
<td></td>
<td>lbs</td>
</tr>
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</table>

**In confidence**

### B. ADVERSE EVENT OR PRODUCT PROBLEM

- **Adverse Event**
- **Product Problem**

**Outcomes Attributed to Adverse Event**

<table>
<thead>
<tr>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**Date of Event**

<table>
<thead>
<tr>
<th>mm/dd/yyyy</th>
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<tbody>
<tr>
<td>06/16/2015</td>
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</table>

**Date of This Report**

<table>
<thead>
<tr>
<th>mm/dd/yyyy</th>
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</thead>
<tbody>
<tr>
<td>06/26/2015</td>
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</tbody>
</table>

**Describe Event or Problem**

*ABOUT 10 MINUTES AFTER A DOSE OF BABY TEETHING TABLETS HIS WHOLE BODY WAS TWITCHING (ARMS AND LEGS) WHICH LASTED ABOUT 15 MINUTES. HAPPENED A SECOND TIME THAT SAME DAY AFTER MOTHER GAVE THE TABLETS AGAIN. MOTHER STATED "I WOULDN'T CALL IT A SEIZURE". MOTHER STATES THAT THE TWITCHING WAS NOT AS DRAMATIC OR VIOLENT AS A SEIZURE WOULD BE. SHE STOPPED USING THE TABLETS AND CHILD HAS NOT HAD A TWITCHING EPISODE SINCE.*

### C. SUSPECT PRODUCT(S)

<table>
<thead>
<tr>
<th>1. Name (Give labeled strength &amp; manufacturer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 HYLAND'S BABY TEETHING TABLETS</td>
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</table>

**Dose, Frequency & Route Used**

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</thead>
<tbody>
<tr>
<td>BID</td>
</tr>
</tbody>
</table>

**Therapy Dates (If Unknown, give duration) (mm/dd/yyyy) (or best estimate)**

<table>
<thead>
<tr>
<th>#1</th>
</tr>
</thead>
</table>

**Diagnosis for Use (Indication)**

| TEMP RELIEF TEETHING |

**Event Abated After Use Stopped or Dose Reduced?**

| No |

**Lot #**

| A29915 |

**Exp. Date**

| JUL 15 |

**NDC or Unique ID**

| 54973-3127-1 |

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

### D. SUSPECT MEDICAL DEVICE

**Brand Name**

**Common Device Name**

| 2a. Procedure |

**Manufacturer Name, City and State**

|   |

**Model #**

| Lot # |

**Catalog #**

| Expiration Date (mm/dd/yyyy) |

**Serial #**

<table>
<thead>
<tr>
<th>Operator of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Professional</td>
</tr>
</tbody>
</table>

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

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

**Is this a Single-use Device that was Reprocessed and Reused on a Patient?**

| Yes | No |

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

### E. INITIAL REPORTER

**Name and Address**

| JUL 1 5 2015 |

**Occupation**

| 3. | NA |

**Initial Reporter Also Sent Report to FDA?**

| Yes | No | Link |

**Phone #**

| (0) (0) |

**Email Address**

**IMMUNIZATIONS JUNE 10**
**F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)**

1. Check One
   - User Facility
   - Importer

2. O5/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
   - Nursing Home
   - Ambulatory Surgical Facility
   - Outpatient Treatment Facility
   - 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

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 Remedial 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 351(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: EDYTA FRANKIEWICZ

2. Phone Number
   - 310-768-0700

3. Report Source (Check all that apply)
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional

4. Date Received by Manufacturer (mm/dd/yyyy)
   - 06/26/2015

5. Type of Report (Check all that apply)
   - 5-day
   - 30-day
   - Periodic
   - 10-day
   - Final
   - Follow-up #

6. If IND, Give Protocol #

7. Manufacturer Report Number
   - 54973 AE # 1619

8. Adverse Event Term(s)
   - POSSIBLE SEIZURES

---

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

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

SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 06/26/2015
PRODUCT: BABY TEETHING TABLETS
ITEM CODE: BTET—T135
SIZE: 135 TABS
LOT NO.: A29615
REPORTE: N/A
ADDRESS: N/A
N/A
CITY: N/A
STATE: (5) (6)
COUNTRY: USA
ZIP CODE: N/A
PHONE #: (0) (15)
E-MAIL: N/A

NATURE OF COMPLAINT: MOTHER HAS BEEN GIVING CHILD 3 TABS ON AND OFF SPORADICALLY. GAVE HIM 3 TABS 1.5 WEEKS AGO ABOUT 16 MINUTES AFTER THIS DOSE HIS WHOLE BODY WAS TWITCHING (ARMS AND LEGS) WHICH LASTED ABOUT 15 MINUTES. HAPPENED A SECOND TIME THAT SAME DAY AFTER SHE GAVE THE TABLETS AGAIN. MOTHER STATED "I WOULDN'T CALL IT A SEIZURE". MOTHER STATES THAT THE TWITCHING WAS NOT AS DRAMATIC OR VIOLENT AS A SEIZURE WOULD BE. SHE STOPPED USING THE TABLETS AND HE HAS NOT HAD A TWITCHING EPISODE SINCE. HAD AN IMMUNIZATION ON JUNE 10TH 4.5 DAYS BEFORE GETTING THE TWITCHING. 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 INVESTIGATION REPORT

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS:

ADVERSE EVENT REPORTED ON: 06/26/2015
BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 07-07-15

cc: QA / QC
Production
Shipment / Receiving

Form # V01
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A29815, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the 164(4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A29815 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 # A29815. The Baby Teething bulk lot # 125254 was tested for total Atropine and Scopolamine and the results were within specification of <400 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-0525-2015) has been received for Hyland's Baby Teething Tablets lot # A29815. 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 # A29815.

Manufacture and processing occurred within established procedures to ensure product quality.
**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(identification info)</td>
<td>(age)</td>
<td>(female/male)</td>
<td>(weight in kg)</td>
</tr>
</tbody>
</table>

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

- [ ] Adverse Event and/or [ ] Product Problem (e.g., deficiencies/labeling)

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & manufacturer)
   - [ ] HYLAND'S BABY TEETHING TABLETS

2. Description of Dosage, Frequency & Route Used
   - [ ] UNKOWN

3. Therapy Dates/Period (if known, give duration)
   - [ ] UNKOWN

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

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

6. Lot #
   - [ ] UNKOWN

7. Exp. Date
   - [ ] UNKOWN

8. Event Reappeared After
   - [ ] Yes | [ ] No | [ ] Doesn't Apply

9. NDSS or Unique ID
   - [ ] 54973-3127-3

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 #

5. Operator of Device
   - [ ] Health Professional
   - [ ] Non-Healthcare 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. 9, Enter Name and Address of Reprocessor

**DSS**

**E. INITIAL REPORTER**

1. Name and Address
   - [ ] NA

2. Phone #

3. Initial Reporter Also Sent Report to FDA
   - [ ] Yes | [ ] No | [ ] NA

4. Other Relevant History, Including Pre-existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, nephrotic syndrome, etc.)

**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/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)
    - 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
    - Inpatient 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)

   Name
   EDYTA 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 (Check all that apply)
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Distributor
   - Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
   07/01/2015

5. (A)NDA #

6. IND #

7. BLA #

8. PMA 510(k) #

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

10. Manufacturer Report Number
    54973 AB 1820

11. Adverse Event Term(s)
    BRAIN BLEED, SEIZURES, DEVELOPMENTAL DELAY

**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
   - Reimboring
   - 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 corrections/repairing removal reporting number:

10. Additional Manufacturer Narrative
    and/or

11. Corrected Data

---

**Footer:**

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

Please DO NOT RETURN this form to the above PRA Staff small address.
CUSTOMER COMPLAINT RECORD

SECTION I:  COMPLAINT

TAKEN BY:  EDYTA FRACKIEWICZ  
DATE OF COMPLAINT:  07/01/2015  

PRODUCT:  BABY TEETHING TABLETS  
ITEM CODE:  BTET  

SIZE:  N/A  
LOT NO.:  N/A  

REPORTER:  N/A  
ADDRESS:  N/A  
CITY:  N/A  
STATE:  N/A  
COUNTRY:  USA  
ZIP CODE:  N/A  
PHONE #:  N/A  
E-MAIL:  N/A  

NATURE OF COMPLAINT:  CUSTOMER POSTED THE FOLLOWING ON 8/8: U HYLANDS MY BABY WAS BORN NORMAL UNTIL I GAVE HER UR DAM TEETHING TABLETS, THEN SHE ENDED UP WITH A BLEED IN HER BRAIN AND SEIZURES. I HATE UR COMPANY. U TOOK MY BADIES LIFE FROM HER, SHE WILL NEVER B NORMAL OR DO NORMAL THINGS. SHE IS FOREVER DELAYED, WITH SPEECH, WALKING, PLAYING. I HATE HATE HATE U FOR THIS!!!!

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

Individual Case Safety Report

11279245-01-00-03

SECTION II: INVESTIGATION

INVESTIGATION:  PLEASE SEE ATTACHED INSPECTION REPORT  

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:  DSS  
DATE:  JUL 16 2015  

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS:  Y / N  
BY:  EDYTA FRACKIEWICZ  
ADVERSE EVENT REPORTED ON:  07/01/2015  

SECTION V:

REVIEWED BY MANAGEMENT BY:  DSS  
DATE:  07-09-15  
DATE:  JUL 15 2015

cc: QA / QC  
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 in the last twelve months that there have been one hundred thirty-two (132) Adverse Events (AE) which also included forty-nine (49) 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 lots for atropine, scopolamine and CBOT testing. The results for Clostridium botulinum have been "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.
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:

DSS
JUL 16 2015

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:
REVIEWED BY MANAGEMENT BY: DATE: 07-09-15
BY: DATE: 07-09-15

JUL 15 2015

DISTRIBUTION: FDA AVERSE EVENT FILE FORM SAED1
**A. PATIENT INFORMATION**

1. Patient Identifier (if used) [12345]
2. Age at Time of Event: 8 months
3. Sex: Male
4. Weight: 20 lbs

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. Outcomes Attributed to Adverse Event
   - Death: [Yes/No]
   - Disability or Permanent Damage: [Yes/No]
   - Life-threatening: [Yes/No]
2. Diagnosis (e.g., fever, rashes, diarrhea)
   - [Other Serious/Important Medical Events/Indications]
3. Date of Event (mm/dd/yyyy) 06/30 - 07/01/15
4. Date of This Report (mm/dd/yyyy) 07/08/15

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strengths and manifestations) NYLAND'S BABY TEETHING TABLETS
2. Lot #: [A/B/C]
3. Therapy Dates (If unknown, give duration) 1st: [A/B/C]
4. Diagnosis for Use (Indication) TEMP RELIEF TEETHING PAIN
5. Event Abated After Use Stopped or Dose Reduced? Yes/No
6. Exp. Date [A/B/C]
7. Event Reappeared After Reintroduction? Yes/No

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #: [A/B/C]
5. Catalog #: [A/B/C]
6. Expiration Date (mm/dd/yyyy) [A/B/C]
7. Unique Identifier (UDI) #: [A/B/C]
8. Operator of Device: [Health Professional, Lay User/Patient, Other]
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
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

---

**Received**

**JUL 22 2015**

**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

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 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(4), list corrections/removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

---

**DSS JUL 28 2015**

**Jul 22 2015**

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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.
COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ

PRODUCT: HYLAND'S BABY TEETHING TABLETS

SIZE: 135 TABS

REPORTER: N/A

ADDRESS: N/A

CITY: N/A

COUNTRY: USA

PHONE #: (602)

E-MAIL: N/A

DATE OF COMPLAINT: 07/07/2015

ITEM CODE: BTET—T135

LOT NO.: N/A

NATURE OF COMPLAINT:

MOTHER REPORTS THAT CHILD HAS HAD 5 SEIZURES THAT DOCTORS HAVE ATTRIBUTED TO HYLAND'S BABY TEETHING TABLETS. THE FIRST SEIZURE WAS ON (602) AND WAS DESCRIBED AS TREMBLING, EYES ROLLING BACK, CHOKING ON TONGUE. CHILD HAD A TOTAL OF 5 SEIZURES FROM (602). THE 5TH SEIZURE OCCURRED A FEW MINUTES AFTER A DOSE OF BABY TEETHING TABLETS WAS ON (602) AND SINCE THEN CHILD HAS NOT HAD ANOTHER SEIZURE. DOCTORS AT FIRST DIAGNOSED SEIZURES AS FEBRILE BUT THE CHILD HAD NO FEVER SO THEY CHANGED THE DIAGNOSES TO SEIZURES CAUSED BY BABY TEETHING TABLETS. CHILD WAS HOSPITALIZED FOR 1.5 DAYS FOR OBSERVATION. HAS A CT SCAN AND EEG SCHEDULED AUGUST 12TH. NO VACCINATIONS RECENTLY, NO HISTORY OF HEAD INJURY, AND NO FAMILY HISTORY OF 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:

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:

CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY:

ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y

ADVERSE EVENT REPORTED ON: 07/07/2015

BY: EDYTA FRACKIEWICZ

Individual Case Safety Report

DATE: 07-10-15

JUL 22 2015

DSS

JUL 23 2015

AE #: 1621

07/07/2015

07-10-15

11301071-01-00-03

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 in the last twelve months that there have been one hundred thirty-four (134) Adverse Events (AE) which also included fifty (50) 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 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 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

Date

JUL 28 2015

DSS

JUL 22 2015
AE #: 1021
COMPLAINT #: 2631

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

NAME: [REDACTED]
ADDRESS: 
CITY: 
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:

DSS
JUL 23 2015

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

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

DISTRIBUTION: FDA ADVERSE EVENT FILE
FORM SAMB1
The FD A Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION
1. Patient Identifier: (0) (0)
2. Age at Time of Event or Date of Birth:
   16 Months
3. Sex: 
   ☐ Female
   ☑ Male
4. Weight: 29 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. Outcome(s) Attributed to Adverse Event
   (Check all that apply)
   ☐ Death
   ☐ Disability or Permanent Damage
   ☐ Life-threatening
   ☐ Congenital Anomaly/Hereditary Defect
   ☐ Hospitalization - inpatient prolonged
   ☐ Other Serious Important Medical Events
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
6. Date of Event: (mm/dd/yyyy)
   08/09/2015
7. Date of this Report: (mm/dd/yyyy)
   08/09/2015
8. 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):
   ☑ Hyland's Teething Tablets
   Manufacturer: Hyland's Inc.
2. Name:
   Strength:
   Manufacturer:

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

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.
My name is [Redacted] and I have a 17 month old son by the name of Jack. I am here to tell you my story. After my son’s first birthday, he started growing his teeth. He was teething and his gums were in pain, so I went to Rite-Aid and I purchased Hyland’s Teething Tablets. I started giving them to my son and as needed for a few months. As of [Redacted] my son had a seizure and I called the paramedics and they rushed him to the hospital. They sent us home and on [Redacted] he had 2 more seizures and we were rushed to the hospital again. They gave him a CAT scan and I have EEG and an MRI. He was also admitted and I have all the proof and papers and I also have the same bottle of Hyland’s Teething Tablets that I was giving my son for his teething. Today I searched on Google what can cause seizures in toddlers and it came up that Hyland’s Teething Tablets Causes Seizure. I was so shocked to see that the same teething tablets I was giving my son causes seizures and I immediately looked into what I need to do to get help. Please contact me as soon as possible for further information. Thank you!

My Number is [Redacted] and my email is [Redacted]

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

[Redacted] he was tested for comprehensive metabolic panel, urinalysis, XR chest 1 view, portable, drug screen/tox, CBC component, CLINTEST. As of [Redacted] he was admitted. As of [Redacted] he had an MRI. As of [Redacted] he had an EEG. As of [Redacted] he had an MRI.

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:
Allergies:
Important Information:

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

RX Meds: LEVETIRACETAM KEPRA
OTC Meds:
**A. PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Patient Identifier</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Sex</td>
<td>Female</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td></td>
</tr>
<tr>
<td>Date of Birth</td>
<td></td>
</tr>
</tbody>
</table>

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

- **Adverse Event:** CHILD EXPERIENCED SEIZURE LIKE ACTIVITY WITH POSSIBLE HOSPITALIZATION.
- **Product Problem:**
  - Defects/Deficiencies:
    - Death
    - Disability or Permanent Damage
    - Life-threatening
    - Congenital Anomaly/Birth Defect
    - Hospitalization
    - Other Serious
    - Other (If other, please state)

**C. SUSPECT PRODUCT(S)**

1. **Name:** MILAND’S BABY TEETHING TABLETS
2. **Other (If other, please state):**
3. **Therapy Dates:**
4. **Diagnosis for Use:** TEMP RELIEF TEETHING PAIN
5. **Event Altered After Use:**
6. **Lot #:**
7. **Exp. Date:**
8. **Event Resumed After Reintroduction:**
9. **NDC or Unique ID:** 54973-3127-3
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 #:**
5. **Catalog #:**
6. **Serial #:**
7. **Lot #:**
8. **Expiration Date:**
9. **Operator of Device:**
10. **If Implanted, Give Date:**
11. **If Explanted, Give Date:**
12. **Is this a Single-use Device that was Reprocessed and Reused on a Patient:**
13. **If Yes:**
14. **If No:**
15. **If Yes to Item 13, Enter Name and Address of Reprocessor:**

**E. INITIAL REPORTER**

1. **Name and Address:**
2. **Health Professional:**
3. **Occupation:**
4. **Initial Reporter Also Sent Report to FDA:**

**F. OTHER INFORMATION**

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/yyyy)**

5. **Labeling 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(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: EDETA FRANKIEWICZ
   - Address: HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: STANDARD@HYLANDS.COM

2. **Phone Number**
   - 310-760-0700

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

4. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 07/28/2015

5. **(ANDA #, IND #, BLA #)**
   - PMA/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 # 1623

8. **Adverse Event Term(s)**
   - SEIZURE LIKE ACTIVITY

---

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

ON BABY TEETHING TABLETS FACEBOOK PAGE WAS PROVIDED WITH 2 OTK: 1) YOUR TABLETS CAUSED SEIZURE LIKE ACTIVITY IN GUR.
2) STOP MAKING THESE DANGEROUS PILLS. MY BABY HAS BEEN
CONVERSATION OVER THE PHONE WITH MY KIDS AROUND. IS THERE
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 INSPECTION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:
07/28/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:
EDYTA FRACKIEWICZ

CORRECTIVE ACTION(S) COMPLETED BY: EDYTA FRACKIEWICZ
DATE: 07/28/2015

ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y  N
ADVERSE EVENT REPORTED ON: ____________________________ BY: ____________________________

REVIEWED BY MANAGEMENT BY: ____________________________
DATE: 08-06-15
DATE: 08-05-15

cc: QA/QC Production Packaging 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 twenty-nine (129) Adverse Events (AE) which also included fifty-three (53) 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 lots for atropine, scopolamine and CBOT testing. The results for Clostridium botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤100 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.
SE EVENT DATA FORM

AE #: 1623
COMPLAINT #: 2633

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: 08-06-15

BY: 
QAY QC DIRECTOR

DATE: 08-05-15
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
3. Sex
4. Weight

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. Outcomes Attributed to Adverse Event
   (Check all that apply)
   - Death
   - 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 (Devices)

6. Date of Event (mm/dd/yyyy) 08/14/2015
7. Date of this Report (mm/dd/yyyy) 08/15/2015

8. 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: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name: Teething Tablets
   Strength: Antihistamine
   Manufacturer: Hyland's

2. Name: Teething Tablets
   Strength: Hyland's Teething Tablets
   Manufacturer: Hyland's

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 gave my 5.5 month old son 2 hyland's teething tablets (as directions state) and 20 minutes or so he began throwing up (not baby spitting up, actually vomiting)

8.6. Relevant Tests/Laboratory Data, Including Dates (continued)

8.7. 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: Healthy normal infant boy

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

RX Meds: None
OTC Meds: None at the time, Tylenol infant liquid occasionally
See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

See additional page(s) 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 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:

[mm/dd/yyyy]

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   
   #1: Nighttime Teething Tablets
   Strength:
   Manufacturer: Hyland's Baby

   #2: [Blank]
   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.
We used Hyland's nighttime teething tablets on my 7 month old daughter starting 3/9/2015. She was given 2 tablets each following night before bedtime. That was the only time of day we gave her any pills. On 8/11/15, I noticed her have an episode which lasted approximately 5 minutes where she was repeatedly tilting her head to the right (ear to shoulder) and it appeared involuntary. This happened 4 other times throughout that day, but the morning episode went on for the longest amount of time. I got a video of her having one of her episodes that night.

The following day, 8/12/15, she had 5 episodes throughout the day increasing in duration and her head tilts were getting jerkier and making her torso tilt towards that side. I have a video from that day midday. We saw her pediatrician 8/12/15 to show her the video and see if she had any idea what could be causing it. We didn't think to mention the teething tablets since they were homeopathic and had no warning labels about these adverse effects. On 8/12/15 my daughter got much worse and was having torso and head spasms. I have a video of her having an episode in her high chair where her head and torso collapsed onto the tray and bobbed there. I drove her to Children's Hospital in 2 hours away. The doctors did a CT scan, found nothing wrong, and they admitted her to the neurology wing of the hospital. The next morning 8/13/15 they ran an MRI which came back normal and did an EEG that afternoon. The neurologist filmed my video from 8/12/15 because he said he had never seen anything like this. They discharged her after saying that her symptoms and spasms weren't lining up with any condition 100%. This whole time I hadn't given her any teething tablets because I had forgotten to pack them. She had very few episodes in the hospital. When we arrived home on 8/12/15 I gave her a dose of 2 tablets that night before bed and the next morning she had an episode ten minutes after waking and several more throughout the day. I haven't given her any teething tablets since then and every day she has had less episodes. 8/20/15 and 8/21/15 she had zero head tilts or episodes of spasms. We will be following up with another neurologist, but our pediatrician's office said this could very well be a reaction to the Hyland Nighttime Teething Tablets and to discontinue use of them right now. I called Hyland's and they said they will be conducting testing on her lot. I would be happy to send you all of her videos if you need to see her reactions and how fast her condition worsened.

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

8/12/15-CT Scan came back perfect (0) MRI came back perfect and EEG came back perfect with one possible Rapid Eye Movement

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. Was not premature. Has never been ill.

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

RX Meds: none.

OTC Meds: We just used Hyland's Nighttime Teething Tablets.
### A. PATIENT INFORMATION

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<th>Patient Identifier (0006)</th>
<th>Age at Time of Event or Date of Birth: 3 Months (90 Days)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>☐ Female</td>
<td>17 lb or 8 kg</td>
</tr>
</tbody>
</table>

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
   - ☐ 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) 08/23/2015
4. Date of this Report (mm/dd/yyyy) 08/24/2015

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: (mm/dd/yyyy)

### D. SUSPECT PRODUCT(S)

1. ☐ Name: Hylands teething tablets
2. ☐ Name: 
   - Strength: 
   - Manufacturer: 

### E. SUSPECT MEDICAL DEVICE

1. Brand Name: AUG 25 2015
2. Common Device Name: CTU
3. Manufacturer Name, City and State: 

### 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: 
   - City: 
   - State: 
   - ZIP: 

2. Phone #: (000-0000)
3. E-mail: [Redacted]

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: [Redacted]
After taking Hylands teething tablets my 8 month old was extremely agitated and had involuntary twitching of her legs and abdomen. She seemed extremely uncomfortable for hours after having consumed them for the first time. I googled side effects and found the FDA warning for belladonna I was previously unaware of and wanted to report the issues we experienced.

8.6. Relevant Tests/Laboratory Data, Including Dates  (continued)

8.7. 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:

P. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)  (continued)
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 21 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:
1. Adverse Event □ Product Problem (e.g., defects/malfunctions)
2. 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]: 08/21/2015
4. Date of this Report [mm/dd/yyyy]: 09/03/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, including Dates

See additional page(s) 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 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)

□ Name: Hyland’s Teething Tablets
□ Strength: 2-3 tablets
□ Manufacturer: Hyland Inc

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.
My baby is now 10 months old and I used the Hyland's Teething Tablets on him for approximately 7-8 days in which during that time, he began to suffer from what began as increasing eye blinks/winking to eye fluttering which turned into full blown eye twitching/spasms which was happening at least every 10-15 minutes throughout the day. Sometimes it occurred more often and often there would be several occurrences at once. I sought out help from his pediatrician who advised to stop the use of the teething tablets. It took about 2 days without any teething tablets and the extent of the twitching began to decrease as well as the frequency. It has been approximately 6 days now without the teething tablets and we were only seeing 2-3 brief twitches throughout the day. As of mid day today as I write this, there have been no twitches. When this first occurred, there were NO other changes in routine, no new foods introduced, no other types of medications, nothing else that we can correlate with the start time of the twitching and nothing else has changed in his or our lifestyle to explain the decrease in the twitching other than the stopping of the use of the tablets. There was also an instance at approximately 3-4 months of age when I used the teething tablets and he experienced body twitching which I did not correlate with the teething tablets until now because that also stopped when he was not taking the tablets. At this time we are unsure if there is any other damage.

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

None yet at this 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: none

Allergies: none

Important Information: none

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

RX Meds: none

OTC Meds: currently-none, previously used Tylenol-prn
**A. PATIENT INFORMATION**

<table>
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<tbody>
<tr>
<td>010000</td>
<td>CHILD</td>
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</table>

**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)
   - 08/06/2015

4. **Date of This Report** (mm/dd/yyyy)
   - 08/20/2015

5. **Describe Event or Problem**
   - CHILD HAS SEIZURES AFTER USING THE PRODUCT.

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & ndls/labeler)
   - #1 HYLAND'S BABY TEETHING TABLETS

2. **Dose, Frequency & Route Used**
   - #1
   - #2

3. **Therapy Dates** (If unknown, give duration or best estimate)
   - #1
   - #2

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

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

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)

**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

7. **Catalog #**

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

9. **Serial #**

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

11. **If Explanted, 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. 8, Enter Name and Address of Reprocessor**

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

15. **Returned to Manufacturer on:**
   - (mm/dd/yyyy)

16. **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
   - NA
CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S E-MAIL: MY SONS HAVE BEEN USING THESE TABLETS FOR A WHILE MY OLDEST SON NOW HAS SEIZURES WITHOUT WARNING. HE HAS BEEN TO SEVERAL DOCTORS AND ASKED US TO NAME EVERYTHING HE USES. WHEN I WENT BACK 3 WEEKS LATER, THEY TOLD US AN INGREDIENT YOU USE CAN CAUSE SEIZURES EVENTUALLY LEADING TO THE BRAIN BLEEDING. WHY ARE YOU STILL SELLING THIS PRODUCT? YOU SHOULD INFORM THE PUBLIC OF ITS RISK. I KNOW I AM.

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/17/2015
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: 08/17/2015 BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

BY: QA / QC DIRECTOR

cc: QA / QC Packaging
Production Shipping / Receiving

DSS SEP - 8 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-five (135) Adverse Events (AE) which also included forty-nine (49) 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 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

2. Age at Time of Event: 8 Months

3. Sex: Female

4. Weight:

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): 08/20/15

4. Date of This Report (mm/dd/yyyy): 08/24/15

5. Describe Event or Problem
   CHILD HAVING SYMPTOMS OF HEAD JERKING/DROPPING, TORSO TILTING AND UPPER BODY SPASMS SEVERAL TIMES A DAY.

6. Relevant Tests/Laboratory Data, Including Dates
   CT Scan, MRI, and EEG were normal

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfgr/batch)
   HYLAND'S BABY NIGHTTIME TEETHING TABLETS

2. Dose, Frequency & Route Used
   #1 TABS QHS X 1 WEEK

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

4. Diagnosis for Use (Indication)
   #1 TEMP RELIEF NITE TEETHING PAIN
   #2 N/A

5. Event Aborted After Use
   Stepped or Dose Reduced?
   Yes No

6. Let #
   #831914

7. Exp. Date
   #1
   #2

8. NDC or Unique ID
   54973-3197-1

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 #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
**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
   - No
   (mm/dd/yyyy)

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

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: DOTTA FRACKIEWICZ
   - Address: HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: STANDARD@HYLANDS.COM

2. Phone Number:
   - 310-769-9700

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)
   - 08/21/15

5. A(ANDA) # __________
   - 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 AE # 1650

9. Adverse Event Term(s)
   - SEIZURES

**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. Additional manufacturer Narrative and/or corrected data

10. Additional Manufacturer Narrative

11. Corrected Data

**Department of Health and Human Services**
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASastaff@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."
Please DO NOT RETURN this form to the above PRA Staff email address.
CUSTOMER POSTED THE FOLLOWING ON (08/15):

"WE STARTED USING THE NIGHTTIME TEETHING TABLETS ABOUT 3 WEEKS AGO. MY DAUGHTER HAD "HEAD DROPS" A FEW DAYS AFTER WE STARTED THESE PILLS AND WE TOOK HER TO CHILDREN'S HOSPITAL IN (08/15). THEY SAID HER EPISODES WERE GETTING MORE FREQUENT AND WORSE. THE PEDIATRICIANS AND NEUROLOGISTS DIDN'T KNOW WHAT WAS WRONG AND I HAD FORGOTTEN THAT I HAD BEEN GIVING HER THESE PILLS. I ALSO LEFT THE BOTTLE AT HOME AND SHE GOT SO MUCH BETTER QUICKLY. AFTER WE RETURNED HOME, I DIDN'T GIVE HER THE PILLS AND SHE HASN'T HAD ANY EPISODES IN THE LAST TWO DAYS. I'M WAITING ON A CALL BACK FROM OUR PEDIATRICIAN ABOUT THIS BEING RELATED TO HER UNEXPLAINED CONDITION. BUT THE TIMING OF HER EPISODES AND THE USE OF THIS MEDICATION LINKS UP. WE JUST REALIZED THIS TODAY AFTER ANOTHER MOM ASKED IF WE HAD BEEN USING THESE TABLETS AFTER SEEING OUR VIDEO. I AM VERY CONCERNED AND UPSET ABOUT THIS. SPOKE WITH THE MOTHER THAT SAME DAY. CHILD STARTED HAVING SYMPTOMS OF HEAD JERKING/DROPPING, TORSO TILT AND UPPER BODY SPASMS SEVERAL TIMES A DAY (08/15). CHILD WAS TAKEN TO THE HOSPITAL. NEUROLOGY SAID THAT THEY DON'T KNOW WHAT THE EXACT DIAGNOSIS IS FOR SURE BECAUSE THEY HAVE NEVER SEEN THIS BEFORE BUT GAVE MOTHER A DIAGNOSIS OF BENIGN PAROXYSMAL TORTICOLLIS AND SPASMS SUSPECTED. CHILD HAS HAD FEWER EPISODES. MOTHER HAS READ THAT BELLADONNA CAN CAUSE SPASMS. MOTHER WOULD LIKE TO KNOW HOW TO TEST IF THE TABLETS CAUSED THE SYMPTOMS. MOTHER WANTS A REFUND OF SRP FOR ONE BOTTLE OF BTNT AND ONE BOTTLE OF BTET BECAUSE SHE IS AFRAID TO USE THEM IN HER BABY. SHE IS NOT HAPPY WITH THE PRODUCT."

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:

ADVERSE EVENT FORWARDED 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:

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-31-15

DATE: 08-28-15

QA / QC DIRECTOR

cc: QA / QC
Hey ladies! Here is my update on my baby girl who I took to the hospital a couple of weeks ago for head drops and spasms. We saw a neurologist today and he said she looks perfect. We have gone 5 days with no symptoms now. The neurologist believes that the nighttime testing tablets we had just started giving her caused the seizures. He called them seizures but said they weren't epileptic, that they were likely triggered by the magnesium and/or belladonna in the tablets. We had started giving her the nighttime version about 3 days before her seizures became very obvious and I forgot to bring the bottle to the hospital to give her so she had less seizures up there. I gave her a couple of tablets when we got home that next night and the next day she had more seizures. Then I discontinued use and she had less each day then the day prior and now it's been 5 days seizure free. We didn't even think of those tablets causing any issues because she had the regular ones (not nighttime) several times with no reaction. We really believed that they were completely safe to give her because they were natural. We are relieved it was something that is easy to fix and we appreciate everyone's prayers. I will be contacting the company's legal department to complain and push them to put a warning on them that it could trigger a neurological reaction.

Edited to add: She has had an MRI, EEG, CT scan. All came back perfect. I took her to children's hospital where she was looked after by a team of neurologists and I took her to a separate neurologist who diagnosed her. We have looked into every possible condition or cause and the only thing that is possible or likely is that those tablets caused it. The dr especially believes that due to her timing of getting worse lining up with being on the medication for a couple of days and her getting better and becoming symptom free after stopping use.

[REDACTED]

 Called me today listening to speak with the legal department. She stated that she gave you a report last week about her child having seizures from the nighttime testing tablets. She said that she had gone to the ER and that the ER could not figure out what was wrong. She said the ER took a video and that she posted it on lots of moms groups and that it has 40,000 views in 12 hours. She said she took her child to a neurologist who told her he believes it is from the tablets specifically the mag phos and belladonna. She said that the neurologist says they are non-epileptic seizures since the child had 4 while on EEG and that they did not show up on the EEG. She says she owes a lot of money in hospital bills and that she is not going away. She also said the kids are happy and now is a good time to call. I told her I would have someone in management get back to her by end of business today. She said also said there should be a warning label on the tablets. I asked her phone number and state she was calling from. She said 09/10/15 and phone 09/10/15.

Individual Case Safety Report

11500192-01-00-04

SEP 10 2015

DSS

SEP 11 2015
Individual Case Safety Report

CaseID: 11500192

Device Event

SAE-0039-2015

Product in Inventory:

No (0) units of Hyland's Baby Nighttime Teething Tablets (BTNT), lot # B31914, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (94) units have been distributed.

Review of Records:

The Hyland's Baby Nighttime Teething Tablets (BTNT), lot # B31914, 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 Nighttime Teething Tablets (BTNT), lot # B31914. The Nighttime Baby Teething bulk lot # 125307 was tested for total Atropine and Scopolamine and the results were within specification of ≤(37) 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 and not other complaints for this lot have been reported.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Nighttime Teething Tablets (BTNT), lot # B31914.

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

Prepared by

Date 8/25/2015
The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier (00-00)  
   In confidence

2. Age/Time of Event or Date of Birth:  
   15 Months (06/06)

3. Sex:  
   Female
   Male

4. Weight:  
   29.6 lb

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event  
2. Product Use Error  
3. Problem with Different Manufacturer of Same Medicine

Outcomes Attributed to Adverse Event (Check all that apply)

- Deafness (mm/dd/yyyy)
- Disability or Permanent Damage
- Life-Threatening
- Congenital Malformation/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): 09/10/2015  
Date of this Report (mm/dd/yyyy): 09/14/2015

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 (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   - Name: Hyland Baby teething tablets
     - Manufacturer: Hyland's 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. Operator of Device
   - Health Professional
   - 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)

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
   - Distribution/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:  

DSS SEP 15 2020

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.
On [redacted] my 15 month son had a seizure a hour after taking this product. I gave him two tablets. He was taken to the hospital immediately.

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)

Race: --

Medical Conditions: none

Allergies: none

Important Information:

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)  (continued)
A. PATIENT INFORMATION
1. Patient Identifier (0) (6)
2. Age at Time of Event: CHILD
   Date of Birth: 00/00/0000
3. Sex
   - Female
   - Male
4. Weight
   lbs
   kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Yes Adverse Event and/or Product Problem (e.g., defects or 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/Disability (Devices)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
   09/03/15
5. Describe Event or Problem
   CHILD HAD SEIZURES WHEN THEY TOOK THE TABLETS.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer or other identifier)
   HYLAND'S BABY NIGHTTIME TEETHING TABLETS
2. Dose, Frequency & Route Used
   #2 N/A
3. Therapy Dates (If unknown, give duration)
   - Transits (or best estimate)
   - #1
   - #2
4. Diagnosis for Use (Indication)
   TEMP RELIEF NITE TEETHING PAIN
5. Event Abated After Use Stopped or Dose Reduced?
   - #1 Yes No Doesnt Apply
   - #2 Yes No Doesn't Apply
6. Lot #
7. Exp. Date
   09/03/15
8. Event Reappeared After Reintroduction?
   - #1 Yes No Doesn't Apply
   - #2 Yes No Doesn't Apply
9. NDC# or Unique ID
   54973-3197-1

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, Gave Date (mm/dd/yyyy)
7. IF Implanted, Gave 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
SEP 1 6 2015

E. INITIAL REPORTER
1. Name and Address (8) (6)
2. Health Professional? Yes No
3. Occupation
   - NA
4. Initial Reporter Also Sent Report to FDA
   - Yes No Unk.

SEP 1 5 2015
### 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>Malfunction</td>
<td>Device Evaluation</td>
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</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>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
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<tr>
<td>Evaluation Summary Attached</td>
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<tr>
<td>No</td>
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<tr>
<th>5. Labeled for Single Use?</th>
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<tbody>
<tr>
<td>Yes</td>
<td>No</td>
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</table>

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<thead>
<tr>
<th>6. Event Problem and Evaluation Codes (Refer to coding manual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P - Patient Code</td>
</tr>
<tr>
<td>D - Device Code</td>
</tr>
<tr>
<td>M - Method</td>
</tr>
<tr>
<td>R - Results</td>
</tr>
<tr>
<td>C - Conclusions</td>
</tr>
</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>Reuse</td>
</tr>
<tr>
<td>Repair</td>
<td>Unknown</td>
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<tr>
<td>Replace</td>
<td></td>
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<tr>
<td>Patient Monitoring</td>
<td></td>
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<tr>
<td>Relabelling</td>
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<tr>
<td>Modification/Adjustment</td>
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<tr>
<td>Other</td>
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| 9. If action reported to FDA under 21 USC 360(i), list correction/removal reporting number: | |

<table>
<thead>
<tr>
<th>10. Additional Manufacturer Narrative</th>
<th>11. Corrected Data</th>
</tr>
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<tbody>
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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>
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<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>
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<tr>
<td>Literature</td>
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<td>Other</td>
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<tr>
<th>4. Date Received by Manufacturer (mm/dd/yyyy)</th>
<th>5. (A/NDA #)</th>
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<tbody>
<tr>
<td>08/31/15</td>
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<tr>
<th>6. IF IND, Give Protocol #</th>
<th>7. Type of Report (Check all that apply)</th>
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<td></td>
<td>5-day</td>
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<td></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 # 1637</td>
<td>SEIZURES</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 38 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:
**CaseID: 11516350**

<table>
<thead>
<tr>
<th>TAKEN BY:</th>
<th>EDYTA FRACKIEWICZ</th>
<th>DATE OF COMPLAINT:</th>
<th>08/31/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT:</td>
<td>HYLAND'S BABY NIGHTTIME TEETHING TABLETS</td>
<td>ITEM CODE:</td>
<td>BTNT-T135</td>
</tr>
<tr>
<td>SIZE:</td>
<td>135 TABS</td>
<td>LOT NO.:</td>
<td>N/A</td>
</tr>
<tr>
<td>REPORTER:</td>
<td>(N/A)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADDRESS:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CITY:</td>
<td>N/A</td>
<td>STATE:</td>
<td>N/A</td>
</tr>
<tr>
<td>COUNTRY:</td>
<td>USA</td>
<td>ZIP CODE:</td>
<td>N/A</td>
</tr>
<tr>
<td>PHONE #:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-MAIL:</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NATURE OF COMPLAINT:**
CUSTOMER POSTED THE FOLLOWING ON (B) (E) AND DID NOT RESPOND TO HYLAND'S REQUEST TO CONTACT HYLAND'S. MY SON EX'S CHILD HAD SEIZURES WHEN THEY TOOK THE TEETHING TABS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

<table>
<thead>
<tr>
<th>PRODUCT RECEIVED FOR INSPECTION:</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>(CIRCLE ONE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PRODUCT BEING RETURNED FOR INSPECTION:</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>(CIRCLE ONE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| DATE REQUESTED PRODUCT BE RETURNED:    |     |
| (PLEASE SPECIFY)                      |     |

<table>
<thead>
<tr>
<th>UPS CALL TAG ISSUED:</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>(CIRCLE ONE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| DATE PRODUCT RECEIVED: |     |
| (PLEASE SPECIFY)       |     |

**SECTION II: INVESTIGATION**

INVESTIGATION:
PLEASE SEE ATTACHED INSPECTION REPORT

**SECTION III: CORRECTIVE ACTION**

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

<table>
<thead>
<tr>
<th>DATE:</th>
<th></th>
</tr>
</thead>
</table>

**SECTION IV: ADVERSE EVENT REPORTS**

<table>
<thead>
<tr>
<th>ADVERSE EVENT SERIOUS:</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>(CIRCLE ONE)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADVERSE EVENT REPORTED ON:</th>
<th>08/31/2015</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>BY: EDYTA FRACKIEWICZ</th>
</tr>
</thead>
</table>

**SECTION V:**

REVIEWED BY MANAGEMENT BY:

**DATE:** 09-08-15

<table>
<thead>
<tr>
<th>BY: QA / QC DIRECTOR</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>DATE: 09-08-15</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>oc: QA / QC Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Shipping / Receiving</td>
</tr>
</tbody>
</table>

Form # VD1
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 nine (9) Adverse Events (AE) which also included eight (8) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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 ≤10 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: 9/3/2015
AE #: 1637

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

NAME: UNKNOWN
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: 09-09-15

BY: ___________________________ DATE: 09-08-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE
A. PATIENT INFORMATION
1. Patient Identifier (b)(6)
2. Age at Time of Event: CHILD
3. Sex: Male
4. Weight in lbs: 0
5. Date of Birth: 00/00/0000

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 (Defect)
3. Date of Event (mm/dd/yyyy): 00/00/0000
4. Date of This Report (mm/dd/yyyy): 09/02/15
5. Describe Event or Problem:

REPORTER POSTED ON (b)(6) MOTHER GAVE THE TABLETS TO THE CHILD AND SHORTLY AFTERWARDS HE STARTED VOMITING AND HIS TEMPERATURE ROSE TO 104 DEG FAHRENHEIT. DOCTORS SAW WAX BUILD UP IN HIS EAR, SO THEY LABELED IT AS AN EAR INFECTION, BUT THEY SAW NO ACTUAL INFECTION.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & refill/total):
   - #1 RYLAND'S BABY NIGHTMINE TEETHING TABLETS
   - #2 N/A
2. Dose, Frequency & Route Used
   - #1 UNKNOWN
   - #2 N/A
3. Therapy Dates (If known, give duration) from/to or (best estimate)
   - #1 N/A
   - #2 N/A
4. Diagnosis for Use (Indication)
   - #1 TEP NITE TEETHING PAIN
   - #2 N/A
5. Event Aborted After Use
   - #1 Yes
   - #2 N/A
6. Lot # You Received:
   - #1 NA
   - #2 NA
7. Exp. Date
   - #1 NA
   - #2 NA
8. Event Reappeared After Reintroduction
   - #1 Yes
   - #2 No
9. NDC# or Unique ID
   - #1 54973-2197-1
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. 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?
   - #1 Yes
   - #2 No
10. If Yes to Item No. 8, Enter Name and Address of Reprocessor
11. Device Available for Evaluation? (Do not send to FDA)
   - #1 Yes
   - #2 No
12. Returned to Manufacturer:
   - #1 NA
   - #2 NA
13. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

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

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 NIGHTTIME TEETHING TABLETS
SIZE: 135 TABS
REPORTER: N/A
ADDRESS: N/A
CITY: N/A
COUNTRY: USA
PHONE #: N/A
E-MAIL: N/A

NATURE OF COMPLAINT:
CUSTOMER POSTED THE FOLLOWING POST IN RESPONSE TO A BABY NIGHTTIME TEETHING TABLETS POST AND DID NOT CONTACT HYLAND'S DIRECTLY TO PROVIDE MORE INFORMATION. HAS ANYONE HAD ANY ISSUES WITH HIGH FEVER AFTER THESE TABLETS? I GAVE MY SON TABLETS AND SHORTLY AFTERWARDS HE STARTED VOMITING AND HIS TEMP WENT UP TO 104. THE DOCTOR DOESN'T KNOW WHAT'S WRONG. THEY SAW WAX BUILD UP IN HIS EAR, SO THEY LABELED IT AS AN EAR INFECTION, BUT THEY SAW NO ACTUAL INFECTION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/27/2015
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: 08/27/2015 BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: DATE: 09-09-15

cc: QA / QC
Packaging
Production
Shipping / Receiving

SEP 15 2015
Form # VD1
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 eight (8) Adverse Events (AE) which also included seven (7) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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

9/13/2015
Received
SEP 15 2015

CDR

Submission of a report does not constitute an admission that medical personnel, user facilities, importers, distributors, manufacturers 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
   - [ ] Other:

3. Device Evaluated by Manufacturer?
   - [ ] Not Returned to Manufacturer
   - [ ] NotReturned 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
   - [ ] Repackaged
   - [ ] Other:

9. If action reported to FDA under 21 USC 368(f), list corrections/ removal reporting number:

10. Additional Manufacturer Narrative
    - [ ] Yes
    - [ ] No

11. Corrected Data

---

**G. ALL MANUFACTURERS**

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

2. Phone Number
   - [ ] 310-768-0700

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

4. Data Received by Manufacturer (mm/dd/yyyy)
   - 08/29/15

5. (A)NDA #
   - [ ] IND #
   - [ ] BLA #
   - [ ] PMR #
   - [ ] 510(k) #
   - [ ] Combination Product
   - [ ] Pre-1938
   - [ ] OTC
   - [ ] Initial
   - [ ] Other:

6. If IND, Give Protocol #

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

8. Manufacturer Report Number
   - 54973 AE # 1635

9. Adverse Event Term(s)
   - SEIZURES

---

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, and providing the needed data. 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.
TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 08/29/2015

PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS

ITEM CODE: BTNT-T15

SIZE: 135 TABS

LOT NO.: N/A

REPORTER: (0) (0)

ADDRESS: N/A

CITY: N/A

STATE: N/A

COUNTRY: USA

ZIP CODE: N/A

PHONE #: N/A

E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING POST IN RESPONSE TO A POST ABOUT BABY NIGHTTIME TEETHING TABLETS: THESE HAVE ALSO CAUSED MY DAUGHTER TO HAVE SEIZURES AT 7 MONTHS OLD. WAS HOSPITALIZED AND HAD NUMBERS OF TEST DONE TO HER, YES IT MAY NOT HAVE HAPPENED TO EVERY CHILD BUT IT HAS HAPPENED TO MORE CHILDREN THEN YOU THINK. DO YOU RESEARCH. BUS HERO WHO WANTS TO RIDE IN A AMBULANCE TO THE NEAREST HOSPITAL THAT'S AN HOUR AWAY WITH YOUR CHILD SCREAMING AND YOU CAN'T DO ANYTHING ABOUT IT? OR NUMBERS IT TEST, TO BE TOLD SOMETHING SO NATURAL GAVE MY CHILD SEIZURES?

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 INSPECTION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/29/2015

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: 08/29/2015

SECTION V:

REVIEWED BY MANAGEMENT BY: RW 09-09-15

DATE: 09-08-15

DATE: 09-08-15

OA / QC DIRECTOR

cc: QA / QC

Packaging

Production

Shipping / Receiving

Form # VD1

SEP 1 5 2015
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 seven (7) Adverse Events (AE) which also included six (6) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething lots for atropine, scopolamine 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 35 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.

9/3/2015
Date
EVENT DATA FORM

AE #: 1635

COMPLAINT #: 2645

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: 09-09-15

BY: ____________________________ DATE: 09-08-15

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

CaseID: 11516354
A. PATIENT INFORMATION
1. Patient Identifier (h) (6)
2. Age at Time of Event:
   INFANT
3. Sex
   □ Female
   □ Male
4. Weight
   lbs
   kgs
   Date of Birth:
   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)
   06/03/2015
4. Date of This Report (mm/dd/yyyy)
   08/31/15

5. Describe Event or Problem
   CHILD HAD SEIZURES AROUND THE TIME HE WAS USING THE PRODUCT. THE SEIZURES RESOLVED WHEN THE PRODUCT WAS DISCONTINUED.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer)
   HYLAND'S BABY NIGHTTIME TEETHING TABLETS

   2. Dose, Frequency & Route Used
   3. Therapy Dates (If unknown, give duration)

   4. Diagnosis for Use (Indication)
   5. Event Abated After Use

   6. Lot #
   7. Exp. Date

   8. Event Reappeared After Reintroduction?

   9. NDC# or Unique ID
   54973-3197-1

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

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
   □ NA

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>Field</th>
<th>Details</th>
</tr>
</thead>
</table>
| 1. Type of Reportable Event | - Death  
- Serious Injury  
- Malfunction  
- 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  
- Yes  
- No |
| 4. Device Manufacture Date (mm/dd/yyyy) | - |
| 5. Labeled for Single Use? | - Yes  
- No |
| 6. Event Problem and Evaluation Codes (Refer to coding manual) | - |
| 7. If Remedial Action Initiated, Check Type | - Recall  
- Notification  
- Repair  
- Inspection  
- Replace  
- Patient Monitoring  
- Retaining  
- Modification/Adjustment  
- Other |
| 8. Usage of Device | - Initial Use of Device  
- Reuse  
- Unknown  
- 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

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Contact Office (and Manufacturing Site for Devices)</td>
<td>EDYTA FRACKENBUSCH</td>
</tr>
</tbody>
</table>
| Address | HYLAND'S, INC.  
154 W. 131ST STREET  
LOS ANGELES, CA 90061 |
| Email Address | STANDARD@HYLANDS.COM |
| 4. Date Received by Manufacturer (mm/dd/yyyy) | 08/29/15 |
| 5. (A)NDA # | - |
| IND # | - |
| BLA # | - |
| PMA/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. Adverse Event Term(s) | SEIZURES |
| 9. Manufacturer Report Number | 54973 AE # 1634 |

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@fda.hhs.gov  
Please DO NOT RETURN this form to the above PRA Staff email address.
TAKEN BY: EDYTA FRACKIEWICZ  
PRODUCT: HYLAND'S BABY NIGHTIME TEETHING TABLETS  
SIZE: 135 TABS  
REPORTER: (N/A)  
ADDRESS: N/A  
CITY: N/A  
COUNTRY: USA  
PHONE #: N/A  
E-MAIL: N/A  

COMPLAINT #: 2644  
DATE OF COMPLAINT: 08/29/2015  
ITEM CODE: BTNT-T130  
LOT NO.: N/A  

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING MESSAGE ON (N/A) AND DID NOT CONTACT HYLAND'S TO PROVIDE MORE INFORMATION. I'M ACTUALLY VERY GLAD I CAME ACROSS THIS. A FEW MONTHS BACK I BROUGHT MY SON IN FOR WHAT I THOUGHT WAS SEIZURES. AROUND THAT SAME TIME HE WAS USING THIS SAME PRODUCT AND ONCE WE STOPPED GIVING HIM, EVERYTHING STOPPED AND THERE WAS NO NEED FOR TESTS. HE'S BEEN PERFECTLY FINE EVER SINCE WE STOPPED USING HYLANDS TABLETS. BUT I NEVER THOUGHT THAT THEY COULD BE THE CAUSE.  

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 INSPECTION REPORT.  

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/29/2015  
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: 08/29/2015  
BY: EDYTA FRACKIEWICZ  

SECTION V: REVIEWED BY MANAGEMENT BY: DATE: 09-02-15  
DATE: 09-02-15  

QA / QC DIRECTOR  

cc: QA / QC  
Production  
Packaging  
Shipping / Receiving  

Form # VO1
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 six (6) Adverse Events (AE) which also included five (5) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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 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.
AE #: 1634
COMPLAINT #: 2644

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

NAME: ____________________________
ADDRESS: ____________________________
CITY: __________________ 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: 09-02-15
BY: Eric Rawl DATE: 09-02-15
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SA601

CaseID: 11516357
Received
SEP 1 5 2015
CDR

Customer gave her child the tablets on two occasions and he had two head drops in the day after receiving them.
### G. ALL MANUFACTURERS

<table>
<thead>
<tr>
<th>1. Contact Office (and Manufacturing Site for Devices)</th>
<th>2. Phone Number</th>
<th>3. Report Source (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDITA FRACKIEMICH</td>
<td>310-768-0700</td>
<td>Foreign, Study, Literature, Consumer, Health Professional, User Facility, Company Representative, Distributor, Other:</td>
</tr>
<tr>
<td>HYLAND'S, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>154 W. 131ST STREET</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOS ANGELES, CA 90061</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td><a href="mailto:STANDARD@HYLANDS.COM">STANDARD@HYLANDS.COM</a></td>
<td></td>
</tr>
<tr>
<td>4. Date Received by Manufacturer (mm/dd/yyyy)</td>
<td>08/27/15</td>
<td></td>
</tr>
<tr>
<td>5. (A)NDA #</td>
<td>IND #</td>
<td>BLA #</td>
</tr>
<tr>
<td>6. If IND give Protocol #</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Type of Report (Check all that apply)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-day</td>
<td>30-day</td>
<td>7-day</td>
</tr>
<tr>
<td>8. Manufacturer Report Number [54973 AE # 1633]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Manufacturer Name/Address</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 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, Additional Information, Response to FDA Request, Device Evaluation</td>
</tr>
<tr>
<td>Serious Injury</td>
<td></td>
</tr>
<tr>
<td>Malfunction</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Device Evaluated by Manufacturer?</th>
<th>4. Device Manufacturing Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>Evaluation Summary Attached</td>
</tr>
<tr>
<td>No</td>
<td>Attach page to explain why not or provide code</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>
<th>8. Usage of Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code</td>
<td></td>
</tr>
<tr>
<td>Device Code</td>
<td></td>
</tr>
<tr>
<td>Method</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>Conclusions</td>
<td>Initial Use of Device, Reuse, Unknown</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
<th>9. If action reported to FDA under 21 U.S.C 380(c)(7)(A), list correction/removal reporting number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recall</td>
<td></td>
</tr>
<tr>
<td>Notification</td>
<td></td>
</tr>
<tr>
<td>Repair</td>
<td></td>
</tr>
<tr>
<td>Inspection</td>
<td></td>
</tr>
<tr>
<td>Replace</td>
<td></td>
</tr>
<tr>
<td>Patient Monitoring</td>
<td></td>
</tr>
<tr>
<td>Relabeling</td>
<td></td>
</tr>
<tr>
<td>Modification/Adjustment</td>
<td>Other:</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. Additional Manufacturer Narrative</th>
<th>11. Corrected Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CUSTOMER POSTED THE FOLLOWING TWO MESSAGES ON (6) AND DID NOT CONTACT HYLAND'S TO PROVIDE MORE INFORMATION: POST #1: I HAD GIVEN MY SON THE NIGHT TIME TABLETS ON 2 DIFFERENT OCCASIONS AND HE HAD 2 HEAD DROPS IN THE DAYS AFTER I HAD GIVEN THEM TO HIM. I THOUGHT SOMETHING WAS UP BUT HE DIDN'T DO IT AGAIN AND I DIDN'T USE THE TABLETS AFTER THAT. I REALLY HOPE YOUR LITTLE ONE WILL BE ALRIGHT, THIS SCARES ME SO MUCH. POST #2: I WILL BE FOLLOWING Y'ALL'S STORY. I CAN'T HELP FINANCIALLY BUT I AM ON YOUR SIDE!!! MY SON ONLY TOOK THE TABLETS TWICE BUT HAD THE SAME HEAD DROPS YOUR DAUGHTER HAS. I DIDN'T KNOW WHAT TO THINK AT THE TIME BUT SEEING THIS IT SCARES THE HELL OUT OF ME TO THINK I HAVE HIM SOMETHING THAT DID THAT TO HIM. FOR ADDITIONAL SPACE PLEASE USE reverse OR ATTACH A SEPARATE SHEET.
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 five (5) Adverse Events (AE) which also included four (4) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething 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 10 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)(6)

2. Age at Time of Event: INFANT

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
   - ☐ 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
   MOTHER USED LESS THAN THE RECOMMENDED DOSE AND BABY STARTED SEIZING AND SPASMSING. RESOLVED.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
   #1 HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used

3. Therapy Dates (If unknown, give duration)

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

5. Event Abated After Use Stopped or Dose Reduced?

6. Lot #

7. Exp. Date

8. Event Reappeared After Reintroduction?

9. NDC# or Unique ID
   54973-3127-3

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 #

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

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 (b)(6)

2. Health Professional?
   - ☑ Yes
   - ☐ No

3. Occupation
   NA

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

Received
SEP 15 2015
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**

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
   - 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

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

9. **If action reported to FDA under 21 USC 367(e), 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: 4HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: STANDARDHYLANDS.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)**
   - 08/27/2015

5. **If IND, Give Protocol #**
   - IND #
   - BLA #
   - PMA/S10(s) #
   - 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

7. **Manufacturer Report Number**
   - 54973 AE # 1632

8. **Adverse Event Term(s)**
   - SEIZING, SPASMING

---

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.

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 #: 2642
DATE OF COMPLAINT: 08/27/2015
PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET
LOT NO.: N/A
REPORTER: N/A
ADDRESS: N/A
CITY: N/A
STATE: N/A
COUNTRY: USA
ZIP CODE: N/A
PHONE #: N/A
E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON AND DID NOT CONTACT HYLAND'S BY PHONE:
MY SON IS 3 WHEN HE WAS A BABY AND ONLY A FEW MONTHS OLD AND TEETHING I TRIED HYLANDS TEETHING TABLETS. I DIDN'T EVEN USE THE FULL SUGGESTED DOSE AND MY BABY STARTED SEIZING OR SPASMING. I STOPPED IMMEDIATELY. THEN THE SIDE EFFECTS STOPPED.
FROM THEN ON I ONLY USED FROZEN PACHIERS TO SOOTHE HIS TEETHING. I AM CONVINCED THOSE TABLETS WERE THE CAUSE AS HE IS A PERFECT LITTLE BOY, AND HAS NEVER DONE THAT BEFORE OR AFTER I STOPPED THOSE.

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 INSPECTION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/27/2015
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: 08/27/2015
BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: 
DATE: 09-02-15
DATE: 09-02-15

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

Form # VD1
SEP 15 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-six (136) Adverse Events (AE) which also included fifty (50) 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 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 <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.
SE EVENT DATA FORM

AE #: 1632
COMPLAINT #: 2642

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: ___________________________
A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>1. Patient Identifier</th>
<th>2. Age at Time of Event: 7 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3. Sex</td>
</tr>
<tr>
<td></td>
<td>Female</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: 
- [ ] 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): 04/01/2013

4. Date of This Report (mm/dd/yyyy): 08/26/15

5. Describe Event or Problem

CHILD STOPPED BREATHING, HAD NO PULSE, AND HAD TO BE RESUSCITATED. NO SEQUELAE.

C. SUSPECT PRODUCT(S)

<table>
<thead>
<tr>
<th>1. Name (Give labeled strength &amp; mf/lot/serial #)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYLAND'S BABY NIGHTTIME TEETHING TABLETS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Dose, Frequency &amp; Route Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Therapy Dates (If unknown, give duration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Diagnosis for Use (Indication)</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 TEMP RELIEF NITE TEETHING PAIN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Event Adjusted After Use Stopped or Dose Reduced?</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 Yes No Doesn't Apply</td>
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</table>

<table>
<thead>
<tr>
<th>6. Lot #</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Exp. Date</th>
</tr>
</thead>
<tbody>
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<td>#1</td>
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</tbody>
</table>

9. Lot or Unique ID: 549373-3197-1

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

D. SUSPECT MEDICAL DEVICE

<table>
<thead>
<tr>
<th>1. Brand Name</th>
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<table>
<thead>
<tr>
<th>2. Common Device Name</th>
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</table>

<table>
<thead>
<tr>
<th>3. Manufacturer Name, City and State</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>5. Operator of Device</th>
</tr>
</thead>
</table>

D. SUSPECT MEDICAL DEVICE

<table>
<thead>
<tr>
<th>1. Brand Name</th>
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<thead>
<tr>
<th>5. Operator of Device</th>
</tr>
</thead>
</table>

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

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

E. INITIAL REPORTER

<table>
<thead>
<tr>
<th>1. Name and Address</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>2. Health Professional?</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>4. Initial Reporter Also Sent Report to FDA</th>
</tr>
</thead>
</table>

Received: SEP 1, 2015

CDR
**H. DEVICE MANUFACTURERS ONLY**

<table>
<thead>
<tr>
<th>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>

**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 90051
   - **Email Address:** STANARD@HYLANDS.COM

2. **Phone Number**
   - **310-768-0700**

3. **Report Source**
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - User Facility
   - Company Representative
   - Other:

4. **Date Received by Manufacturer (mm/dd/yyyy)**
   - 08/25/15

5. **A/NODA #**
   - IND #
   - BLA #
   - PMA/ST(0) #

6. **Type of Report**
   - Combination Product
   - Pre-1938
   - OTC Product

7. **Manufacturer Report Number**
   - 54973 AE # 1631

8. **Adverse Event Term(s)**
   - LACK OF VITAL SIGNS

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
PRA/Stamp Accelerate Law.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 POSTED THE FOLLOWING ON (8/6) AND DID NOT CONTACT HYLAND'S BY PHONE TO PROVIDE MORE INFORMATION. MY NIECE USED NIGHT TIME TEETHING TABLETS AND STOPPED BREATHING. THEN PULSE. THEY HAD TO RESUSCITATE HER. SHE IS FINE NOW, BUT THEY NOW STAY AWAY FROM ALL MEDICATIONS WITH HER. SHE IS A YEAR NEXT MONTH. THIS HAPPENED WHEN SHE WAS 7 MONTHS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 08/25/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION

CORRECTIVE ACTION(S) COMPLETED BY: 

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: 

ADVERSE EVENT REPORTED ON: 08/25/2015
BY: EDDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT:

REVIEWED BY MANAGEMENT:

DATE: 

FORM # V01
Product in Inventory:

The reporter only provided the product name, Hyland's Baby Nighttime Teething Tablets (BTNT) 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 four (4) Adverse Events (AE) which also included three (3) Serious Adverse Events (SAE) reported for Hyland's Baby Nighttime Teething Tablets (BTNT). 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 BTNT lot number cannot be determined Standard Homeopathic Company does submit all Baby Nighttime Teething lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulimum 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.
AE #: 1631

COMPLAINT #: 2641

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

NAME: (b)(6)

ADDRESS: 

CITY: 

STATE: 

COUNTRY: 

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: 09-02-15

BY: 

DATE: 09-02-15

QA / QC DIRECTOR

DISTRIBUTION: FDA

ADVERSE EVENT FILE

FORM SAE-H
A. PATIENT INFORMATION
1. Patient Identifier (b) (s) 
2. Age at Time of Event: 
   or 6 Months
3. Sex
   Female
4. Weight
   lbs
   or
   Male
   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 (Devises)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. N/A
6. N/A
7. N/A
8. N/A
9. N/A
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & mfr/labeler)
   HYLAND'S TEETHING TABLETS
2. N/A
3. Therapy Dates (If unknown, give duration)
   from/to (or best estimate)
   DOSE IN 2009
   #1
   #2
   N/A
4. Diagnosis for Use (Indication)
   TEMPEE RELIEF TEETHING PAIN
   #1
   #2
   N/A
5. Event Abated After Use
   Stopped or Does Reduced?
   Yes
   No
   Doesn't Apply
6. Lot #
7. Exp. Date
   #1
   #2
   N/A
8. Event Reappeared After Reintroduction?
   Yes
   No
   Doesn't Apply
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. Operator of Device
   □ Health Professional
   □ User/Patient
   □ Other:
6. Catalog #
7. Expiration Date (mm/dd/yyyy)
8. N/A
9. Serial #
10. Unique Identifier (UDI) #
11. N/A

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
   NA

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

RECEIVED
SEP 15 2015
CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates
   UNKNOW

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

(Continue on page 3)

(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>
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</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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<td></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>
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<tbody>
<tr>
<td>Not Returned to Manufacturer</td>
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<tr>
<td>Yes</td>
<td>Evaluation Summary Attached</td>
</tr>
<tr>
<td>No (Attach page to explain why no) or provide code.</td>
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</tbody>
</table>

<table>
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<tbody>
<tr>
<td>Yes</td>
<td>Patient Code [ ] [ ] [ ]</td>
</tr>
<tr>
<td>No</td>
<td>Device Code [ ] [ ] [ ]</td>
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<tr>
<td></td>
<td>Method [ ] [ ] [ ] [ ]</td>
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<td>Results [ ] [ ] [ ] [ ]</td>
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<td></td>
<td>Conclusions [ ] [ ] [ ]</td>
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</tbody>
</table>

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

| 9. If action reported to FDA under 21 USC 366(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: EDITA FRACKIEMICZ
   - Address: HYLAND'S, INC.
   - 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: GATUNH@HYLAND.COM

2. **Phone Number:** 310-768-0700

3. **Report Source (Check all that apply):**
   - Foreign
   - Study
   - Literature
   - Consumer
   - Health Professional
   - Manufacturer

4. **Date Received by Manufacturer (mm/dd/yyyy):** 09/03/15

5. **(A)NDA #:**
   - IND # [ ] [ ] [ ]
   - BLA # [ ] [ ] [ ]
   - PMA/510(k) # [ ] [ ] [ ]
   - Combination Product [ ] [ ] [ ]
   - Pre-1938 [ ] [ ] [ ]
   - Other: [ ] [ ] [ ]

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 # 1641

9. **Adverse Event Term(s):** STOPPED BREATHING, 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 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
Paperwork Reduction Act (PIRA) Staff
PRASPRAStaff@fda.hhs.gov

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

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."
COMPLAINT #: 2051
DATE OF COMPLAINT: 09/03/2015
PRODUCT: HYLAND'S TEETHING TABLETS
SIZE: N/A
REPORTER: (6) (4)
ADDRESS: N/A
CITY: (6) (6)
COUNTRY: USA
PHONE #: N/A
E-MAIL: N/A
LOT NO.: N/A

NATURE OF COMPLAINT:
THIS NEWS STORY APPEARED ON (6) (6)
ACCORDING TO THE NEWS STORY
MOTHER STATED THAT AFTER GIVING CHILD A DOSE OF TEETHING TABLETS, "HE JUST WAS KIND OF "OFF", NOT REALLY ACTING HIMSELF, SORT OF OUT OF IT, AND THEN HE STARTED VOMITING. HE STARTED TURNING COLORS AND I SAID, HE IS NOT REALLY BREATHING AND WE WERE TRYING TO TALK TO HIM AND HIS EYES WERE ROLLING IN THE BACK OF HIS HEAD. HIS PUPILS WERE LIKE MARBLES, JUST BIG BLACK EYES."
CHILD WAS RUSHED BY AMBULANCE TO A HOSPITAL. "THEY CHECKED HIM OUT AND HE EVENTUALLY WAS OK. THE ER DOCTOR WAS FAMILIAR WITH THE TEETHING TABLETS AND TOLD ME TO DO SOME RESEARCH ON IT AND WHAT HE SAID WAS BELLADONNA IN LATIN WAS BEAUTIFUL LADY AND PEOPLE TOOK SOME OF THAT PLANT TO BE MORE ATTRACTIVE BECAUSE IT WOULD DILATE THEIR PUPIL." 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: 09/03/2015
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: 09/03/2015 BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: 
DATE: 09-11-15
DATE: 09-11-15

cc: QA / QC Packaging Production Shipping / Receiving

Form # V01
CaseID: 11516539
DSS SEP 1 6 2015
SEP 1 5 2015
Serious Adverse Event  
SAE-0050-2015

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 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, 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 nine (9) Adverse Events (AE) which also included eight (8) 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.
EVENT DATA FORM

AE #: 1641
COMPLAINT #: 2651

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

NAME: 
ADDRESS: 
CITY: 
STATE: 
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: SEP 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: 
DATE: 09-11-15

BY: 
DATE: 09-11-15

DISTRIBUTION: FDA
ADVERSE EVENT FILE
A. PATIENT INFORMATION
1. Patient Identifier: (b)(6)
2. Age at Time of Event: 5 Months
3. Sex: Female
4. Weight: lbs
   or Date of Birth: 
In confidence

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. Yes
   Adverse Event
   and/or
   Yes
   Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event
   (Check all that apply)
   Yes
   Death (mm/dd/yyyy)
   Yes
   Disability or Permanent Damage
   Yes
   Life-threatening
   Yes
   Congenital Anomaly/Birth Defect
   Yes
   Hospitalization - initial or prolonged
   Yes
   Other Serious (Important Medical Events)
   Yes
   Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy): 08/26/2015
4. Date of This Report (mm/dd/yyyy): 08/28/2015
09/04/15

5. Describe Event or Problem
REPORTER SENT BY E-MAIL A MESSAGE THAT AFTER GIVING HER CHILD ONE DOSE OF BABY TEETHING TABLETS ON 8/26/15 WITHIN 2 HOURS THE CHILD STOPPED BREATHING. ON 8/26/15 HER MOTHER GAVE THE CHILD ANOTHER DOSE OF BABY TEETHING TABLETS AND SHE HAD 3 SEIZING EPISODES WITHIN 15 MINS. CHILD WAS TAKEN TO THE HOSPITAL. CHILD HAD TESTS BUT DOCTORS COULD NOT DETERMINE CAUSE OF THE EPISODES. ON 09/04/15 FOLLOW UP BY PHONE: TABLETS WERE DISCONTINUED. SYMPTOMS HAVE NOT RETURNED.

C. SUSPECT PRODUCT(S)
1. Name (Give labeled strength & manufacturer): HYLAND'S BABY TEETHING TABLETS
2. N/A

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
   Yes
   Health Professional
   Yes
   Lay User
   Patient
   Yes
   Other

7. If Implanted, Give Date (mm/dd/yyyy)
8. If Explanted, Give Date (mm/dd/yyyy)
(Continue on page 3)

9. Date Received: SEP 15 2015
   CDR

(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.

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

2. Phone # (b)(6)
3. Email Address

4. Initial Reporter Also Sent Report to FDA
   Yes
   No

(Continue on page 3)
### G. ALL MANUFACTURERS

1. **Contact Office (and Manufacturing Site for Devices):**
   - Name: EDITA FRACKIESIUS
   - 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):** 09/02/15

5. **IND #**
   - Type of Report:
     - Check all that apply:
       - 5-day
       - 7-day
       - 10-day
       - Initial
       - Follow-up

6. **Manufacturer Report Number**
   - 5973 AE # 1540
   - STOPPED BREATHING, SEIZURES

7. 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 SENT THE FOLLOWING E-MAIL MESSAGE: I JUST READ YOUR UPDATED RECALL ARTICLE & AS A NEW MOTHER OF A LITTLE GIRL THAT IS NOW MY LIFE, I BEG YOU TO PUT A WARNING LABEL ON YOUR PRODUCT! LAST WEEK I BEGAN GIVING MY ALMOST 5 MONTH OLD YOUR TEETHING TABLETS. ON TUESDAY, I GAVE HER ONE DOSE AND WITHIN 2 HOURS SHE STOPPED BREATHING. ON WEDNESDAY I GAVE HER ANOTHER DOSE AND SHE HAD 3 SEIZING EPISODES WITHIN 15 MIN! WE HAD TO RUSH HER TO THE HOSPITAL. AFTER SEVERAL TESTS, DOCTORS COULD NOT EXPLAIN WHY SHE HAD THE EPISODES. I'M NOT ASKING YOUR COMPANY TO REMOVE THE PRODUCT, AS MANY CHILDREN HAVE TAKEN THE TABLETS WITH NO REACTION. I'M JUST BEGGING TO PUT A WARNING LABEL ON THEM. IN CASE CHILDREN DO HAVE EPISODES, IT WILL CLICK FOR PARENTS TO DISCONTINUE THE USE OF THEM. IMAGINE IF IT WAS YOUR CHILD...

CUSTOMER RESPONDED ON 9/3/2015 WITH THE FOLLOWING INFORMATION: I'M NOT SURE WHERE TO LOCATE THE LOT #. I'M SEEING 2 NUMBERS IN THE BOTTLE, ONE IS DARK BLACK 4435105, ANOTHER ONE READS NDC 54773-3127-1. 09/04/15 F/U BY PHONE. NKA. NO FAMILY HX OF SEIZURES, NO FEVER. NO ILLNESS. SEIZURES HAVE STOPPED WHEN TABLETS WERE STOPPED. DOCTOR COULDN'T FIND A REASON FOR THE SEIZURES. TAKEN TO THE ER AND RELEASED. NO PREEXISTING CONDITIONS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET
Product in Inventory:

No (0) units of Hyland’s Baby Teething Tablets (BTET), lot # A43515, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the 84(0) units have been distributed.

Review of Records:

The Hyland’s Baby Teething Tablets lot # A43515 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 # A43515. The Baby Teething bulk lot # 125412 was tested for total Atropine and Scopolamine and the results were with in 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 three other complaints (CC-0337-2015, CC-0434-2015 & CC-0578-2015) have been received for Hyland’s Baby Teething Tablets lot # A43515. 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 # A43515.

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

Prepared by

Date

DSS
SEP 16 2015

SEP 15 2015
# A. PATIENT INFORMATION

1. **Patient Identifier (b)(6)**
2. **Age at Time of Event:** 5 Months
3. **Sex:**  Male
4. **Weight:** lbs

# B. ADVERSE EVENT OR PRODUCT PROBLEM

8. **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 Event)
   - Required Intervention to Prevent Permanent Impairment/Damage (Device)

9. **Date of Event (mm/dd/yyyy):** 07/14/2015
10. **Date of This Report (mm/dd/yyyy):** 08/04/15

5. **Describe Event or Problem:**

Child started experiencing seizure-like activity following use of baby teething tablets and the symptoms occur one or two times per week. Stopped using the baby teething tablets on 07/14/15, but symptoms are continuing. Episodes look like child is nodding his head and arms curl up to his chest and he shakes them. Doctors are performing tests.

# C. SUSPECT PRODUCT(S)

1. **Name (Give labeled strength & mf/labeler):**
   - #1 Hyland's Baby Teething Tablets
   - #2 N/A

2. **Dose, Frequency & Route Used:**
   - #1 1 tab 3x/day X 3 weeks
   - #2 N/A

3. **Therapy Datas (if unknown, give duration):**
   - #1 No data
   - #2 No data

4. **Diagnosis for Use (Indication):**
   - #1 Temp Relief Teething Pain
   - #2 No data

5. **Event Abated After Use or Disease Reduced?**
   - #1 No
   - #2 Yes

6. **Lot #:** A68015
7. **Exp. Date:** #1
8. **Event Reappeared After Reintroduction?**
   - #1 No
   - #2 No

9. **NDC# or Unique ID:** 54373-3127-1
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. **Catalog #:**
7. **Expiration Date (mm/dd/yyyy):**
8. **Serial #:**
9. **Unique Identifier (UDI #:**

# E. INITIAL REPORTER

1. **Name and Address (b)(6):**
2. **Phone #:**
3. **Email Address:**
4. **Health Professional?**
   - 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.
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

Please DO NOT RETURN this form to the above PRA Staff email address.
TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 135 TABS
REPORTER: 
ADDRESS: 
CITY: 
STATE: 
COUNTRY: USA
PHONE #: 
E-MAIL: 
LOT NO.: A68015

COMPLAINT #: 2648
DATE OF COMPLAINT: 09/01/2015
ITEM CODE: BTET-T136

NATURE OF COMPLAINT:
CUSTOMER SENT THE FOLLOWING E-MAIL: AFTER USING YOUR RECOMMENDED PRODUCT MY SON STARTED HAVING SEIZURE LIKE ACTIVITY AND YOUR PRODUCT IS THE ONLY THING THAT WAS ADDED TO MY SONS DIET AND THESE SEIZURES STARTED JULY 14TH AND HE HAS ABOUT ONE TO TWO A WEEK. I HAVE NO LONGER BEEN USING YOUR PRODUCTS AND I CAN ASSURE YOU I HAVE TOLD EVERYONE AND WILL CONTINUE TO TELL EVERYONE TO NEVER USE YOUR PRODUCTS. MY SON HAS BEEN IN AND OUT OF THE HOSPITAL FOR THIS REOCCURRING ISSUE. YOU CAN FEEL FREE TO CONTACT ME AND I WILL BE CONTACTING A LAWYER TO TAKE LEGAL ACTION AGAINST YOUR COMPANY. ON 9/2/2015 CUSTOMER SENT THE FOLLOWING MESSAGE AND INCLUDED HER PHONE NUMBER: THE NUMBER ON THE BOTTLE SAYS NDC 64973-3127-1 THERE IS ALSO A NUMBER ON THE SIDE OF THE BOTTLE 669016. I SPOKE TO THE CUSTOMER'S HUSBAND ON 9/7/2015. SYMPTOMS DESCRIBED AS SEIZURE LIKE ACTIVITY HAS BEEN TO THE DOCTOR AT (03432) 6789012 AND THEY ARE RUNNING TESTS. STOPPED USING THE BABY TEETHING TABLETS ON JULY 14TH. GIVING 2 TABS BID X 3 WEEKS. EPISODES LOOK LIKE CHILD IS NODDING HIS HEAD AND ARMS CURL UP TO HIS CHEST AND HE SHAKES THEM. I OFFERED A REFUND AND CUSTOMER DECIDED.

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: 09/01/2015
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: 09/01/2015
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY: 
DATE: 09-11-15 

cc: QA / QC Packaging Production Shipping / Receiving Form # VD1
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # A68015, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the sold units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A68015 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 # A68015. The Baby Teething bulk lot # 125644 was tested for total Atropine and Scopolamine and the results were within 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 specifications.

The inspection did not yield any results that may be related to his 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-0612-2015 & CC-0672-2015) have been received for Hyland's Baby Teething Tablets lot # A68015. 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 # A68015.

Manufacture and processing occurred within established procedures to ensure product quality.
AE #: 1638

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

NAME: (b)(6)
ADDRESS:
CITY: 
COUNTRY: 
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: SEP 16 2015

SECTION IV:

REVIEWED BY MANAGEMENT BY: 
DATE: 09-11-15

BY: QA/QC DIRECTOR
DATE: 09-11-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

CaseID: 11516601
Individual Case Safety Report

A. PATIENT INFORMATION
1. Patient Identifier [000] [ ]
   [ ] Age at Time of Event or Date of Birth:
   [ ] 10 Months
   [ ] 3. Sex [ ] Female [ ] Male
   [ ] 4. Weight [ ] 35 lb [ ] kg
   [ ] In confidence

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
(Check all that apply)
[ ] Death (mm/dd/yyyy)
[ ] Disability or Permanent Damage (mm/dd/yyyy)
[ ] Life-threatening (mm/dd/yyyy)
[ ] Congenital Anomaly/Birth Defect (mm/dd/yyyy)
[ ] Hospitalization - initial or prolonged (mm/dd/yyyy)
[ ] Other Serious (important medical events) (mm/dd/yyyy)
[ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices) (mm/dd/yyyy)

3. Date of Event (mm/dd/yyyy) 09/17/2015
4. Date of this Report (mm/dd/yyyy) 09/19/2015

5. Describe Event, Problem or Product Use Error

See additional page(s) 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 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 (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   [ ] Name: Hyland's teething tablets
   [ ] Strength:
   [ ] Manufacturer: Hyland

   [ ] Name:
   [ ] Strength:
   [ ] Manufacturer:

2. SEVENTEEN (17) OF 20

3. Triage and Sequence # 1565.28

4. FDA USE ONLY

5. Event Abated After Use Stopped or Dose Reduced?
   [ ] Yes [ ] No [ ] Doesn't Apply

6. Diagnosis or Reason for Use (Indication)
   #1 [ ] Teething pain

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

See additional page(s) for complete text.

E. SUSPECT MEDICAL DEVICE
1. Brand Name

2. Model Name, City and State

3. Manufacturer Name, City and State

4. Lot #

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

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

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 10 month old son used Hyland's teething tablets, he is experiencing lethargy muscle weakness constipation and skin flushing.

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)

Race: Hispanic/Latino
Medical Conditions:
Allergies:
Important Information:

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)
On (Aug) 3rd at 3:30 am my thirteen month old son had a seizure due to a high fever. Around 1am he woke up with teething pain and I had given him two Hyland's teething tablets to help with the pain, two and a half hours later I had to call 911 where an ambulance came to my home and transported him to the hospital.

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)

Race: White

Medical Conditions:

Allergies:

Important Information:

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

RX Meds:

OTC Meds: Hyland's teething tablets Hyland's Cold medicine ALL STOPPED BEING USED.
A. PATIENT INFORMATION
1. Patient Identifier (b)(6) [ ]
2. Age at Time of Event: 15 Months
3. Sex [ ] Female [ ] Male
   or [ ] Kgs
4. Weight [ ] or [ ] lbs
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
   (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) 9/11/2018
4. Date of This Report (mm/dd/yyyy) 09/15/13

5. Describe Event or Problem
   CHILD RECEIVED A DOSE OF 2 TABLETS AND WITHIN AN HOUR THE CHILD WAS IN THE PLAYPEN SLUMPED OVER HAVING A SEIZURE, FOAM IN HIS MOUTH, CLAMMY, COULD NOT STAND/WEAKNESS. AN AMBULANCE WAS CALLED, CHILD WAS TAKEN TO THE EMERGENCY ROOM AND RELEASED. EPISODE DIAGNOSED AS A SEIZURE BY THE DOCTOR. CUSTOMER HAD USED THE PRODUCT ON TWO PRIOR OCCASIONS WITH NO PROBLEM.

C. SUSPECT PRODUCT(S)
1. Name (Give dosage strength & mfr/labeler)
   #1 HYLAND'S BABY TEETHING TABLETS
   #2 N/A
2. Dose, Frequency & Route Used
   #1
   #2
3. Therapy Dates (If unknown, give duration)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1 TEMPE RELIEF TEETHING PAIN
   #2 N/A
5. Event Abated After Use Stopped or Dose Reduced?
   #1 Yes [ ] No [ ] Doesn't Apply
   #2 Yes [ ] No [ ] Doesn't Apply
6. Lot # #1800215
7. Exp. Date #1
8. Event Reappeared After Reintroduction?
   #1 Yes [ ] No [ ] Doesn't Apply
   #2 Yes [ ] No [ ] Doesn't Apply
9. NDC# or Unique ID 54973-3127-1

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. If Yes to Item No. 9, Enter Name and Address of Reprocessor
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER
1. Name and Address (b)(6)
2. Phone # (b)(6)
3. Occupation NA
4. Initial Report Also Sent 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

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 Manufacturer Data (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(h), 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 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. If you have comments regarding the burden estimate for any other aspect of this collection of information, including suggestions for reducing this burden, please write to the Office of Information and Regulatory Affairs, Department of Health and Human Services, New Executive Building, Room 5134, Washington, DC 20501, or email to bernadine.king@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 #: 2652
DATE OF COMPLAINT: 09/14/2015
ITEM CODE: BTET-T130
LOT NO.: B00215

NATURE OF COMPLAINT:
MOTHER GAVE 2 TABS OF THE PRODUCT AND WITHIN AN HOUR THE CHILD WAS IN THE PLAYPEN SLUMPED OVER HAVING A SEIZURE. FOAM IN HIS MOUTH, CLAMPY, COULDN'T STAND/WEEKNESSES. CALLED AN AMBULANCE, CHILD TAKEN TO THE EMERGENCY ROOM AND RELEASED. NOT ADMITTED TO A HOSPITAL. EPISODE DIAGNOSED AS A SEIZURE BY THE DOCTOR, NO TEMPERATURE. CUSTOMER STATED THAT DOCTOR ATIBUTED THE SEIZURE TO BELLADONNA IN THE BABY TEETHING TABLETS. HAS USED THE MEDICATION 3 TIMES OVER THE COURSE OF 1 1/2 WEEKS. CUSTOMER CALLED AND SPOKE WITH THE FDA TODAY AND FILED A REPORT. CUSTOMER WAS UPSET AND STATED THAT SHE THINKS THAT THE PRODUCT SHOULD BE TAKEN OFF THE MARKET BECAUSE IT IS NOT FDA APPROVED. I OFFERED THE CUSTOMER A REFUND AND SHE STATED THAT SHE WOULD LIKE A REFUND.

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

INVESTIGATION:
PLEASE SEE ATTACHED INVESTIGATION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/14/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y
ADVERSE EVENT REPORTED ON: 09/14/2015
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

BY: QA / QC DIRECTOR

DSS
OCT 06 2015
Product in Inventory:

No (0) units of Hyland's Baby Teething Tablets (BTET), lot # B00215, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the [4] units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # B00215 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 # B00215. The Baby Teething bulk lot # 126373 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 no other complaints have been received for Hyland's Baby Teething Tablets lot # B00215.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Tablets lot # B00215.

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

Prepared by: [Signature]  
Date: 9/22/2015
A. PATIENT INFORMATION

1. Patient Identifier (ID) (e.g., Social Security Number, ID number)
2. Age at Time of Event
   - Date of Birth
3. Sex
   - Male
4. Weight
   - lbs
   - kg

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event
2. Outcome Attributed to Adverse Event
   - Death (mm/dd/yyyy)
   - Disability or Permanent Damage
   - Life-threatening
   - Congenital Anomaly/Birth Defect
   - Hospitalization - Initial or protracted
   - Other Serious (Important Medical Events)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & manufacturer)
   - HYLAND'S BABY TEETHING GEL
2. Drug Frequency & Route Used
   - FREQUENTLY X 2 WEEKS
3. Therapy Dates (If unknown, give duration in years or last estimate)
   - #1
   - #2
4. Diagnosis for Use (Indication)
   - TEMP RELIEF SK PAIN, REDNESS
5. Event Altered After Use Stopped or Dose Reduced?
   - #1
   - #2
6. Lot #
7. Exp Date
8. Event Repeated 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. Lot #
6. Catalog #
7. Expiration Date (mm/dd/yyyy)
8. Operator of Device
   - Health Professional
   - Lay User/Patient
   - Other
9. Serial #
10. Unique Identifier (UID) #
11. If Implanted, Give Date (mm/dd/yyyy)
12. If Implanted, Give Date (mm/dd/yyyy)

E. INITIAL REPORTER

1. Name and Address
2. Health Professional?
3. Occupation
   - Physician
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

<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>
</tr>
<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</td>
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<tr>
<td>□ No</td>
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<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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<td>--------------</td>
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<thead>
<tr>
<th>7. If Remedial Action Initiated, Check Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Recall</td>
</tr>
<tr>
<td>□ Repair</td>
</tr>
<tr>
<td>□ Repeal</td>
</tr>
<tr>
<td>□ Replace</td>
</tr>
<tr>
<td>□ Notification</td>
</tr>
<tr>
<td>□ Inspection</td>
</tr>
<tr>
<td>□ Patient Monitoring</td>
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<tr>
<td>□ Modification/Adjustment</td>
</tr>
<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>□ Repair</td>
</tr>
<tr>
<td>□ Repeal</td>
</tr>
<tr>
<td>□ Replace</td>
</tr>
<tr>
<td>□ Unknown</td>
</tr>
</tbody>
</table>

| 9. If action reported to FDA under 21 USC 367, fill correction/removal reporting number: |

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

<table>
<thead>
<tr>
<th>11. Corrected Data</th>
</tr>
</thead>
</table>

---

### G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices)
   - Name: HYLAND'S, INC.
   - Address: 154 W. 131ST STREET
   - LOS ANGELES, CA 90061
   - Email Address: STANDARDS@HYLANDS.COM

2. Phone Number: 510-768-0700

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)
   - 09/23/2015

5. (A)NDA #
   - IND #
   - BLA#
   - PMA #
   - 510(k) #

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
   - 5-day
   - 7-day
   - 10-day
   - 15-day

8. Manufacturer Report Number
   - 54973 AE 1645

9. Adverse Event Term(s)
   - TONIC CLONIC SEIZURES

---

**OCT - 7 2015**

**OCT - 8 2015**
SECTION I: COMPLAINT

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 09/23/2015
PRODUCT: HYLAND'S BABY TEETHING GEL
ITEM CODE: T9EL-U0.5Z
SIZE: 0.5 OZ.
LOT NO.: 12628
REPORTER: N/A
ADDRESS: N/A
CITY: N/A
STATE: N/A
COUNTRY: USA
ZIP CODE: N/A
PHONE #: N/A
E-MAIL: N/A

NATURE OF COMPLAINT:

DOCTOR STATED THAT A 16 MONTH OLD PATIENT WAS ADMITTED TO THE HOSPITAL FOR SEIZURES THAT DEVELOPED AROUND 1.5 TO 2 WEEKS AGO. WAS ADMITTED AND THEN DISCHARGED HOME AND CONTINUED TO HAVE BREAKTHROUGH SEIZURES. FINALLY HAS STOPPED HAVING SEIZURES DUE TO PHENOBARBITAL USED AS AN ANTICONVULSANT. PARENTS RELATED THAT THEY HAVE BEEN USING THE HYLAND'S BABY TEETHING GEL FREQUENTLY DURING THE TIME THE PATIENT HAS HAD THE SEIZURES. HE HAS NOTED TO THE RECALL WITH THE TEETHING TABLETS AND INTRODUCED TO KNOW IF THERE ARE ANY ABNORMALITIES WITH THE TEETHING GEL. SEIZURE DIAGNOSED AS TONIC CLONIC SEIZURES WITH RIGHT AFFECTING MORE THAN LEFT.

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 ON: 09/23/2015
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: 09/23/2015
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT BY:

REVIEWED BY MANAGEMENT BY: ___________________________ DATE: ________________

BY: ___________________________ DATE: ________________

cc: QA/QC Production Packaging Shipping / Receiving

Form # VD1

DSS OCT - 8 2015

OCT - 7 2015
Product in Inventory:

No units of Hyland's Baby Teething Gel (TGE1), lot #126288, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, 501 units, has been distributed.

Review of Records:

The TGE1 lot #126288 was manufactured using bulk lot #126288. The associated manufacturing and packaging records were reviewed and did not reveal any issues.

The Certificate of Analysis was reviewed and indicated all results, including Micro, were within specification for Hyland's Baby Teething Gel lot #126288. In addition it was tested for Total Atropine and Scopolamine levels and was found to meet the specification of 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 two other complaints (CC-0596-2015 & CC-0701-2015) have been received for Hyland's Baby Teething Gel lot #126288. The complaints were reviewed and they do not appear to be related. SHC will continue to monitor reports for trends.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland's Baby Teething Gel lot #126288.

Manufacture and processing occurred within established procedures to ensure product quality.
AE #: 1645
COMPLAINT #: 2655

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

NAME: UNKNOWN
ADDRESS:
CITY: STATE: 0100
COUNTRY: USA
PHONE #:
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

Teething Gel

DSS
OCT - 8 2015

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

SECTION IV:

REVIEWS BY MANAGEMENT BY: __________________________ DATE: 10-01-15

QA / QC DIRECTOR:

DISTRIBUTION: FDA ADVERSE EVENT FILE
C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/producer)
   #1: HYLAND'S BABY TEETHING TABLETS

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

3. Therapy Dates (if unknown, give duration)
   #1: 

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

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

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

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

DSS OCT - 8 2015

E. INITIAL REPORTER

1. Name and Address

2. Health Professional? 3. Occupation
   □ Yes □ No 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

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)
   - [ ] 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 (mm/dd/yyyy)
    - [ ] No (mm/dd/yyyy)

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

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)
   - Name: EDITA FRANKIEWICZ
   - 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
   - [ ] User Facility
   - [ ] Company Representative
   - [ ] Distributor
   - [ ] Other:

4. Data Received by Manufacturer (mm/dd/yyyy)
   - 09/23/2019

5. IND #
   - [ ] IND #
   - [ ] BLA #
   - [ ] PMA
     - [ ] 510(k) #
     - [ ] Pre-1538
     - [ ] OTC Product
     - [ ] Yes

6. If IND, Give Protocol #

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

8. Manufacturer Report Number
   - 54973 AR # 1646

9. Adverse Event Term(s)
   - SEIZURES

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
   - [ ] Evaluation Summary Attached
   - [ ] No (Attach page to explain why) 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 Remediial Action Initiated, Check Type
   - [ ] Recall
   - [ ] Notification
   - [ ] Repair
   - [ ] Inspection
   - [ ] Replace
   - [ ] Patient Monitoring
   - [ ] Relabeling
   - [ ] Modification/Adjustment
   - [ ] Other:

8. If action reported to FDA under 21 U.S.C. 366(f), list corrective removal reporting number:

9. Additional Manufacturer Narrative
   - [ ] Yes
   - [ ] No

10. [ ] Additional Manufacturer Narrative

11. Corrected Data

DSS
OCT - 8 2015

OCT - 7 2015

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

TAKEN BY: EDYTA FRACKIEWICZ
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: NOT PROVIDED
REPORTER: [Graffiti]
ADDRESS: N/A
CITY: N/A
COUNTRY: USA
PHONE #: [Graffiti]
E-MAIL: [Graffiti]

DATE OF COMPLAINT: 09/23/2015
ITEM CODE: BTET
LOT NO.: NOT PROVIDED

CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S E-MAIL: HELLO, IF THERE IS AN ACTIVE STUDY GOING ON REGARDING THE HYLAND BABY TEETHING TABLETS AND SEIZURES THEN I NEED TO ADVISE YOU OF MY SON. WHEN MY SON WAS 18 MONTHS OLD ON 09/16, HE HAD 3 PROLONGED SEIZURES. I HAD GIVEN HIM SOME OF THE TEETHING TABLETS ON 08/19 AND A FEW DAYS PRECEDING WE WERE IN PICU FOR 2 NIGHTS, 3 DAYS. THERE HASN'T BEEN ANY CAUSE FOR THE SEIZURES FOUND NOR HAS HE HAD ANY RECURRING SEIZURES. PLEASE UPDATE ME ON ANY INFORMATION YOU HAVE REGARDING SEIZURES AND THE TEETHING TABLETS. THANK YOU.

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: [Blank]

DATE PRODUCT RECEIVED: [Blank]

INVESTIGATION

INVESTIGATION:

PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 09/23/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CORRECTIVE ACTION:

INDIVIDUAL CASE SAFETY REPORT

11614940-01-00-03

DATE

DSS OCT - 8 2015

ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y N

ADVERSE EVENT REPORTED ON: 09/23/2015

DATE

REVIEWED BY MANAGEMENT BY:

DATE 10-01-15

BY:

QA / QC DIRECTOR

QA / QC

PACKAGING

SHIPPING / RECEIVING

DATE 10-01-15

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 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 there have been one hundred thirty-six (136) Adverse Events (AE) which also included fifty-one (51) 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 lots for atropine, scopolamine and Clostridium botulinum testing. The total Atropine and Scopolamine levels was found to meet the specification of 50 ppm and Clostridium botulinum testing was negative.

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 #: 1646
COMPLAINT #: 2856

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: OCT - 8 2015

SECTION IV:
REVIEWED BY MANAGEMENT BY: DATE: 10-01-15
BY: QA / QC DIRECTOR DATE: 10-01-15

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM BAG91

OCT - 7 2015
GENERAL INFORMATION

1. Patient Identifier
   [Redacted]

2. Age at time of Event or Date of Birth
   [Redacted]

3. Sex
   Female

4. Weight
   18 lbs

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. 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)

6. Date of Event (mm/dd/yyyy)
   09/27/2015

7. Date of this Report (mm/dd/yyyy)
   10/09/2015

8. Describe Event, Problem or Product Use Error:

   See additional page(s) for complete text.

9. Relevant Tests/Laboratory Data, Including Dates:

   See additional page(s) for complete text.

10. Other Relevant History, Including Pre-existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/fish/every problems, etc.):

   See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

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

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from label)
   #1: Hylands
   Strength: teething tablets and gel
   Manufacturer:

   #2: Hylands
   Strength: [Redacted]
   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.
My 6 month was given both hylands teething tablets and the gel. A few days later she started to display clusters of jerking movements at different times throughout the day. After visiting the emergency, her primary doctor, another primary doctor and calling 911 I finally found a hospital with doctors who knew what my daughter was experiencing. She has been experiencing what is known as infantile spasms or west syndrome.

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

My 6 month old was admitted into the hospital on [unclear]. She was given an EEG and diagnosed with infantile spasms on the morning of [unclear]. Later that day [unclear] she had an MRI which came back normal. It is [unclear] and we are still in the hospital waiting for blood and urine test results.

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: None

Allergies: None

Important Information: None

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

RX Meds: Ibuprofen and ACTH therapy for infantile spasms

OTC Meds: None
A. PATIENT INFORMATION
1. Patient Identifier (O/B) [ ]
2. Age at Time of Event: CHILD
   Date of Birth: [ ]
4. Weight [ ] lbs [ ] kgs
   in confidence

B. ADVERSE EVENT OR PRODUCT PROBLEM
1. [ ] Adverse Event and/or [0] Product Problem (e.g. defect/malfunction)
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) 09/27/2015
4. Date of This Report (mm/dd/yyyy) 10/01/2015
   [ ]
5. Describe Event or Problem
   CUSTOMER STATED IN AN E-MAIL THAT CHILD HAS BEEN HAVING
   SEIZURES SINCE HE HAS BEEN TAKING THE BABY TEETHING
   TABLETS.

(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:
   Catalog #
   Expiration Date (mm/dd/yyyy)
   Serial #
   Unique Identifier (UDI) #
7. If implanted, give date (mm/dd/yyyy)
8. If Explanted, Give Date (mm/dd/yyyy)

(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 FDA [ ] Yes [ ] No [ ] Link
   [ ]

(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.
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 the Department of Health and Human Services, Office of Information and Regulatory Affairs, OMB clearance request 0990-0823, Department of Health and Human Services, Food and Drug Administration, Office of the 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.

<table>
<thead>
<tr>
<th><strong>1. Type of Reportable Event</strong></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>- Malfunction</td>
<td>- Device Evaluation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>3. Device Evaluated by Manufacturer?</strong></th>
<th>4. Device Manufacture Date (mm/dd/yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- No Returned to Manufacturer</td>
<td></td>
</tr>
<tr>
<td>- Yes Evaluation Summary Attached</td>
<td></td>
</tr>
<tr>
<td>- No (Attach page to explain why not or provide code.)</td>
<td></td>
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</tbody>
</table>

<table>
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<tr>
<th><strong>5. Labeled for Single Use?</strong></th>
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<tbody>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>No</td>
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<thead>
<tr>
<th><strong>6. Event Problem and Evaluation Codes (Refer to coding manual)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Code</td>
</tr>
<tr>
<td>Device Code</td>
</tr>
<tr>
<td>Method</td>
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<tr>
<td>Results</td>
</tr>
<tr>
<td>Conclusions</td>
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<thead>
<tr>
<th><strong>7. If Remedial Action Initiated, Check Type</strong></th>
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<tbody>
<tr>
<td>Recall</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>
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<tr>
<td>Modification/Adjustment</td>
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<tr>
<td>Other</td>
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</tbody>
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<tr>
<th><strong>8. Usage of Device</strong></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 360(f), list correction/ removal reporting number:** |

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

<table>
<thead>
<tr>
<th><strong>G. ALL MANUFACTURERS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Contact Office (and Manufacturing Site for Devices)</strong></td>
</tr>
<tr>
<td>Name: HYLAND'S, INC.</td>
</tr>
<tr>
<td>Address: 154 W. 131ST STREET</td>
</tr>
<tr>
<td>Email Address: <a href="mailto:STANDARD@HYLAND.COM">STANDARD@HYLAND.COM</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>4. Date Received by Manufacturer (mm/dd/yyyy)</strong></th>
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<tbody>
<tr>
<td>30/27/2015</td>
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</table>

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<tr>
<th><strong>5. (A)NDA #</strong></th>
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<tbody>
<tr>
<td>IND #</td>
</tr>
<tr>
<td>BLA #</td>
</tr>
<tr>
<td>PMA #</td>
</tr>
<tr>
<td>510(k) #</td>
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</tbody>
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<tr>
<th><strong>7. Type of Report</strong> (Check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-day</td>
</tr>
<tr>
<td>Follow-up</td>
</tr>
<tr>
<td>Yes</td>
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<tr>
<th><strong>8. Adverse Event Term(s)</strong></th>
</tr>
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<tbody>
<tr>
<td>SEIZURES</td>
</tr>
</tbody>
</table>

| **DSS OCT 15 2015** |

<table>
<thead>
<tr>
<th><strong>CaseID: 11639456</strong></th>
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<tbody>
<tr>
<td>FDA ONLY</td>
</tr>
</tbody>
</table>
PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: NOT PROVIDED
REPORTER: [Redacted]
ADDRESS: N/A
CITY: N/A
STATE: N/A
COUNTRY: USA
ZIP CODE: N/A
PHONE #: N/A
E-MAIL: [Redacted]

NATURE OF COMPLAINT:
CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S E-MAIL: I WAS WONDERING WHO WOULD SPEAK TO ABOUT YOU GUYS TEETHING TABLETS BECAUSE SINCE MY SON HAS BEEN TAKEN THEM HE'S BEEN HAVING SEIZURES. I WILL BE SPEAKING TO A LAWYER MONDAY MORNING ABOUT THIS AND HOW TO TAKE FURTHER PERCUSSION ABOUT THIS MATTER.

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: 09/27/2015
BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: 

DATE: 10-07-15
DATE: 10-06-15

cc: QA / QC
Packaging  Production
Shipping / Receiving
Serious Adverse Event
SAE-0057-2015

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 fifty-four (54) 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 lots for atropine, scopolamine and Clostridium botulinum testing. The total Atropine and Scopolamine levels was found to meet the specification of 200 ppm and Clostridium botulinum testing was negative.

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: [Redacted]
2. Age at Time of Event: 4 Months
3. Sex: [Redacted]
4. Weight: lbs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event: [Redacted]
2. Outcomes Attributed to Adverse Event:
   - Life-threatening
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Other Serious (Important Medical Events)
3. Date of Event: 10/06/2015
4. Date of This Report: 10/07/2015
5. Describe Event or Problem:
   - A 6 MONTH OLD CHILD'S FACE BECAME FLUSHED RED AND CHILD WAS HARDLY BREATHING AFTER TAKING TWO (2) OF THE HYLAND'S TEETHING TABLETS.

C. SUSPECT PRODUCT(S)

1. Name (Brand/Labeled Strength & Mfr/Replier):
   - HYLAN’D BABY TEETHING TABLETS
2. Dose, Frequency & Route Used:
   - UNKNOWN
3. Therapy Dates (If Unknown, give duration from/to or best estimate):
   - #1
   - #2
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 #:
7. Exp. Date:
8. Event Reappeared After Readministration:
   - Yes
   - No
   - Doesn’t Apply
9. NDC# or Unique ID:
   - [Redacted]
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 #:
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:

E. INITIAL REPORTER

1. Name and Address:
2. Health Professional?:
3. Occupation:
   - Medical
4. Initial Reporter Also Sent Report to FDA:
   - Yes
   - No
   - Don’t Know

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>□ Abnormality</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</td>
<td>□ Evaluation Summary Attached</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Labeled for Single Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes</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</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Recall</td>
</tr>
<tr>
<td>□ Repair</td>
</tr>
<tr>
<td>□ Replace</td>
</tr>
<tr>
<td>□ Relabeling</td>
</tr>
<tr>
<td>□ Other</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>9. If action reported to FDA under 21 USC 380(h)(1), list correction/removal/reporting number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>10. Additional Manufacturer Narrative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>11. Corrected Data</th>
</tr>
</thead>
</table>

---

**G. ALL MANUFACTURERS**

1. Contact Office (and Manufacturing Sites for Devices)
   - **Name:** EDYTA FRACKKIEWICZ
   - **Address:** KYLAND'S, INC.
     154 W. 131ST STREET
     LOS ANGELES, CA 90061
   - **Email Address:** STANDARD@KYLAND.COM
   - **Phone Number:** 310-768-0700

2. Phone Number
   - **310-768-0700**

3. Report Source
   - **(Check all that apply):** Foreign, Study, Literature

4. Date Received by Manufacturer (mm/dd/yyyy)
   - **10/06/2015**

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

6. Manufacturer Report Number
   - **84973 AE # 1649**

7. Adverse Event(s)
   - **FLUSHED FACE, DIFFICULTY BREATHING**

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**OCT 22 2015**

**DSS**

**OCT 23 2015**

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**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."

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**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Chief Information Officer**

**Paperwork Reduction Act (PRA) Staff**

**PR4Staff@hsa.hhs.gov**

**Please DO NOT RETURN this form to the above PRA Staff email address.**
PRODUCT: HYLAND'S BABY TEETHING TABLETS

NATURE OF COMPLAINT:
CUSTOMER (MOTHER) CALLED TO REPORT HER 4 MONTH OLD CHILD'S FACE BECAME FLUSHED RED AND THAT THE CHILD WAS HARDLY BREATHING AFTER GIVING THE CHILD TWO (2) OF THE HYLAND'S BABY TEETHING TABLETS. MOTHER STATES SHE BROUGHT THE CHILD TO THE HOSPITAL WHERE CHILD WAS ADMITTED FOR FURTHER EVALUATION. MOTHER STATES THE CHILD'S DOCTOR TESTED THE TABLETS TODAY AND INFORMED HER THE TABLETS CONTAINED TWICE THE AMOUNT OF BELLADONNA STATED ON THE LABEL. MOTHER ALSO REPORTS VIEWING A VIDEO POSTED ON THE FDA WEBSITE WHERE THE RISK AND DANGERS OF THE TEETHING TABLETS WERE DISCUSSED. SHE INSISTED THE VIDEO WAS CURRENT AND THAT THE FDA TESTED THE TEETHING TABLETS LAST MONTH AND FOUND ISSUES WITH IT. CUSTOMER REFUSED TO PROVIDE ANY ADDITIONAL INFORMATION INCLUDING HER NAME, ADDRESS, NAME OF CHILD, PRODUCT INFORMATION, NAME OF HOSPITAL, ETC. CUSTOMER STATED SHE WANTS TO OBTAIN THAT INFORMATION FROM HER LAWYERS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

SECTION II: INVESTIGATION

INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/06/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CATHERINE DOW

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: ERIC BANK

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y
ADVERSE EVENT REPORTED ON: 10/06/2015

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 10-14-15
BY: DATE: 10-09-15
QA / QC DIRECTOR

cc: QA / QC, Production, Packaging, 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 twenty-four (124) Adverse Events (AE) which also included forty-nine (49) 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 lots for atropine, scopolamine and Clostridium botulinum testing. The total Atropine and Scopolamine levels was found to meet the specification of 4.5 ppm and Clostridium botulinum testing was negative.

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.
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 Staff@FDA.HHS.GOV. Please DO NOT RETURN this form to the above PRA Staff email address.
CUSTOMER COMPLAINT RECORD

Individual Case Safety Report

COMPLAINT #: 2660
DATE OF COMPLAINT: 10/14/2015
ITEM CODE: BTET
LOT NO.: NOT PROVIDED

REPORTER: [redacted]
ADDRESS: NA
CITY: NA
COUNTRY: USA
PHONE #: NA
E-MAIL: [redacted]

NATURE OF COMPLAINT: CUSTOMER SENT THE FOLLOWING E-MAIL AND DID NOT RESPOND TO HYLAND'S REQUEST FOR CONTACT:
SINCE USING THESE TABLETS MY CHILD HAS BEEN HAVING 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 INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/14/2015
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: 10/14/2015 BY: EDYTA FRACKIEWICZ

SECTION V:
REVIEWED BY MANAGEMENT BY: __________________________ DATE: 10-20-15
BY: __________________________ DATE: 10-20-15
Co. QA / QC DIRECTOR

cc: QA / QC Packaging Production Shipping / Receiving Form # VD1
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 twenty-five (125) Adverse Events (AE) which also included fifty (50) 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 lots for atropine, scopolamine and Clostridium botulinum testing. The total Atropine and Scopolamine levels was found to meet the specification of 500 ppm and Clostridium botulinum testing was negative.

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.

Reviewed by: ___________________________  Date: 10/19/2015
A. PATIENT INFORMATION

1. Patient Identifier (b) (8)

2. Age at Time of Event:
   - Years
   - Months
   - Days

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
   - 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)

3. Date of Event (mm/dd/yyyy)
   - 09/03/2015

4. Date of This Report (mm/dd/yyyy)
   - 10/30/2015

5. Describe Event or Problem
   - MOTHER REPORTED THAT CHILD WAS BREATHING REALLY WEIRD ON 9/3/2015 AND SHE CALLED 911 AND CHILD WAS TAKEN TO THE HOSPITAL. CHILD WAS UNCONSCIOUS WITH A BREATHING TUBE IN THE HOSPITAL AND SHE HAD SEIZURES. A FOLEY CATHETER WAS ALSO PLACED. WAS HOSPITALIZED FOR ONE WEEK. CURRENTLY CHILD IS ON SEIZURE MEDICATION AND HAS A FOLLOW UP APPOINTMENT WITH A NEUROLOGIST. BABY HAD A FEVER OF 102 DEGREES WHEN THE SEIZURES OCCURRED. HOSPITAL ATTRIBUTED SEIZURES TO THE LEVEL AND QUALITY OF CARE THE CHILD WAS RECEIVING AT HOME.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & refill/lot number)
   - HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   - #2

3. Therapy Dates (If unknown, give duration)
   - From (or 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

7. Exp. Date
   - #1

8. Event Reappeared After Reintroduction?
   - Yes
   - No
   - Doesn't Apply

9. NDC or Unique ID
   - 54973-3127-3

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 #

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 or (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
   - NA

3. Occupation

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

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
   - 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
   - □ Repair
   - □ Replacement
   - □ Reuse
   - □ Unknown

9. **If action reported to FDA under 21 USC 360(i), list correction/removal reporting number:**
   - NO

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

11. **Corrected Data**

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**G. ALL MANUFACTURERS**

1. **Contact Office (and Manufacturing site for devices)**
   - Name: EDITA FRACIENIUSZ
   - Address: HYLAND'S, INC., 154 M. 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 Relationship
   - □ Distributor
   - □ Other:

4. **Date Received by Manufacturer**
   - (mm/dd/yyyy)
   - 10/30/2015

5. **(A)NDA #**
   - IND #
   - BLA #
   - 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 # 1651

8. **Adverse Event Term(s)**
   - SEIZURES, LOSS OF CONSCIOUSNESS

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**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Chief Information Officer**

**Paperwork Reduction Act (PRA) Staff**

**PRASS@fda.hhs.gov**

**OMS 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.

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**NOV - 3 2015**

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COMPLAINT #2661
DATE OF COMPLAINT: 10/16/2015

PRODUCT: HYLAND'S BABY TEETHING TABLETS
ITEM CODE: BTET-T40
LOT NO.: A76715

REPORTER: EDYTA FRACKIEWICZ
ADDRESS: N/A
CITY: N/A
COUNTRY: USA
PHONE #: (0)(6)
EMAIL: N/A

NATURE OF COMPLAINT: WHEN CHILD WAS 3 MOS OLD ON (0)(6) OR (0)(6) SHE WAS BREATHING REALLY WEIRD. MOTHER CALLED 911

AND CHILD TAKEN TO THE HOSPITAL. WHEN SHE GOT TO THE HOSPITAL SHE HAD SEIZURES. SHE WAS IN HOSPITAL FOR A WEEK IN GRAVE CONDITION. DOCTORS PUT IN A BREATHING TUBE AND FOLEY CATHETER. SHE WAS UNCONSCIOUS. CURRENTLY IS ON SEIZURE MEDICATION AND HAS A FOLLOW UP APPOINTMENT WITH NEUROLOGIST. MOTHER WAS USING BABY TEETHING TABLETS AROUND THAT TIME. PUT 2-3 TABS AND UNDER THE TONGUE BID X 2 WEEKS. LAST DOSE WAS 3 DAYS BEFORE THIS EPISODE OCCURRED. BABY HAD A FEVER WHEN THE SEIZURES OCCURRED OF 102 DEGREES. NO FAMILY HISTORY OF SEIZURES. SHE READ INFORMATION ON FACEBOOK THAT BTET TABS CAUSE SEIZURES AND BLEEDING TO THE BRAIN.

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:

DATE RECEIVED:

INDIVIDUAL CASE SAFETY REPORT
11699338-01-00-03

INVESTIGATION
PLEASE SEE ATTACHED INSPECTION REPORT

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/16/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE: 

ADVERSE EVENT SERIOUS: Y N
ADVERSE EVENT REPORTED ON: 10/16/2015
ADVERSE EVENT REPORTED ON: 10/16/2015
BY: EDYTA FRACKIEWICZ

REVIEWED BY MANAGEMENT BY: DATE: 10-27-15

QA / QC DIRECTOR

QA / QC DIRECTOR

FORM # VD1
Product in Inventory:

No (0) units of Hyland’s Baby Teething Tablets (BTET), lot # A76715, are currently in the Standard Homeopathic Co. (SHC) warehouse. All other units of the (4) units have been distributed.

Review of Records:

The Hyland’s Baby Teething Tablets lot # A76715 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 # A76715. The Baby Teething bulk lot # 126005 was tested for total Atropine and Scopolamine and the results were in 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 no other complaints have been received for Hyland’s Baby Teething Tablets lot # A76715.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland’s Baby Teething Tablets lot # A76715.

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

Prepared by

Date: 10/23/15

Infant started having seizures after taking Hyland Teething tablets.

8.6. Relevant Tests/Laboratory Data, Including Dates (continued)

Watch test. Took teething tablets to lab for analysis. They did a urine analysis.

8.7. 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

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

**RX Meds:** none

**OTC Meds:** none
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
   Yes

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)
   05/04/2015

4. Date of This Report (mm/dd/yyyy)
   11/06/2015

5. Describe Event or Problem
   MOTHER CALLED ABOUT HER CHILD WHO HAD A SEIZURE (b)(6)
   WHEN HE WAS 1 YEAR OLD. SHE HAD BEEN GIVING HIM BABY TEETHING TABLETS A WEEK PRIOR, AS RECOMMENDED. HE HAD NO KNOBBY FEVER BEFORE THE SEIZURE. IN ALL, SHE USED 10-15 TABLETS, 1 TABLET PER DOSE. THE SEIZURE OCCURRED IN THE MORNING, AND THE LAST DOSE OF PRODUCT WAS GIVEN THE DAY BEFORE. HIS MOTHER WAS RESPONSIBLE TODAY AFTER SHE HEARD ON THE NEWS THAT THERE WAS A POSSIBLE CONNECTION BETWEEN TEETHING TABLETS AND SEIZURE/BRAIN BLEEDS.
   THE SEIZURE LASTED 30 MINUTES, WITH JERKING AND EYES ROLLING TO THE BACK OF THE HEAD. THE CHILD WAS UNRESPONSIVE TO HIS NAME. HE WAS TAKEN TO THE LOCAL HOSPITAL FOR 4 HOURS WHERE HE WAS STABILIZED, AND GIVEN NO MEDICATION. THEY REFERRED HIM TO THE STATE HOSPITAL WHERE HE WAS ADMITTED FOR 2 DAYS. A FEVER DEVELOPED AFTER THE SEIZURE, AND HE WAS NOT RELEASED UNTIL IT SUBSIDED. THEY DID BLOOD TESTS, MRI AND CHECKED BRAIN ACTIVITY WHILE ASLEEP AND AWAKE. IT WAS ALL NORMAL.
   THE CAUSE OF THE SEIZURE WAS NOT DETERMINED. THE MOTHER WAS TOLD TO JUST WATCH HIM. HE WAS NOT TAKING ANY MEDICATION, HAD NO KNOBBY PREGNANCY, AND ANY PRE-EXISTING CONDITIONS. HE HAD HIS LAST IMMUNIZATION AT 6 MONTHS.

6. Relevant Tests/Laboratory Data, Including Dates
   HE WAS TESTED FOR BRAIN ACTIVITY WHILE ASLEEP AND AWAKE; GIVEN BLOOD TESTS, MRI AND X-RAYS.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & route/admin)
   HYLAND'S BABY TEETHING TABLETS

2. Dose, Frequency & Route Used
   1 TAB, AS NEEDED, ORAL

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

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

5. Event Abated After Use
   Yes

6. Lot #
   #1

7. Exp. Date
   #1

8. NDC# or Unique ID
   54973-0127-3

9. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
   (Continue on next page)

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
   - Other

7. Catalog #

8. Expiration Date (mm/dd/yyyy)

9. Serial #

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

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

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.
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:
B.5: Describe Event or Problem (continued)
HE WAS BEING FED ON FORMULA FROM POWDERED MILK. FOLLOW UP VISITS HAVE SHOWN NORMAL RESULTS.

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, hepatocellular 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

NOV 27 2015

NOV 30 2015
COMPLAINT #: 2864
DATE OF COMPLAINT: 11/08/2015
ITEM CODE: BTET—T40
LOT NO.: A74414

PRODUCT: HYLAND'S BABY TEETHING TABLETS
SIZE: 40 TABS
REPORTER: N/A
ADDRESS: N/A
CITY: N/A
STATE: (0) (0)
COUNTRY: USA
ZIP CODE: N/A
PHONE #: (0) (0)
EMAIL: N/A

NATURE OF COMPLAINT:
MOTHER CALLED ABOUT HER CHILD WHO HAD A SEIZURE (b)(6) WHEN HE WAS 1 YEAR OLD. SHE HAD BEEN GIVING HIM BABY TEETHING TABLETS A WEEK PRIOR, AS NEEDED FOR TEETHING. HE HAD NO KNOWN FEVER BEFORE THE SEIZURE. IN ALL, SHE USED 10-15 TABLETS, 1 TABLET PER DOSE. THE SEIZURE OCCURRED IN THE MORNING, AND THE LAST DOSE OF PRODUCT WAS GIVEN THE DAY PRIOR. THE MOTHER WAS RESPONDING TODAY AFTER SHE HEARD ON THE NEWS THAT THERE WAS A POSSIBLE CONNECTION BETWEEN TEETHING TABLETS AND SEIZURE/BRAIN BLEEDS. THE SEIZURE LASTED 30 MINUTES, WITH JERKING AND EYES ROLLING TO THE BACK OF THE HEAD. THE CHILD WAS UNRESPONSIVE TO HIS NAME. HE WAS TAKEN TO THE LOCAL HOSPITAL FOR 4 HOURS WHERE HE WAS STABILIZED, AND GIVEN RACEMEPHEDIM. THEY REFERRED HIM TO THE STATE HOSPITAL WHERE HE WAS ADMITTED FOR 2 DAYS. A FEVER DEVELOPED AFTER THE SEIZURE, AND HE WAS NOT RELEASED UNTIL IT SUBSIDED. THEY DID BLOOD TESTS, MRI AND CHECKED BRAIN ACTIVITY WHILE ASLEEP AND AWAKE. IT WAS ALL NORMAL. THE CAUSE OF THE SEIZURE WAS NOT DETERMINED. THE MOTHER WAS TOLD TO JUST WATCH HIM. HE WAS NOT TAKING ANY MEDICATION, HAD NO KNOWN ALLERGIES, NOR ANY PRE-EXISTING CONDITIONS. HE HAD HIS LAST IMMUNIZATION AT 6 MONTHS. HE WAS BEING FED ON FORMULA FROM POWDERED MILK. FOLLOW UP VISITS HAVE SHOWN NORMAL RESULTS.

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 INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/08/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:
CORRECTIVE ACTION(S) COMPLETED BY: DSS
DATE: 

SECTION IV: ADVERSE EVENT REPORTS
ADVERSE EVENT SERIOUS: Y / N
ADVERSE EVENT REPORTED ON: 11/06/2015
BY: TUTTI GOULD

SECTION V: REVIEWED BY MANAGEMENT BY: 
DATE: 11-17-15
BY: QA/QC DIRECTOR
DATE: 11-17-15

cc: QA/QC Production
Packaging Shipping / Receiving

NOV 2 7 2015
Form #: VD1
Product in Inventory:

No (0) units of Hyland’s Baby Teething Tablets (BTET), lot # A74414, are currently in the Standard Homeopathic Co. (SHC) warehouse. All units of the lot have been distributed.

Review of Records:

The Hyland’s Baby Teething Tablets lot # A74414 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 # A74414. The Baby Teething bulk lot # 123797 was tested for total Atropine and Scopolamine and the results were within specification of <20 ppm.

RetentionPolicy 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 # A74414.

Conclusion:

The investigation did not reveal any issues with the manufacturing or packaging processes for these lots of Hyland’s Baby Teething Tablets lot # A74414.

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

Prepared by ____________________________

Date 11/13/15

**NOV 27 2015**

**DSS**

**NOV 30 2015**

CC-0935-2015

AE-0527-2015
AE #: 1654

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

NAME: (b)(5)

ADDRESS: N/A

CITY: N/A

COUNTRY: USA

PHONE #: (b)(6)

E-MAIL: N/A

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: 11-17-15

BY: ___________________________ DATE: 11-17-15

DSS ___________

DISTRIBUTION: FDA ADVERSE EVENT FILE

NOV 30 2015
A. PATIENT INFORMATION
1. Patient Identifier: (b) (6) [Redacted]
2. Age at Time of Event: 10 Months
3. Sex: Female
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): 00/00/0000
4. Date of This Report (mm/dd/yyyy): 11/12/2015
5. Describe Event or Problem:
   MOTHER POSTED ON (b) (6) [Redacted] THAT CHILD EXPERIENCED BELLADONNA POISONING AND SEIZURES AFTER THE USE OF BABY TEETHING TABLETS. CHILD NOW HAS TO BE SEEN BY NEUROLOGISTS AND REQUIRES MEDICAL CARE.

C. SUSPECT PRODUCT(S)
1. Name: NYLAND'S BABY TEETHING TABLETS
2. Dose, Frequency & Route Used:
   - Tab TID X 1 Day
3. Therapy Dates (If unknown, give duration)
   - #1
   - #2
4. Diagnosis for Use (indication)
   - TEMP RELIEF TEETHING PAIN
5. Event Altered After Use: Stopped or Dose Reduced?
   - #1 Yes No
   - #2 Yes No
6. Lot #
   - #1
   - #2
7. Exp. Date
   - #1
   - #2
8. NDC# or Unique ID: 54973-3127-3

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. Catalog #
7. Expiration Date (mm/dd/yyyy)
8. Serial #
9. If Implanted, Give Date (mm/dd/yyyy)

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
### 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 Removal 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
   - Other:

9. **If action reported to FDA under 21 USC 380(d); list correction/removal reporting number:**

10. **Additional Manufacturer Narrative**

11. **Corrected Data**

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**G. All Manufacturers**

1. **Contact Office (and Manufacturing Site for Devices)**
   - Name: EDYTA FRACKIEWICZ
   - Address: HYLAND'S, INC.
   - Phone Number: 310-768-0700
   - 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. **Data Received by**
   - Manufacturer (mm/dd/yyyy)
   - 11/06/2015

5. **(A)INDA #**
   - IND #
   - BLA #
   - PMA/510(k) #
   - Combination Product
   - Pre-1938
   - OTC Product

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

7. **Manufacturer Report Number**
   - 54973

8. **Adverse Event Term(s)**
   - BELLADONNA POISONING, 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
PRASA@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 #: 2090
DATE OF COMPLAINT: 11/06/2015
ITEM CODE: BTFE--T40
LOT NO.: N/A

REPORTER: N/A
ADDRESS: N/A
CITY: N/A
COUNTRY: USA
PHONE #: N/A
E-MAIL: N/A

NATURE OF COMPLAINT: CUSTOMER POSTED THE FOLLOWING ON THE INTERNET AND WOULD NOT CALL HYLAND'S AFTER SEVERAL REQUESTS. DEAR HYLAND'S, WE HAVE A 6 MONTH OLD DAUGHTER. THINKING YOUR PRODUCT WAS SAFE LANDED MY DAUGHTER IN THE HOSPITAL. WE HAD A VERY FRIGHTFUL NIGHT THAT ENDED IN AN ER VISIT MANY SLEEPLESS NIGHTS DUE TO POISONING FROM YOUR TEETHING TABLETS. THE DOCTOR SAID HE WAS DAMAGED THAT YOUR PRODUCT IS Labeled SAFE since BELLA DONNA IS STILL IN IT. NOTHING CAN REPLACE THE DAYS I SPENT WITH DAUGHTER SITTING UP FROM YOUR TABLETS. THE FEAR HER FATHER AND I WENT THROUGH. AS A MOM I WILL NEVER USE YOUR PRODUCT AGAIN. I WANT TO STAY WITH PEOPLE WHO ARE SAFER FOR MY DAUGHTER. AN ACTING INGREDIENT WHICH IS MADE FROM THE DEATHLY PLANT KNOW AS NIGHT SHADE. IT IS NOT URGED PARENTS THINK FALLING ASLEEP INSTANTLY OR THE LITTLE SMALL THINGS ARE TEETHING RELATED AND USE YOUR PRODUCT WHEN ITS THE PRODUCT ITSELF CAUSING PROBLEMS. IM LUCKY ENOUGH TO SAY MY DAUGHTER IS ALRIGHT BUT NOW HAS TO SEE NEUROLOGISTS AND MY EXPENSE BECAUSE I READ THE WORD SAFE ON YOUR PRODUCT LABEL AND ONLY 3 TABLETS INTO THE BOTTLE LANDED MY DAUGHTER IN THE HOSPITAL. PS THEY CHECKED HER FOR EVERYTHING AND IT WAS BELLA DONNA POISONING. AFTER THE DIAGNOSIS WE Began TO DIG AND FOUND THE FDA HAS A VIDEO OUT URGING PARENTS THIS COULD HAPPEN TO THEIR KIDS. ALSO SENT THE FOLLOWING E-MAILS #1. I RECENTLY PURCHASED A BOTTLE OF 150 COUNT FROM FAMILY DOLLAR AND MY DAUGHTER EXPERIENCED SEIZURES SHORTLY AFTER THE THREE TABLETS. I GAVE HER ALL THREE WERE GIVEN AT SEPARATE TIMES OVER A 24 HR PERIOD. WE HAVE DOCUMENTATION SHE SUFFERED FROM SEIZURES FROM THE BELLA DONNA IN YOUR PRODUCT. WHAT DO YOU PLAN ON DOING TO PREVENT THIS. #2 A REFUND WONT PAY FOR THE BILLS WE HAVE NOW. IF THE POISONING OR GET THE NEWS OUT THERE YOUR PRODUCT ISN'T SAFE. I HAVE ALREADY STARTED MEETING WITH AN ATTORNEY REGARDING THIS PROBLEM SINCE MY DAUGHTER NOW REQUIRES MEDICAL CARE. I ALREADY KNOW ABOUT BELLA DONNA THANKS TO POISON CONTROL AND THE FDA I WAS FORCED TO MEET WITH AFTER ONLY 3 TABLETS OF YOUR PRODUCT.

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: N/A
UPS CALL TAG ISSUED: N [CIRCLE ONE]
DATE PRODUCT RECEIVED: N/A

SECTION II: INVESTIGATION
INVESTIGATION: PLEASE SEE ATTACHED INSPECTION REPORT.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/06/2015
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION
CORRECTIVE ACTION(S) COMPLETED BY: N/A
DATE: N/A

SECTION IV: ADVERSE EVENT REPORTS

ADVERSE EVENT SERIOUS: Y [CIRCLE ONE]
ADVERSE EVENT REPORTED ON: 11/06/2015
BY: EDYTA FRACKIEWICZ

SECTION V: REVIEWED BY MANAGEMENT: 
By: NOV 27 2015
QA / QC DIRECTOR 
DSS

cc: QA / QC
Packaging
Production
Shipping / Receiving

NOV 80 2015

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 in the last twelve months that there have been one hundred and three (103) Adverse Events (AE) which also included forty-seven (47) 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 lots for atropine, scopolamine and Clostridium botulinum testing. The total Atropine and Scopolamine levels was found to meet the specification of 2.0 ppm and Clostridium botulinum testing was negative.

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 Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier (9-15)
   [Redacted]

2. Age at time of Event or Date of Birth:
   [Month/day/year]
   - [Day] [Month] [Year]

3. Sex
   - Female
   - Male

4. Weight
   - 20 lb
   - [Redacted]

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 Event
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)
   - 12/28/2015

4. Date of this Report (mm/dd/yyyy)
   - 12/28/2015

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)
   - Name: Hyland's Teething Tablets
     - Strength: unknown
     - Manufacturer: Hyland's

2. Name:
   - Strength:
     - Manufacturer:

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

C. PRODUCT AVAILABILITY

Please note the following:

1. Name and Address
   - Phone #
   - E-mail

2. Health Professional
   - Yes
   - No

3. Occupation
   - [Redacted]

4. Also Reported to:
   - Manufacturer
   - 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)

Case ID: 11878433

Form Approved: OMB No. 0910-0251, Expires: 12/31/2011

See OMB statement on reverse.
I've been giving my son Hyland's teething tablets for about a month now and he has been sleeping a lot, being constipated. Is this a serious problem?

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)

Race: American Indian/Alaskan Native

Medical Conditions:

Allergies:

Important Information:

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier: [Redacted]
2. Age at Time of Event or Date of Birth: [Redacted]

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

1. Adverse Event: [Redacted]
2. Product Problem (e.g., defects/malfunctions): [Redacted]
3. Product Use Error: [Redacted]
4. Problem with Different Manufacturer of Same Medicine: [Redacted]

C. OUTCOME ATTRIBUTED TO ADVERSE EVENT

1. Outcome: [Redacted]
2. Disability or Permanent Damage: [Redacted]
3. Death (mm/dd/yyyy): [Redacted]
4. Life-Threatening (mm/dd/yyyy): [Redacted]
5. Hospitalization - Initial or Prolonged: [Redacted]
6. Other Serious (Important Medical Events): [Redacted]
7. Required Intervention to Prevent Permanent Impairment/Damage (Devices): [Redacted]

D. DATE OF EVENT

1. Date of Event: 9/19/15
2. Date of this Report: 9/19/15

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's teething tablets
2. Common Device Name: [Redacted]
3. Manufacturer Name, City and State: [Redacted]
4. Model #: [Redacted]
5. Operator of Device: [Redacted]
6. If Implanted, Give Date (mm/dd/yyyy): [Redacted]
7. If Explanted, Give Date (mm/dd/yyyy): [Redacted]
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: [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:
   - 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.
January 25, 2016

MedWatch
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852-9787

RE: Party Name:
Party Date of Incident:

Dear Sir or Madam:

Enclosed please find Form FDA 3500 (2/13) which has been completed on behalf of my client in regards to injuries sustained on [redacted] from the use of the product “Hyland’s Teething Tablets.” Should you have any questions, please give Attorney [redacted] a call at [redacted] to discuss this matter further. With kindest regards, I am

Very truly yours

Enclosure: Form FDA 3500 (2/13)
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier:

2. Age at Time of Event or Date of Birth:
   6 Months
   (a) 6
   (b) 6
   In confidence

3. Sex:
   □ Female
   □ Male

4. Weight:
   19 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 Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy):
   01/31/2016

4. Date of this Report (mm/dd/yyyy):
   02/03/2016

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:

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
   □ Name:
   □ Hyland's Baby Teething Tablets
   □ Strength:
   Manufacturer:

   #2 Name:
   □ Strength:
   Manufacturer:

See additional page(s) for complete text.

E. 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. 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:

Phone #:

E-mail:

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: □
B.5. Describe Event or Problem (continued)

Administered Hyland's Teething Tablets (2 tablets, recommended dosage) to infant baby at 7:30pm. Infant weighs 19lbs. At 10:00pm infant experienced excessive vomiting, nausea, and labored breathing. No other variables were introduced that day. Infant is exclusively breastfed. Symptoms lasted approximately 30 minutes, no reoccurrence afterward.

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)

Race: White

Medical Conditions:

Allergies:

Important Information:

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

2. Age at Time of Event, or Date of Birth:

3. Sex

4. Weight

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 (Device)

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

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

5. Describe Event, Problem or Product Use Error

   Nine month old son was healthy and up-to-date on shots and doctor visits at the time. Son is teething and parents gave him Hyland's Teething Tablets as recommended by a family member. Son was given two tablets and within three hours later he had experienced a seizure. He was unresponsive, parents dialed 911, and child was taken to the ER. He improved and was not admitted to hospital. Doctor ran tests and found nothing. Father is concerned that his son's seizure is related to bella donna in product. He cites youtube video of a NIH case study by the FDA. Son has twin sister & parents monitor all new food introduced to kids for any possible allergic reactions.

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)
   Hyland's Teething Tablets

2. Dose or Amount

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

4. Diagnosis or Reason for Use (indication)

5. Event Altered After Use
   Stopped or Dose Reduced?

6. Lot #

7. Expiration Date

8. Event Reaunched After Reproduction?

9. NDC or Unique ID

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 No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCUMITANT) 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

FEB 12 2016

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
2. Age at time of Event or Date of Birth: 6 Months
3. Sex
   - Male
   - Female
4. Weight
   - 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 (e.g., problem with different manufacturer of same medicine)

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)
   - 03/17/2016
4. Date of this Report (mm/dd/yyyy)
   - 03/19/2016
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

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
   - Name:
   - Strength:
   - Manufacturer:
2. Name:
   - Strength:
   - Manufacturer:

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
   - CTU
   - MAR 21 2016
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)

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:
   - 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:
8.5. Describe Event or Problem  (continued)

Gave infant low dose Hyland teething tablets, took to doctor where blood tests confirmed mild dehydration. No other drugs were administered and baby was in good health prior. Baby was eating expressed breastmilk normally. No change in diet.

8.6. Relevant Tests/Laboratory Data, Including Dates  (continued)

Blood panel showed mild dehydration

8.7. 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:

Allergies:

Important Information:

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

Individual Case Safety Report

12197698-01-00-02

DSS
MAR 21 2016
**A. PATIENT INFORMATION**

<table>
<thead>
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<th>2. Age</th>
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<td>Month(s)</td>
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In Confidence:

5.a. Ethnicity (Check single best answer)

- Asian
- American Indian or Alaskan Native
- Black or African American
- Hispanic/Latino
- Native Hawaiian or Other Pacific Islander
- White
- Not Hispanic/Latino

5.b. Race (Check all that apply)

- Asian
- American Indian or Alaskan Native
- Black or African American
- Hispanic/Latino
- Native Hawaiian or Other Pacific Islander
- White
- Non-Hispanic/Latino

**B. ADVERSE EVENT, PRODUCT PROBLEM**

1. Outcome Attributed to Adverse Event (Check all that apply)

- Adverse Event
- Product Problem (e.g., defects, malfunctions)
- Product Use Error
- Problem with Different Manufacturer of Same Medicine

2. Death

Include date (dd-mm-yyyy)

- Life-threatening
- Disability or Permanent Damage
- Hospitalization - initial or prolonged
- Congenital Anomaly/Birth Defects
- Other Serious (Important Medical Events)
- Shaking
- Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

11-Jun-2016

4. Date of this Report (dd-mm-yyyy)

14-Jun-2016

5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

See additional page(s) for complete text.

**C. PRODUCT AVAILABILITY**

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

- Yes
- No

**D. SUSPECT PRODUCTS**

1. Name and Strength (from product label)

- #1 - Name and Strength
  - Hyland's Baby Teething Tablets

- #2 - Name and Strength
  - Hyland's Inc.
  - A15116

- #2 - Name and Strength
  - Hyland's Inc.

- #3 - Name and Strength
  - Hyland's Inc.

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name

- CTU

2. Common Device Name

- JUN 15 2016

3. Manufacturer Name, City and State

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

Product names and therapy dates (Exclude treatment of event)

See additional page(s) for complete text.

**G. REPORTER (See confidentiality section on back)**

1. Name and Address

2. Health Professional?

- Yes
- No

3. Occupation

4. Also Reported to:

- Manufacturer/Componder
- User Facility
- Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box:

---

**FDA USE ONLY**

- Triage unit sequence #
- FDA Rec. Date

- Event Abated After Use Stopped or Dose Reduced?

- Yes
- No
- Doesn't apply

- Event Reappeared After Reintroduction?

- Yes
- No
- Doesn't apply

- Is this a single-use device that was reprocessed and reused on a patient?

- Yes
- No

---

**Submission of a report does not constitute an admission that medical device was the product caused or contributed to the event.**
B.5. Describe Event or Problem (continued)

We gave our daughter hylands teething tablets as directed and she is 16 months old and weighs about 25lbs and we noticed her shaking, like a really bad tremble, and it gradually wore off over the next few hours, she slept almost all day for 2 days after that, and I just read online that kids had seizures from it so I wanna get her checked out now, so scheduling an appointment. Just wanted to let someone know because we don't want any other parents to see that, it scared me at first yanno?

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

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

Medical Conditions: None

Allergies: None

Important Information: Healthy baby

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

RX Meds: None

OTC Meds: Tylenol, motrin, alternating every 8 hours
The FDA Safety Information and Adverse Event Reporting Program

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier (01) (02)  
   3. Sex (01) (02) (03) (04)  

5. a. Ethnicity (Check single best answer)  
   b. Race (Check all that apply)  
   c. Hispanic/Latino  
   d. Not Hispanic/Latino  

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply  
   a. Adverse Event  
   b. Product Problem (e.g., defects, malfunctions)  
   c. Product Use Error (e.g., problem with different manufacturer of same medicine)  

2. Outcome Attributed to Adverse Event (Check all that apply)  
   a. Death (dd-mmm-yyyy)  
   b. Life-threatening (dd-mmm-yyyy)  
   c. Disability or Permanent Damage (dd-mmm-yyyy)  
   d. Hospitalization - initial or prolonged (dd-mmm-yyyy)  
   e.Congenital Anomaly (dd-mmm-yyyy)  
   f. Other Serious (dd-mmm-yyyy)  

3. Date of Event (dd-mmm-yyyy)  
4. Date of this Report (dd-mmm-yyyy)  

5. Describe Event, Problem or Product Use Error  
   See additional page(s) for complete text.  

6. Relevant Tests/Laboratory Data, Including Dates  
   See additional page(s) for complete text.  

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, kidney problems, etc.)  
   See additional page(s) for complete text.  

C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? (Do not send product to FDA)  
   a. Yes  
   b. No  
   c. Returned to Manufacturer on (dd-mmm-yyyy)  

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)  
   a. Name and Strength  
   b. Manufacturer/Compounder  
   c. NDC # or Unique ID  
   d. Hyland's Teething Tablets  
   e. Hyland's  
   f. Number of Units Used  
   g. Lot #  
   h. Date of Administration (dd-mmm-yyyy)  

2. Name, Manufacturer/Compounder  
   a. Number of Units Used  
   b. Lot #  
   c. Date of Administration (dd-mmm-yyyy)  

3. Name, Manufacturer/Compounder  
   a. Number of Units Used  
   b. Lot #  
   c. Date of Administration (dd-mmm-yyyy)  

4. Name, Manufacturer/Compounder  
   a. Number of Units Used  
   b. Lot #  
   c. Date of Administration (dd-mmm-yyyy)  

E. SUSPECT MEDICAL DEVICE

1. Brand Name  

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

4. Model #  
5. Lot #  

6. Operator of Device  
   a. Health Professional  
   b. Lay User/Patient  
   c. Other  

7. Catalog #  
8. Expiration Date (dd-mmm-yyyy)  
9. If Implanted, Give Date (dd-mmm-yyyy)  
10. If Implanted, Give Date (dd-mmm-yyyy)  

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)  
See additional page(s) for complete text.  

G. REPORTER

1. Name and Address  
2. Health Professional?  
3. Occupation  
4. Also Reported to:  
   a. Manufacturer/Compounder  
   b. User Facility  
   c. Distributor/Importer  

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box:  

FORM FDA 3500 (10/15)  
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
The baby sitter gave my 8 month old Hyland's teething tablets and he suddenly had muscle weakness and fell into a deep sleep. She had to wake the baby up by rubbing his chest and placed cold water on his face to get him to wake up.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
I took my 8 month old to his pediatrician. She read the ingredients on the bottle and immediately advised me to throw them away.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
Medical Conditions: healthy baby boy
Allergies: none
Important Information: none

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)
RX Meds: none
OTC Meds: Children's Tylenol
My daughter took Hylands teething tabs (2 tablets that morning) and had a seizure in the evening. She was 5 months old at the time and was WAY under the maximum dose. She consumed a total of 4 tablets in 24 hours. 2 tablets the previous day and 2 tablets the morning of the seizure. We brought her to children's hospital and she was admitted and they did an EEG and found nothing wrong with our little girl.

Normal growth and development evaluation and an EEG.

Medical Conditions: No other medications. The dates listed here are estimated. I do not know hospitalization date at the top of my head.

Allergies: No known allergies.

Important Information: None.

Individual Case Safety Report

12491395-01-00-02
### A. PATIENT INFORMATION

1. Patient Identifier (e.g., Social Security Number)
2. Age
   - Year(s)
   - Month(s)
   - Week(s)
   - Day(s)
3. Sex
   - Female
   - Male
4. Weight
   - In Confidence

#### 5. Ethnicity
- American Indian or Alaskan Native
- Black or African American
- Asian
- Hispanic/Latino
- Not Hispanic/Latino
- Native Hawaiian or Other Pacific Islander

#### 6. Race
- Asian
- American Indian or Alaskan Native
- Black or African American
- Not Hispanic/Latino
- Not Hispanic/Latino
- Native Hawaiian or Other Pacific Islander

### B. ADVERSE EVENT / PRODUCT PROBLEM

1. Check all that apply
   - Adverse Event
   - Product Problem (e.g., defects/malfunctions)

#### 2. Outcome Attributed to Adverse Event
   - Death (dd-mm-yy)
   - Life-Threatening
   - Hospitalization (initial or prolonged)
   - Inpatient Hospitalization (first 60 days)
   - Other Serious (Important Medical Events)
   - Resulted in Permanent Impairment/Damage (Devices)

#### 3. Date of Event (dd-mm-yy)
   - 23-Jul-2016

#### 4. Date of this Report (dd-mm-yy)
   - 27-Jul-2016

#### 5. Describe Event, Problem or Product Use Error

See additional page(s) for complete text.

### C. PRODUCT AVAILABILITY

1. Product Available for Evaluation
2. Returned to Manufacturer
3. Returned to Manufacturer

### D. SUSPECT PRODUCTS

1. Name and Strength
   - Hylands Teething Tablets
2. Name and Strength
   - Hylands
3. Name and Strength
   - Hylands
4. Name and Strength
   - Hylands

### E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Model #
3. Catalog #
4. Expiration Date (dd-mm-yy)
5. Unique Identifier (UDI) #

### F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. Name and Address
2. Phone #
3. E-mail
4. Health Professional
5. Occupation
6. Also Reported to
7. Distributor/Importer
8. User Facility
9. Manufacturer/Companion
10. Other:

### G. REPORTER

1. Name and Address
2. Country
3. ZIP/Postal Code
4. Phone #
5. E-mail
6. Health Professional
7. Occupation
8. Also Reported to
9. Distributor/Importer
10. User Facility
11. Manufacturer/Companion
12. Other:

---

**Note:** For date prompts of "dd-mm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.
B.5. Describe Event or Problem (continued)

Gave 6 month old son 2 Hylands Teething Tablets approx 6:30pm. Within 30 minutes began to notice odd behavior. Baby is normally crawling and playing with good coordination and just fell over. Started acting drunk, delirious and very uncoordinated. Went to the ER and symptoms correlated with belladonna poisoning. Symptoms have continued for four days. He is getting better but not back to normal. He is continuing to act spacey and exhausted with bursts of strange euphoria. He is very tired but also restless at the same time. Went to the ER a second time and blood work was done. Doctors opinion was the ingredients in the teething tablets were still affecting him.

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

Blood work done at medical center.

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

Medical Conditions: None

Allergies: None known

Important Information:

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

RX Meds: None

OTC Meds: None

Individual Case Safety Report

12605520-01-00-02
Individual Case Safety Report

Note: For dates prompt of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example: 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier [ID] (ID)
2. Age [Year(s)] [Month(s)] [Day(s)]
3. Sex [Female] [Male]
4. Weight [lb] [kg]

3. Ethnicity (Check single best answer)
   [Hispanic/Latino] [American Indian or Alaskan Native] [Black or African American] [White]
   [Native Hawaiian or Other Pacific Islander]
4. Race (Check all that apply)
   [Asian] [Black or African American] [White]
   [Native Hawaiian or Other Pacific Islander]

B. AVERSE EVENT, PRODUCT PROBLEM

1. Adverse Event [Product Problem (e.g., defects/ malfunctions)]
2. Product Use Error [Problem with Different Manufacturer of Same Medicine]
3. Outcome Attributed to Adverse Event (Check all that apply)
   [Death] [Disability or Permanent Damage]
   [Hospitalization - initial or prolonged]
   [Other Serious (important Medical Events)]
   [Required Intervention to Prevent Permanent Impairment/Damage (Devices)]
4. Date of Event (dd-mmm-yyyy)
   01-Aug-2016
5. Date of this Report (dd-mmm-yyyy)
   13-Aug-2016
6. Describe Event, Problem or Product Use Error
   See additional page(s) for complete text.
7. Relevant Tests/Laboratory Data, Including Dates
   See additional page(s) for complete text.
8. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
   See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
   [Yes] [No] [Returned to Manufacturer on: ] (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)
   #1 - Name and Strength
   Hyland's Baby Teething Tablets
   #1 - NDC # or Unique ID
   #2 - Name and Strength
   #2 - NDC # or Unique ID
   #3 - Manufacturing/Compounder
   #3 - Lot #

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
   CTU
3. Manufacturer Name, City and State
   AUG 15 2016
4. Model #
5. Operator of Device
   [Health Professional] [Lay User/Patient] [Other:
   Catalog #
5. Expired Date (dd-mmm-yyyy)
6. If Implanted, Give Date (dd-mmm-yyyy)
7. If Explanted, Give Date (dd-mmm-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
   [ ] [ ]
4. Also Reported to:
   [ ] [ ] [ ] [ ]
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: [ ]
B.5. Describe Event or Problem (continued)

I started giving my baby Hyland's Baby Teething Tablet 2 weeks after he turned 4 months. He had multiple seizures and I took him straight to the Children's Hospital. He had an EEG done for 48 hours, an MRI, and a Spinal Tap. Everything came back normal. He was in the hospital for a week and was not taking the teething medicine. During that week I haven't noticed any more seizures until August 12 when I gave him the teething medicine again. An hour after I gave him the medicine he had 2 seizures.

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

He received the Spinal Tap, EEG and MRI.

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

Medical Conditions:

Allergies:

Important Information:

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

Individual Case Safety Report

12654615-01-00-02
# D. SUSPECT PRODUCTS

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<th>Batch Code</th>
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<th>Lot #</th>
<th>NRC of Unique ID</th>
<th>Number of Units</th>
<th>Dispenser/Dispensing Pharmacy</th>
<th>Dispenser/Dispensing Pharmacy Code</th>
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# E. SUSPECT MEDICAL DEVICE

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<th>ID/Serial #</th>
<th>Number</th>
<th>Unit Identification (UN)</th>
<th>Expiration Date (mm/dd/yyyy)</th>
<th>Reason for Use (Training/Real patient)</th>
<th>Patient Identification</th>
<th>Event Date/Time (mm/dd/yyyy)</th>
<th>Event Description</th>
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<th>Your Signature</th>
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# G. REPORTER (See Confidentiality Section on Front)

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# F. OTHER CONCOMITANT MEDICAL PRODUCTS

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# B. ADVERSE EVENT/PRODUCT PROBLEM

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# A. PATIENT INFORMATION

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# Additional Information

- Date of Report: 24-Aug-2016
- Date to Address Event (Check All That Apply): 23-Aug-2016

- Including: Medical Conditions (e.g., allergies, pregnancy, smoking, and alcohol use, known medical problems, etc.)
- Other Relevant Laboratory Data, Including Dates
- Other Relevant Medical History, Including Preceding Medical Conditions (e.g., allergies, pregnancy, smoking, and alcohol use, known medical problems, etc.)
- Names, Model Number, and Series Number

- Product Reason for Use: Training
- Patient Identification: 
- Event Date/Time: 23-Aug-2016
- Event Description: 

- More detailed information provided on subsequent pages.
B.5. Describe Event or Problem (continued)

My daughter is nine months old and experienced symptoms after consuming Hyland's teething tablets. I had been giving her two tablets a day for about five days when I noticed it for the first time. She would suddenly drop her head down and have trouble lifting it back up. She had several episodes, most severely about an hour or two after taking the dose of tablets. She also experienced extreme thirst during/after these episodes and would drink more water or milk in a few hours than she normally drinks most of the day. I now have discovered that these events are tied to the teething tablets and I think it may be an adverse reaction to the belladonna in the tablets. She was getting much less than the recommended daily dose and still had a reaction.

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

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

Medical Conditions: None

Allergies: None

Important Information: None

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

RX Meds: None

OTC Meds: Infant Motrin Concentrated drops (1.25mL, rare occasions) Infant Tylenol (2.5 mL, only when fever is high)

Individual Case Safety Report

12689440-01-00-02
A. PATIENT INFORMATION

1. Patient Identifier (b) [ ]
2. Age [ ]
   a. Year(s) [ ]
   b. Month(s) [ ]
   c. Day(s) [ ]
   or Date of Birth (e.g., 02 Feb 1925) [ ]
3. Sex [ ]
   a. Male [ ]
   b. Female [ ]
   c. Other [ ]
4. Weight [ ]
5. Ethnicity (Choose one best answer)
   a. Hispanic/Latino [ ]
   b. Not Hispanic/Latino [ ]
   c. Asian [ ]
   d. American Indian or Alaskan Native [ ]
   e. Black or African American [ ]
   f. Native Hawaiian or Other Pacific Islander [ ]

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
   a. Adverse Event [ ]
   b. Product Problem (e.g., defects/malfunctions) [ ]
   c. Product Use Error [ ]
   d. Problem with Different Manufacturer of Same Medicine [ ]

2. Outcome Attributed to Adverse Event (Check all that apply)
   a. Death (dd-mm-yyyy) [ ]
   b. Hospitalization - initial or prolonged [ ]
   c. Life-Threatening [ ]
   d. Seizures [ ]
   e. Important Medical Event (e.g., congenital anomaly) [ ]
   f. Permanent Impairment/Deficit (Dev) [ ]

3. Date of Event (dd-mm-yyyy) [ ]
4. Date of this Report (dd-mm-yyyy) [ ]
5. Description of Event, Problem or Product Use Error

See additional page(s) for complete text.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
   a. Yes [ ]
   b. No [ ]
   c. Returned to Manufacturer on: [ ]

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)
   a. Name and Strength: Hyland's Baby Teething Tablets 54973-3127-1
   b. Lot # [ ]

2. Name and Strength
   a. Hyland's
   b. Lot # A60714

3. Name and Strength
   a. Hyland's Baby Teething Tablets 54973-3127-1
   b. Lot # [ ]

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # [ ]
5. Lotus # [ ]
6. Operator of Device
   a. Health Professional [ ]
   b. Lay User/Consumer [ ]
   c. Other [ ]

7. Catalog # [ ]
8. Expiration Date (dd-mm-yyyy) [ ]
9. If Implanted, Give Date (dd-mm-yyyy) [ ]
10. If Implanted, Give Date (dd-mm-yyyy) [ ]

11. Is this a single-use device that was not reprocessed and reused on a patient?
   a. Yes [ ]
   b. No [ ]
   c. Other [ ]

12. If Yes to item 11, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)
See additional page(s) for complete text.

G. REPORTER (See confidentiality section on back)

1. Name and Address
2. Health Professional? [ ]
   a. Yes [ ]
   b. No [ ]

3. Occupation [ ]
4. Also Reported to:
   a. Manufacturer/Compounder [ ]
   b. User Facility [ ]
   c. Distributor/Importer [ ]

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: [ ]
8.5. Describe Event or Problem (continued)

My 15 month old took 3 teething tabs (as directed) and 30 min later had a seizure. 48 hr after that had a second seizure and required sedation and hospitalization.

8.6. Relevant Tests/Laboratory Data, Including Dates (continued)

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

Medical Conditions: None
Allergies: None
Important Information: None, very healthy

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

RX Meds: None
OTC Meds: None

Individual Case Safety Report

12693124-01-00-02

DSS
AUG 26 2016
All dates displayed in the report are in EST(GMT-05:00) time zone

```
<table>
<thead>
<tr>
<th>Basic Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company Unit</strong></td>
</tr>
<tr>
<td><strong>Source Medium</strong></td>
</tr>
<tr>
<td><strong>Priority</strong></td>
</tr>
<tr>
<td><strong>FDA Received Date</strong></td>
</tr>
<tr>
<td><strong>Report Type</strong></td>
</tr>
<tr>
<td><strong>Assign To</strong></td>
</tr>
<tr>
<td><strong>Forward to Department</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Source Form Type</strong></td>
</tr>
<tr>
<td>✓</td>
</tr>
</tbody>
</table>
```

Generated by: system  Generated on: 03-Sep-2016 19:45:06
### Section A - About the Problem

**What kind of problem was it? (Check all that apply)**
- [x] Were hurt or had a bad side effect (including new or worsening symptoms)
- [ ] Used a product incorrectly which could have or led to a problem
- [ ] Noticed a problem with the quality of the product
- [ ] Had problems after switching from one product maker to another maker

**Did any of the following happen? (Check all that apply)**
- [x] Hospitalization - admitted or stayed longer
- [ ] Required help to prevent permanent harm (for medical devices only)
- [ ] Disability or health problem
- [ ] Birth defect
- [ ] Life-threatening
- [ ] Death
- [x] Other serious/important medical incident

**Date of Death**
- [ ]

**Other serious/important medical incident**
- Severe urticaria in infant

**Date the problem occurred**
- 27-Aug-2016

### Tell us what happened and how it happened (Include as many details as possible)

My child presented with severe [urticaria](https://en.wikipedia.org/wiki/Urticaria) after he was given baby orajel for 3 days as directed. My child still has severe urticaria and is being treated with prednisolone once a day and Benadryl every four hours.

### Section B - About the Products

**Name of the product as it appears on the box, bottle, or package (Include as many names as you see)**
- Orajel Teething swabs

**Name of the company that makes (or compounds) the product**
- Church & Dwight

**Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)**
- Yes

**Expiration date**
- 01-Nov-2018

**Lot number**
- Gp6006

**NDC number**
- [ ]

**Strength (for example, 250 mg per 500 ml or 1g)**
- 7.5 % percent

**Quantity**
- 1 Other

**Frequency**
- 4 times a day

**How was it taken or used**
- Topical

**Date the person first started taking or using the product**
- 17-Aug-2016

**Date the person stopped taking or using the product**
- 19-Aug-2016

**Did the problem stop after the person reduced the dose or stopped taking or using the**
- No
Did the problem return if the person started taking or using the product again? | Doesn't Apply
--- | ---
Do you still have the product in case we need to evaluate it? | Yes

Why was the person using the product? (such as what condition was it supposed to treat)
Teething

Section C - About the Medical Device

Name of the company that makes the medical device
Model #
Catalog #
Serial #
Lot #
Unique Identifier (UDI) #
Expiry Date
Was someone operating the medical device when the problem occurred?

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)
Date the implant was put in | Date the implant was taken out (If relevant)
--- | ---

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Section D - About the Person Who Had the Problem

Person's Initials | 0(6)
--- | ---
Sex | Male
Age (specify unit of time for age) | 5 Month(s)
Date of Birth | 
Weight | 7.2 kg(s)
Ethnicity (Choose only one) | Not Hispanic/Latino
Race (Choose all that apply) | 
- American Indian or Alaskan Native
- Native Hawaiian or Other Pacific Islander
- Asian
- White
- Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
None
Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None

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.

OTHER (CONCOMITANT) MEDICAL PRODUCTS

<table>
<thead>
<tr>
<th>Product Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength</td>
<td>If Other</td>
</tr>
<tr>
<td>Therapy Start Date</td>
<td></td>
</tr>
<tr>
<td>Therapy End Date</td>
<td></td>
</tr>
</tbody>
</table>

Section E - About the Person Filling Out This Form

<table>
<thead>
<tr>
<th>Last name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>First name</td>
<td></td>
</tr>
<tr>
<td>Number/Street</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>State/Province</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
<tr>
<td>ZIP or Postal code</td>
<td></td>
</tr>
<tr>
<td>Telephone number</td>
<td></td>
</tr>
<tr>
<td>Email address</td>
<td></td>
</tr>
<tr>
<td>Today's date</td>
<td>03-Sep-2016</td>
</tr>
<tr>
<td>Did you report this problem to the company that makes the product (the manufacturer/compounder)?</td>
<td>No</td>
</tr>
<tr>
<td>If you do NOT want your identity disclosed to the manufacturer, place an X in this box :</td>
<td></td>
</tr>
</tbody>
</table>
Message Subject:
Received Time: Fri Sep 02 08:38:21 EDT 2016
Sender Address: ylaci.duke@fda.hhs.gov
To Addresses: CDER-CTU-Scan@fda.hhs.gov; ylaci.duke@fda.hhs.gov;
CC Addresses:
No. of Inline/Attachments: 1
DUKEY_090216_083530.pdf

Message content follows:
### MEDWATCH

**The FDA Safety Information and Adverse Event Reporting Program**

Note: For date prompts of "mm-dd-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.

### A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Identifier (b) (e)</td>
<td>98765</td>
</tr>
<tr>
<td>Age</td>
<td>42</td>
</tr>
<tr>
<td>Sex</td>
<td>Female</td>
</tr>
<tr>
<td>Weight</td>
<td>150</td>
</tr>
<tr>
<td>Date of Birth (e.g., 06 Feb 1925)</td>
<td>06-Feb-1925</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Hispanic/Latino</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
</tr>
</tbody>
</table>

### B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply:
   - **Adverse Event**
   - **Product Problem (e.g., defects/malfunctions)**
   - **Problem with Different Manufacturer of Same Medicine**

2. Outcome Attributed to Adverse Event (Check all that apply):
   - Death: Date (mm-dd-yyyy): 01-Aug-2016
   - Life-Threatening
   - Hospitalization - initial or prolonged
   - Other Serious (Important Medical Events)
   - Required Interventions to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm-dd-yyyy): 01-Aug-2016

4. Date of this Report (mm-dd-yyyy): 01-Aug-2016

5. Describe Event, Problem or Product Use Error

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, select/medical problems, etc.)

### C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? (Do not send product to FDA)
   - Yes

2. Returned to Manufacturer on: (mm-dd-yyyy)

### D. SUSPECT PRODUCTS

<table>
<thead>
<tr>
<th>Product</th>
<th>Name, Manufacturer/Compounder, Strength (from product label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant Teething Tablets</td>
<td>50779-860-03</td>
</tr>
<tr>
<td>Homelab Inc (Canada)</td>
<td>1 Lot # 41116</td>
</tr>
<tr>
<td></td>
<td>2 NDC # or Unique ID</td>
</tr>
<tr>
<td></td>
<td>2 Lot #</td>
</tr>
</tbody>
</table>

### E. SUSPECT MEDICAL DEVICE

1. Brand Name

### F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

### G. REPORTER (See confidentiality section on back)

1. Name and Address

2. Health Professional?
   - Yes

3. Occupation

4. Also Reported to:
   - Manufacturer/Compounder
   - User Facility
   - Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: No
B.5. Describe Event or Problem (continued)

On [censored] my daughter [censored] had to be rushed to [censored] hospital. She was seizing for approximately 25 minutes, she was unresponsive, cyanotic and gasping for air, upon arrival EMS gave her diazepam IM and she continued to seize while going to the hospital. Diagnosis at the emergency room was Status Epilepticus. The only new item that was introduced to [censored] was the CVS brand Homeopathic theething tablets. Upon inspection at the emergency room, it was discovered that the CVS pills contained Belladonna. Belladonna is a highly toxic substance that was once used to poison people. Although the percentage of Belladonna per the label is 00000000003%. There has been no significant clinical testing to verify that this product is safe for children from 0-3 years of age, as is shown on the label of the CVS product. I have been in touch with CVS regarding the issue and they referred me to the Manufacturer of the product. The CVS representative stated that they market the product only. The representative also stated that the ingredients of the product are imported from China. As a member of the Law Enforcement community, I believe that this product should be inspected to make sure that it is safe for human consumption especially for children. It also states on the box that the ingredients are foreign sources V-30496.

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

I will send lab results upon request.

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

Medical Conditions: No known medical problems, baby has never been sick or inside a hospital since she was born.

Allergies: No known drug allergies

Important Information: N/A

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

PK Meds: None

CTC Meds: CVS Homeopathic Infants Theething Tablets, No other medication