

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

Disclaimers:

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

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

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

Esub Case ID(s) Printed:

11775061	11778980	11779071	11792162	11803222	11823505	11840826
11867472	11911253	12127275	12224038	12273905	12278506	12281261
12306511	12306848	12311125	12341669	12341756	12388846	12389148
12412557	12424787	12429653	12460888	12726345	12756114	

Run by: STEPPERH

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

Total number of cases (Esub): 27



FOIA Case Report Information

Case ID: 11775061

Case Information:

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

DAY)

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

Patient Information:

Age: Sex: Male Weight:

Suspect Products: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Pyrexia NA
Screaming NA
Seizure NA

Event/Problem Narrative:

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MOTHER POSTED ON (6) (6) 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.

of



FOIA Case Report Information

Case ID: 11775061

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

Sender Organization: STANDARD HOMEOPATHIC 503B Compounding Study Report?: No

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 11778980

Case Information:

Country: USA Event Date: 15-Nov-2015 Case Type: EXPEDITED (15- eSub: Y HP: Outcomes: OT

Application Type: NDA

DAY) FDA Rcvd Date: 25-Nov-2015

Mfr Rcvd Date: 15-Nov-2015 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1044659

Application #: 999999

Patient Information:

Age: 213 DAY Sex: Male Weight:

Suspect Products: Dose/ Compounded

Product Name Drug? Frequency **Dosage Text** Indications(s) **End Date** Route **Start Date**

3 DF/ 1 Baby Teething Oral

Interval 1st **Product Name** DeC ReC Lot# **Exp Date** NDC# MFR/Labeler Dose to Event

1 Baby Teething NA Unk STANDARD HOMEOPATHIC

Event Information:

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ReC Preferred Term (MedDRA @ Version: 18.1

NA Dyskinesia Dyspnoea NA Muscle twitching NA

Seizure NA

Tremor NA



FOIA Case Report Information

Case ID: 11778980

Event/Problem Narrative:

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

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 Histo	ry:					
Disease/Surgical Procedu	ire	Si	tart Date	End Date	Continuing?	
Medical History Product(s	s)	Si	tart Date	End Date	Indications	Events
Relevant Laboratory Da Test Name	ata:	Result	Unit	Normal Low Range	Normal High Range	Info Avail N
Concomitant Products:	<u> </u>					
# Product Name	Dose/ Frequency	Route	Dosage Text	Indio	cations(s) Start Date	End Date Interval 1st Dose to Event



FOIA Case Report Information

Case ID: 11778980

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 11779071

Case Information:

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

DAY)

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: Dose/ Compounded

Frequency **Dosage Text** Indications(s) # Product Name Drug? Route **End Date Start Date**

1 Baby Teething PAIN

Interval 1st **Product Name** DeC ReC Lot# **Exp Date** NDC# MFR/Labeler Dose to Event

1 Baby Teething NA Unk 54973-3127- STANDARD HOMEOPATHIC

Event Information:

ReC Preferred Term (MedDRA @ Version: 18.1

NA Tremor

Event/Problem Narrative:

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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. **Application Type: NDA**



FOIA Case Report Information

Case ID: 11779071

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Medical History Product(s) Start Date **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

Sender Organization: STANDARD HOMEOPATHIC 503B Compounding Study Report?: No

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 11792162

Case Information:

Case Type: EXPEDITED (15eSub: Y HP: Country: USA Event Date: Jan-2015 Outcomes: OT

DAY)

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: Dose/ Compounded Frequency **Dosage Text** # Product Name Route Indications(s) **End Date** Drug? **Start Date** 1 DF/ Oral PAIN 1 Baby Teething Interval 1st **Product Name** DeC ReC **Exp Date** NDC# MFR/Labeler Dose to Event Lot# 1 Baby Teething NA Unk 54973-3127- STANDARD HOMEOPATHIC 1

Event Information:

ReC Preferred Term (MedDRA @ Version: 18.1

NA Ear disorder Febrile convulsion NA NA Seizure

Event/Problem Narrative:

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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 TEMEPERATURES 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.

Application Type: NDA



FOIA Case Report Information

Case ID: 11792162

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal Low Range Normal High Range** Unit

Ν

Concomitant Products:

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

1 INFANTS GAS DROPS .3 ML/ Oral

Reporter Source:

Sender Organization: STANDARD HOMEOPATHIC 503B Compounding Study Report?: No

Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 11803222

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: 25-Nov-2015 Outcomes: LT

DAY)

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: Compounded Dose/

Product Name Drug? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk 54973-3127- STANDARD HOMEOPATHIC

3

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Cardio-respiratory arrest NA

Cyanosis

Respiratory arrest NA

Unresponsive to stimuli NA

10

Application Type: NDA



FOIA Case Report Information

Case ID: 11803222

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 Histor BORN AT 36 WEEKS - SLI	and the second second second second second	IRE. NO FAMILY HI	STORY OF SEIZU	RES.				
Disease/Surgical Procedu	re	s	tart Date	End Date	Continuing?			
Medical History Product(s)	s	tart Date	End Date	Indications		Eve	ents
Relevant Laboratory Da	ta:	.54° v 2.1	0.0	2007000000			2.56	
Test Name		Result	Unit	Normal Low Range	Normal	High Range	Info A	Avail
Concomitant Products:								
# Product Name	Dose/ Frequency	Route	Dosage Text	Indic	cations(s)	Start Date	End Date	Interval 1st Dose to Event



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FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11803222

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 11823505

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: Jul-2015 Outcomes: HO

DAY)

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: Dose/ Compounded Frequency **Dosage Text** # Product Name Route Indications(s) **End Date** Drug? **Start Date** 3 DF/ Oral PAIN 1 Baby Teething Interval 1st **Product Name** DeC ReC Exp Date NDC# MFR/Labeler Dose to Event Lot# Yes Unk A61115 54973-3127- STANDARD HOMEOPATHIC Baby Teething 2

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

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

Application Type: NDA

of



FOIA Case Report Information

Case ID: 11823505

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:

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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.

TWICE. HE IS CURRENTLY	TAKING NO OTHER M	IEDICATIONS.						
Disease/Surgical Procedure		Start	Date	End Date	Continuing?			
Medical History Product(s)		Start	Date	End Date	Indications		Even	ts
Relevant Laboratory Data Test Name	:	Result	Unit	Normal Low Range	e Normal	High Range	Info Av	ail
Concomitant Products:								
# Product Name	Dose/ Ro Frequency	oute	Dosage Text	Indi	cations(s)	Start Date	End Date	Interval 1st Dose to Event



FOIA Case Report Information

Case ID: 11823505

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 11840826

Case Information:

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

DAY)

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: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA NA 54973-3127- STANDARD HOMEOPATHIC

3

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Renal failure NA

Event/Problem Narrative:

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

A HEALTH FOOD STORE EMPLOYEE REPORTED WHAT A CUSTOMER TOLD HER ON 12/04/15 WHILE IN THE STORE, (6) (6) THE CUSTOMER SAID HER 15 MONTH OLD DAUGHTER WAS DIAGNOSED WITH KIDNEY FAILURE AND WAS AT HOME PRESENTLY WAITING FOR A BED AT (10) (6) 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.

16

Application Type: NDA



FOIA Case Report Information

Case ID: 11840826

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

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

Dose to Event

Reporter Source:

Sender Organization: STANDARD HOMEOPATHIC 503B Compounding Study Report?: No

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 11867472

Case Information:

Case Type: EXPEDITED (15- eSub: Y DAY)

HP:

Country: USA Event Date: 12-Dec-2015 Outcomes: HO

FDA Rcvd Date: 24-Dec-2015 Mfr Rcvd Date: 16-Dec-2015 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1045865 Application #: 999999

Application Type: NDA

Patient Information:

Age: 1 YR

Sex: Male

Weight:

Suspect Products:

Compounded Drug?

Interval 1st

Dose/ Frequency

Route

Dosage Text

Indications(s)

Start Date

11-Dec-2015

End Date 11-Dec-2015

Product Name 1 Baby Teething

2 DF/QD

NA

Oral

Product Name Baby Teething

Dose to Event

DeC

ReC No

Lot#

Exp Date

NDC#

PAIN

MFR/Labeler

STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version:

18.1

Dehydration

NA

Febrile convulsion

NA

ReC

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. (b) (6) (b) (6) 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.

(b) (6) HE CONTINUED TO HAVE FEVERS WITH SPIKES UP TO 105.8 WHILE IN THE HOSPITAL.



FOIA Case Report Information

Case ID: 11867472

Preferred Term (MedDRA 🖨 Version:	19.0	ReC	

HE WAS TESTED WITH CHEST X-RAY AND CAT SCAN (ALL NORMAL), AND WAS GIVEN IV FOR DEHYDRATION. DIAGNOSIS WAS: FEBRILE SEIZURES, CAUSE UNKNOWN. (6) (6) 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 (b) (6) ... IT RANGED FROM 102 F TO SPIKES UP TO 105.8 F.

Disease/Surgical Procedure Start Date End Date Continuing?

Medical History Product(s)

Start Date End Date Indications Events

Relevant Laboratory Data:

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Test Name Result Unit Normal Low Range Normal High Range Info Avail

Chest X-ray normal N
CAT SCAN - NORMAL N



FOIA Case Report Information

Case ID: 11867472

Concomitant Products:

Dosage Text Indications(s) # Product Name Dose/ Route Start Date **End Date** Interval 1st

Frequency

Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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FOIA Case Report Information

Case ID: 11911253

Case Information:

Case Type: EXPEDITED (15eSub: Y HP: Country: USA Event Date: 30-Dec-2015 Outcomes: OT

DAY)

FDA Rcvd Date: 12-Jan-2016 Mfr Rcvd Date: 05-Jan-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1046405

Application #: 999999

Application Type: NDA

Patient Information:

Age: 152 DAY Sex: Female Weight:

Suspect Products: Dose/ Compounded

Frequency **Dosage Text** # Product Name Route Indications(s) **End Date** Drug? **Start Date**

1 Baby Teething 1 DF/ Oral TEETHING PAIN

Interval 1st

Product Name DeC ReC **Exp Date** NDC# MFR/Labeler Dose to Event Lot#

1 Baby Teething NA Unk B38216 STANDARD HOMEOPATHIC

Event Information:

ReC Preferred Term (MedDRA @ Version: 18.1

NA Seizure

Event/Problem Narrative:

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

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.

of



Study Report?: No

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

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 11911253

Sender Organization: STANDARD HOMEOPATHIC

Relevant Medical History NO RECENT IMMUNIZATIO		HISTORY OF SEIZ	JRES, WAS NOT B	ORN PREMATUI	RE.			
Disease/Surgical Procedure	e		Start Date	End Date	Continuing	?		
Medical History Product(s)		\$	Start Date	End Date	Indications		Eve	ents
Relevant Laboratory Dat	a:							
Test Name		Result	Unit	Normal Low	Range Norma	al High Range	Info A	Avail
Concomitant Products:								
# Product Name	Dose/ Frequency	Route	Dosage Text		Indications(s)	Start Date	End Date	Interval 1st Dose to Event
Reporter Source:								

503B Compounding

Outsourcing Facility?:



DAY)

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12127275

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: 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: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething Oral TEETHING PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Seizure NA

Event/Problem Narrative:

FATHER REPORTED ON (b) (6) THAT HIS SON HAS HAD TWO SEZIURES FOLLOWING THE USE OF BABY TEETHING TABLETS AND IS CURRENTLY HOSPITALIZED.



FOIA Case Report Information

Case ID: 12127275

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12224038

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: 10-Sep-2015 Outcomes: OT

DAY)

FDA Rcvd Date: 30-Mar-2016 Mfr Rcvd Date: 23-Mar-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1049998

Application Type: NDA

Application #: 999999

10-Sep-2015

10-Sep-2015

Patient Information:

Age: Sex: Male Weight:

Suspect Products: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral

Interval 1st

Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething Unk Unk STANDARD HOMEOPATHIC

Event Information:

Product Name

Preferred Term (MedDRA @ Version: 18.1) ReC

Seizure NA

Event/Problem Narrative:

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

HYLAND'S RECEIVED WRITTEN CORRESPONDENCE THAT A CHILD EXPERIENCED A SEIZURE AFTER INGESTION OF A TABLET.

25

TEETHING PAIN



FOIA Case Report Information

Case ID: 12224038

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12273905

Case Information:

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

DAY)

Mfr Rcvd Date: 04-Apr-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1050623 FDA Rcvd Date: 15-Apr-2016 Application #: 999999

Patient Information:

Age: 1 YR Sex: Male Weight:

Suspect Products: Dose/ Compounded

Product Name Frequency **Dosage Text End Date** Drug? Route Indications(s) **Start Date**

Baby Teething Oral **TEETHING PAIN**

2 HYLAND'S TEETHING

GEL

Interval 1st NDC# **Product Name** Dose to Event DeC ReC Lot# **Exp Date** MFR/Labeler

Baby Teething NA Unk 54973-3127 STANDARD HOMEOPATHIC

2 HYLAND'S TEETHING Unk Unk 54973-7521-2

GEL

Event Information:

ReC Preferred Term (MedDRA @ Version: 18.1

Drug withdrawal syndrome NA

NA Petit mal epilepsy

Seizure NA **Application Type: NDA**



FOIA Case Report Information

Case ID: 12273905

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 Hist	ory:					
Disease/Surgical Proced	dure	Si	art Date	End Date	Continuing?	
Medical History Product	t(s)	Si	art Date	End Date	Indications	Events
Relevant Laboratory [Test Name	Data:	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Concomitant Product	s:					N
# Product Name	Dose/ Frequency	Route	Dosage Text	Indio	cations(s) Start Date	End Date Interval 1st Dose to Event



FOIA Case Report Information

Case ID: 12273905

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 12278506

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: 06-Apr-2016 Outcomes: LT, Application Type: NDA

DAY)

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: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral

TEETHING PAIN 06-Apr-2016 06-Apr-2016

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk B30715 STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Aspiration

Choking

Crying

Dyspnoea

Screaming



FOIA Case Report Information

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 His	tory:					
Disease/Surgical Proce	edure	Sta	art Date	End Date	Continuing?	
Medical History Produc	ct(s)	Sta	art Date	End Date	Indications	Events
Relevant Laboratory	Data:					hata Assall
Test Name		Result	Unit	Normal Low Range	Normal High Range	Info Avail N
Concomitant Product	ts:					
# Product Name	Dose/ Frequency	Route	Dosage Text	Indic	cations(s) Start Date	End Date Interval 1st Dose to Event



FOIA Case Report Information

Case ID: 12278506

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 12281261

Case Information:

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

DAY)

FDA Rcvd Date: 19-Apr-2016 Mfr Rcvd Date: 07-Apr-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1050701 Application #: 999999

Patient Information:

Age: Sex: Female Weight:

Suspect Products: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething Oral TEETHING PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething Unk Unk STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Status epilepticus NA

Event/Problem Narrative:

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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.

33

Application Type: NDA



FOIA Case Report Information

Case ID: 12281261

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12306511

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: 10-Apr-2016 Outcomes: HO,OT

Application Type: NDA

FDA Rcvd Date: 26-Apr-2016

DAY)

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: Compounded Dose/

Product Name Drug? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething Oral TEETHING PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk A24214 STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 18.1) ReC

Seizure NA

Event/Problem Narrative:

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

A BABY WAS GIVEN BABY TEETHING TABLETS, DEVELOPED SEIZURES AND HAS BEEN HOSPITALIZED SINCE APPROXIMATELY (b) (6) THE BABY WAS SEDATED IN THE HOSPITAL WITH MEDICATION TO CALM THE BABY DOWN. THE BABY REMAINS HOSPITALIZED.



FOIA Case Report Information

Case ID: 12306511

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

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

Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12306848

Case Information:

Case Type: EXPEDITED (15eSub: Y HP: Country: USA Event Date: 09-Apr-2016 Outcomes: HO

DAY)

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: Dose/ Compounded

Frequency **Dosage Text** # Product Name Route Indications(s) **End Date** Drug? **Start Date**

1 DF/ Oral TEETHING PAIN 15-Mar-2016 1 Baby Teething

Interval 1st

Product Name DeC ReC **Exp Date** NDC# MFR/Labeler Dose to Event Lot#

1 Baby Teething Unk Unk B38415 STANDARD HOMEOPATHIC

Event Information:

ReC Preferred Term (MedDRA @ Version: 18.1

NA Cerebral haemorrhage

Event/Problem Narrative:

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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 (b) (6) 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 (b) (6) WHERE THE DOCTORS DIAGNOSED CHILD'S CONDITION AS "BLEEDING ON HIS BRAIN." CHILD WAS DISCHARGED ON (b) (6) CHILD IS AT HOME NOW. SWELLING IS YET TO GO DOWN.

of

Application Type: NDA



FOIA Case Report Information

Case ID: 12306848

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12311125

Case Information:

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

DAY)

FDA Rcvd Date: 27-Apr-2016 Mfr Rcvd Date: 18-Apr-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1051095 Application #: 999999

Patient Information:

Suspect Products:

COLD TABLETS

Age: 1 YR Sex: Female Weight:

Product Name Drug? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral TEETHING PAIN,

Baby reetning PAIN,
BODY TEMPERATURE
INCREASED

2 HYLAND'S BABY TINY Oral

Interval 1st
Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk B51715 STANDARD HOMEOPATHIC

2 HYLAND'S BABY TINY NA Unk COLD TABLETS

Event Information:

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Preferred Term (MedDRA @ Version: 18.1) ReC

Seizure NA

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Application Type: NDA



FOIA Case Report Information

Case ID: 12311125

Event/Problem Narrative:

CHILD WAS HOSPITALIZED (6) (6) FOR SEIZURES. CUSTOMER STATED THAT CHILD STARTED HAVING SEIZURES A MONTH AGO. LAST USE OF TEETHING TABLETS AND TINY COLD TABLETS PRIOR TO THE THE FIRST SEIZURE OCCURRING 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 Laboratory Data: Test Name	Result Unit	Normal Low Range	Normal High Range	Info Avail
Medical History Product(s)	Start Date	End Date	Indications	Events
Disease/Surgical Procedure	Start Date	End Date	Continuing?	
NEUROLOGIST. Disease/Surgical Procedure	Start Date	End Date	Continuing?	



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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12311125

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 12341669

Case Information:

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

DAY)

FDA Rcvd Date: 06-May-2016 Mfr Rcvd Date: 24-Apr-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1051563 Application #: 999999

Patient Information:

Age: Sex: Male Weight:

Suspect Products: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething Oral TEETHING PAIN 20-Apr-2016

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 19.0) ReC

Seizure NA

Event/Problem Narrative:

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MOTHER POSTED ON (6) (6) THAT HER SON HAD A SEIZURE AFTER TAKING THE TABLETS.

of

Application Type: NDA



FOIA Case Report Information

Case ID: 12341669

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12341756

Case Information:

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

DAY)

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: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething Oral TEETHING PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA & Version: 19.0) ReC

Generalised tonic-clonic seizure NA

Event/Problem Narrative:

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

MOTHER POSTED ON (b) (6) 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.

Application Type: NDA



FOIA Case Report Information

Case ID: 12341756

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12388846

Case Information:

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

DAY)

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: Dose/ Compounded

Product Name Drug? Frequency **Dosage Text** Indications(s) **End Date** Route **Start Date**

1 DF/ 1 Baby Teething Oral TEETHING PAIN, Apr-2016 Apr-2016

FEVER

Interval 1st **Product Name** DeC ReC Lot# Exp Date NDC# MFR/Labeler Dose to Event

Baby Teething NA No B80015 STANDARD HOMEOPATHIC

Event Information:

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

ReC Preferred Term (MedDRA @ Version: 19.0

NA Pyrexia

Rash NA

NA Seizure

Vomiting NA



FOIA Case Report Information

Case ID: 12388846

Event/Problem Narrative:

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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 Historian FATHER HAD SEIZURES	•	TTLE.					
Disease/Surgical Proced	lure	Sta	art Date	End Date	Continuing?		
Medical History Product((s)	Sta	art Date	End Date	Indications	Events	
Relevant Laboratory D Test Name	Data:	Result	Unit	Normal Low Range	Normal High Range	Info Avail	
						N	
Concomitant Products	s:						
# Product Name	Dose/ Frequency	Route	Dosage Text	Indic	cations(s) Start Date	End Date Interval 1st Dose to Event	



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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12388846

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 12389148

Case Information:

Case Type: EXPEDITED (15-HP: Country: USA Event Date: 2016 Outcomes: HO eSub: Y

DAY)

FDA Rcvd Date: 20-May-2016 Mfr Rcvd Date: 09-May-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1052539 Application #: 999999

Patient Information:

Age: 167 DAY Sex: Male Weight:

Suspect Products: Dose/ Compounded

Frequency **Dosage Text** # Product Name Route Indications(s) **End Date** Drua? **Start Date**

BABY TEETHING GEL Topical

(HYLAND HOMEOPATHIC)

Interval 1st

Product Name Dose to Event DeC ReC Lot# **Exp Date** NDC# MFR/Labeler

BABY TEETHING GEI STANDARD HOMEOPATHIC NA Unk

(HYLAND

HOMEOPATHIC)

Event Information:

Preferred Term (MedDRA @ Version: 19.0

NA Seizure

Event/Problem Narrative:

THE REPORTER'S SON, WHO IS 5.5 MONTHS OLD, HAS EXPERIENCED 4 SEIZURES SINCE BEGINNING USE OF THE "TEETHING GEL" PRODUCT. THE REPORTER BEGAN USING THE PRODUCT ON THE CHILD WHEN HE WAS "A LITTLE OVER 2 MONTHS OLD." SHE STATED THAT THEY USED THE PRODUCT AS NEEDED, EVERY TWO OR THREE DAYS. THE REPORTER STATED THAT SHE DID NOT USE THE PRODUCT DAILY. THE CHILD EXPERIENCED HIS FIRST SEIZURE AT THE AGE OF 3 MONTHS. THE REPORTER STATED THAT THE CHILD'S EYES ROLLED BACK INTO HIS HEAD, AND HE BECAME UNRESPONSIVE AND STIFF. SHE STATED THAT THIS EPISODE LASTED FOR 5 MINUTES. PER THE REPORTER, EACH OF THE CHILD'S 4 SEIZURES HAVE BEEN THE SAME. PER THE REPORTER, THE CHILD'S DOCTOR STATED THAT IT SOUNDS AS THOUGH THE CHILD IS HAVING SEIZURES: PER THE REPORTER. THE CHILD HAS HAD AN EEG AND A CT SCAN, BOTH OF WHICH HAVE BEEN NORMAL, THE CHILD HAS AN APPOINTMENT FOR AN MRI ON MAY 24TH: THE REPORTER STATED THAT THE MRI SHOULD GIVE THEM MORE INFORMATION THAN THE CT SCAN. PER THE REPORTER. THE DOCTOR

Application Type: NDA

2016

TEETHING PAIN

ReC



FOIA Case Report Information

Case ID: 12389148

TOLD HER THAT THEY WERE "GOING TO LOOK FOR A CAUSE" OF THE SEIZURES. THE CHILD'S LAST SEIZURE OCCURRED ON (b) (6) THE REPORTER STATED THAT THEY WENT TO THE HOSPITAL ON THIS DATE AND THAT THEY DISCONTINUED USING THE PRODUCT ON THIS DATE.

# Product Name	Dose/ Frequency	Route	Dosage Text	India	cations(s) Start Date	End Date	Interval 1st Dose to Event
Concomitant Produc	ts:	2.4		1 1 1 1 1 1 1 1	0.70 (9.0)		
						N	
Test Name		Result	Unit	Normal Low Range	Normal High Range	Info A	vail
Relevant Laboratory	Data:						
Medical History Produc	ct(s)	St	art Date	End Date	Indications	Eve	nts
Seasonal allergy							
Disease/Surgical Proce	edure	St	art Date	End Date	Continuing?		
SEASONAL ALLERGIE	S						
Relevant Medical His	story:						



FOIA Case Report Information

Case ID: 12389148

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:



FOIA Case Report Information

Case ID: 12412557

Case Information:

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

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

Application #: 999999

Application Type: NDA

Patient Information:

Suspect Products:

FDA Rcvd Date: 08-Jun-2016

Age: 152 DAY Sex: Female Weight:

Interval 1st

Dose/ Compounded # Product Name Frequency Route **Dosage Text** Indications(s) **End Date Start Date** Drug? 1 Baby Teething 1 DF/ Oral TEETHING PAIN 2009 2010

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Yes 105830 STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA @ Version: 19.0) ReC

Seizure NA

Event/Problem Narrative:

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

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.



Literature Text:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12412557

Relevant Medical Histor FAMILY HISTORY OF SEIZ SEIZURES.	-	F-SIBLINGS FRO	M FATHER'S SIDE H	IAD FEBRILE SEIZU	JRES AS INFAN	TS. CHILD HAI	O A FEVER FO	OR FOUR OF THE FIVE
Disease/Surgical Procedu	re		Start Date	End Date	Continuing	?		
Medical History Product(s)		Start Date	End Date	Indications		Eve	ents
Relevant Laboratory Da Test Name	ta:	Result	Unit	Normal Low Rar	nge Norma	al High Range	Info A	Avail
Concomitant Products:								
# Product Name	Dose/ Frequency	Route	Dosage Text	lı	ndications(s)	Start Date	End Date	Interval 1st Dose to Event
Reporter Source: Study Report?: No	Sender Ord	ganization: STAN	DARD HOMEOPATH	IC		503B Comp	ounding	

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Outsourcing Facility?:



FOIA Case Report Information

Case ID: 12424787

Case Information:

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

DAY)

Mfr Rcvd Date: 17-May-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1053003 FDA Rcvd Date: 01-Jun-2016 Application #: 999999

Patient Information:

Age: Sex: Male Weight:

Suspect Products: Dose/ Compounded

Frequency **Dosage Text** Indications(s) **End Date** # Product Name Drug? Route **Start Date**

1 Baby Teething 1 DF/ Oral **TEETHING PAIN**

Interval 1st

Product Name DeC ReC Lot# **Exp Date** NDC# MFR/Labeler Dose to Event

1 Baby Teething Unk Unk STANDARD HOMEOPATHIC

Event Information:

ReC Preferred Term (MedDRA @ Version: 19.0

Seizure NA

Event/Problem Narrative:

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TARGET STORE REPORTED BY E-MAIL THAT CUSTOMER'S SON SUFFERED A SEIZURE AFTER TAKING A BABY TEETHING TABLET.

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Application Type: NDA



FOIA Case Report Information

Case ID: 12424787

Relevant Medical History:

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Test Name Info Avail Result **Normal High Range** Unit **Normal Low Range**

Ν

Concomitant Products:

Dosage Text Start Date # Product Name Dose/ Route Indications(s) **End Date** Interval 1st

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12429653

Case Information:

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

DAY)

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

Patient Information:

Age: 304 DAY Sex: Male Weight:

Suspect Products: Compounded Dose/

Product Name Drug? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral TEETHING PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Yes STANDARD HOMEOPATHIC

Event Information:

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

Preferred Term (MedDRA @ Version: 19.0) ReC

Body temperature abnormal NA

Flushing

Muscle twitching NA

Staring

Unresponsive to stimuli NA

56

Application Type: NDA



FOIA Case Report Information

Case ID: 12429653

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 His	tory:						
Disease/Surgical Proce	dure	Sta	art Date	End Date	Continuing?		
Medical History Produc	et(s)	Sta	art Date	End Date	Indications	Events	
Relevant Laboratory Test Name	Data:	Result	Unit	Normal Low Range	Normal High Range	Info Avail	
Concomitant Product	ts:					N	
# Product Name	Dose/ Frequency	Route	Dosage Text	Indic	cations(s) Start Date		rval 1st se to Event



FOIA Case Report Information

Case ID: 12429653

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

58

of



FOIA Case Report Information

Case ID: 12460888

Case Information:

Application Type: NDA Case Type: EXPEDITED (15eSub: Y HP: Country: USA Event Date: 2016 Outcomes: HO,OT

DAY)

Mfr Rcvd Date: 30-May-2016 Mfr Control #: US-STANDARD HOMEOPATHIC COMPANY-1053730 FDA Rcvd Date: 13-Jun-2016 Application #: 999999

Patient Information:

Age: 152 DAY Sex: Male Weight:

Suspect Products: Dose/ Compounded

Frequency **Dosage Text** # Product Name Route Indications(s) **End Date** Drug? **Start Date**

1 Baby Teething 1 DF/ Oral TEMPERATURE Mar-2016 Apr-2016

INCREASED.

TEETHING PAIN

Interval 1st # Product Name Dose to Event DeC ReC Lot# **Exp Date** NDC# MFR/Labeler

STANDARD HOMEOPATHIC Baby Teething NA NA

Event Information:

ReC Preferred Term (MedDRA @ Version: 19.0

NA Seizure

Event/Problem Narrative:

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

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.



Literature Text:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12460888

Relevant Medical History: NOT BORN PREMATURE, NO FAMILY HISTORY OF SEIZURES. Continuing? **Disease/Surgical Procedure Start Date End Date** Start Date Medical History Product(s) **End Date** Indications **Events Relevant Laboratory Data: Test Name** Info Avail Result **Normal High Range** Unit **Normal Low Range** Ν **Concomitant Products:** # Product Name Dose/ **Dosage Text** Indications(s) **End Date** Route Start Date Interval 1st Frequency Dose to Event **Reporter Source:** 503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC **Outsourcing Facility?:**



FOIA Case Report Information

Case ID: 12726345

Case Information:

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

DAY)

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

Application #: 999999

Application Type: NDA

Patient Information:

Age: 182 DAY Sex: Female Weight:

Suspect Products: Compounded Dose/

Product Name Drug ? Frequency Route Dosage Text Indications(s) Start Date End Date

1 Baby Teething 1 DF/ Oral BODY TEMPERATURE Jun-2016

INCREASED, TEETHING PAIN

Interval 1st

Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Baby Teething NA Unk STANDARD HOMEOPATHIC

Event Information:

Preferred Term (MedDRA & Version: 19.0) ReC

Seizure NA

Event/Problem Narrative:

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

MOTHER STATES THAT WITHIN (6) HOURS OF USING THE BABY TEETHING TABLETS FOR THE FIRST TIME CHILD HAD A SEIZURE. ALL TOGETHER CHILD HAD 4 SEIZURES- ONE IN (6) (6) TWO IN (6) (6) AND ONE IN (6) (6) CHILD WAS TAKEN TO CHILDREN'S HOSPITAL. THE MORNING THAT CHILD WENT TO THE HOSPITAL ER, SHE WAS GIVEN BTET AND WITHIN A COUPLE OF HOURS SHE HAD A SEIZURE. EACH SEIZURE HAPPENED WHILE CHILD WAS NURSING OR FALLING ASLEEP; CHILD CLAMPED DOWN, GOT STIFF AND RIGID AND STARTED TO SHAKE. MOTHER WOULD GENTLY SHAKE HER AND SHE WOULD WAKE UP. AFTER MOTHER DISCONTINUED THE TABLETS, THE SEIZURES STOPPED.



FOIA Case Report Information

Case ID: 12726345

Relevant Medic	cal History:
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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.

Continuing? **Disease/Surgical Procedure Start Date End Date**

Start Date Medical History Product(s) **End Date** Indications **Events**

Relevant Laboratory Data:

Info Avail **Test Name** Result Unit **Normal Low Range** Normal High Range

Ν

Concomitant Products:

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

Frequency Dose to Event

Reporter Source:

503B Compounding Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

Outsourcing Facility?:

Literature Text:

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



FOIA Case Report Information

Case ID: 12756114

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Event Date: 05-Sep-2016 Outcomes: LT

DAY)

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 Weight:

Suspect Products: Dose/ Compounded

Product Name Frequency **Dosage Text End Date** Drug? Route Indications(s) **Start Date**

Baby Teething 1 DF/ Oral **TEETHING PAIN** 05-Sep-2016

05-Sep-2016 2 GRIPE WATER (DIETARY Oral

SUPPLEMENT)

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

Interval 1st MFR/Labeler **Product Name** Dose to Event DeC ReC Lot# **Exp Date** NDC#

Baby Teething NA Unk STANDARD HOMEOPATHIC

2 GRIPE WATER (DIETARY NA Unk SUPPLEMENT)

Event Information:

ReC Preferred Term (MedDRA @ Version: 19.0

Choking NA

NA Dysphagia

63

Application Type: NDA



FOIA Case Report Information

Case ID: 12756114

Event/Problem Narrative:

CUSTOMER REPORTED ON (b) (6) 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.

/: STERED UNKNOV	WN BRAND OF GRI	PE WATER (NO PR	RIOR REACTIONS TO G	GRIPE WATER).		
е	s	tart Date	End Date	Continuing?		
	s	tart Date	End Date	Indications	Ever	nts
a:		0.00	ar Trails			- 2.0
	Result	Unit	Normal Low Range	Normal High Range	Info Av	/ail
Dose/ Frequency	Route	Dosage Text	Indic	cations(s) Start Date	End Date	Interval 1st Dose to Event
	a: Dose/	STERED UNKNOWN BRAND OF GRIS S S a: Result Dose/ Route	STERED UNKNOWN BRAND OF GRIPE WATER (NO PROBLEM START Date Start Date Start Date Result Unit Dose/ Route Dosage Text	STERED UNKNOWN BRAND OF GRIPE WATER (NO PRIOR REACTIONS TO Go Start Date End Date Start Date End Date a: Result Unit Normal Low Range Dose/ Route Dosage Text Indic	STERED UNKNOWN BRAND OF GRIPE WATER (NO PRIOR REACTIONS TO GRIPE WATER). Start Date End Date Continuing? Start Date End Date Indications a: Result Unit Normal Low Range Normal High Range Dose/ Route Dosage Text Indications(s) Start Date	STERED UNKNOWN BRAND OF GRIPE WATER (NO PRIOR REACTIONS TO GRIPE WATER). Start Date End Date Continuing? Start Date End Date Indications Ever a: Result Unit Normal Low Range Normal High Range Info Av N Dose/ Route Dosage Text Indications(s) Start Date End Date



FOIA Case Report Information

Case ID: 12756114

Reporter Source:

Study Report?: No Sender Organization: STANDARD HOMEOPATHIC

503B Compounding Outsourcing Facility?:

Literature Text:

Printer: CDPEDQ5
User: STEPPERH

Date - Time: 04-Nov-2016 08:50 AM Total Number of Cases (Non-Esub): 65

Total Number of Pages: 253 Print Job Number: 12987

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	11614860	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

CacalD: 11008860

Individual Case Safety Report



11008869-01-00-01

y user-facilities, itors and manufacturers (TORY reporting

11 of 5

	Form Appro	ved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse
r-facilities,	Mfr Report #	4
and manufacturers Y reporting	UF/Importer Report #	
5		FDA Use Only
C. SUSPECT PROD	UCT(S)	
Name (Give labeled street	ngth & mfr/labeler)	
#1 HYLAND'S BABY	TEETHING TABLET	'S'
#2		
#1 2TABSLAM3/1063 #2 4. Diagnosis for Use (India #1 TEMP RELIEF TE	3/11;1TABSL #1 APR 0 8 20 52 eation)	5. Event Abated After Use Stopped or Dose Reduced?
#2	WARK	#1 Yes No. Doesn't Apply
6. Lot #	7. Exp. Date	#2 Yes No Doesn't
#1A08815	#1	8. Event Reappeared After Reintroduction?
#2	#2	#1 Yes No Poesn't
9. NDC# or Unique ID 54973-3127-1		#2 Yes No Doesn't
10. Concomitant Medical I	Products and Therapy D	ates (Exclude treatment of event) (Continue on page 3)

(mm/dd/yyyy)

(Continue on page 3)

Initial Reporter Also Sent Report to FDA

Yes No V Unk

D. SUSPECT MED	ICAL DEVICE		Continue on page 3)
I. Brand Name			
2. Common Device Nam	e	2b.	Procode
3. Manufacturer Name, C	ity and State		
1. Model #	Lot#		5. Operator of Device
Catalog #	Expiratio	n Date (mm/dd/yyyy)	Health Professional Lay User/Patient
Serial #	Unique la	dentifier (UDI) #	Other:
6. If implanted, Give Date	e (mm/dd/yyyy)	7: If Explanted, G	ive Date (mm/dd/yyyy)
6. Is this a Single-use De	vice that was Re	processed and Reus	ed on a Patient?

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

E. INITIAL REPORTER

2. Health Professional? 3. Occupation

NA

1. Name and Address

Yes V No

(b) (6)

(b) (6) USA

(b) (b)

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

DSS

Email Address

APR -9 2015 APR - 8 2015

1. Patient Identifier	2. Age at Time		3. Sex	4. Weight
(b) (6)	of Event: B	Months	1	
1	or		☑ Female	or
In confidence	of Birth:		Male	1
B. ADVERSE E	VENT OR PRODU	JCT PROBLE	EM	
1. 📝 Adverse Even		roduct Problem	(e.g., defects/malf	unctions)
(Check all that app	ted to Adverse Event			
Death:	(mm/dd/yyyy)	Disability	or Permanent Da	mage
Life-threatening		Congenit	al Anomaly/Birth [Defect
	n - initial or prolonged	121	rious (Important M	
	rvention to Prevent Pen		Dr. Calledon I. M.	
3. Date of Event (mr. 03/1	13/2015	4. Date of the	s Report (mm/de 03/26/2015	
5. Describe Event or		- L		
WAS FINE. CH	ILD WILL FOLLO	w-OF WITH	THE NEUROLC	eist.
6. Relevant Tests/La	boratory Data, Includi	ing Dates	(Continue or	n page 3)
race, pregnancy, sn	story, Including Preex roking and alcohol use BROTHER AND C	, hepatic/renal dy	sfunction, etc.)	

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

CaseID: 11008869

Individual Case Safety Report

11008869-01-00-02

User Facility	[] Imp	orter			
3. User Facility or Imp	orter Name	e/Address			
' '					
			T= =.		
4. Contact Person			5. Phone I	Number	
		/-	<u> </u>	la n	(7): 5
6. Date User Facility o Importer Became		7. Type of Repo	ort	8. Date of	of This Report (d/yyyy)
Aware of Event (mm	n/dd/yyyy)	Initial		1	
		Follow-up #	<u></u>	.	
9. Approximate	10. Event	Problem Codes	(Refer to coo	ling manual)
Age of Device	Patient [
	Code				
	Device Code		-		
11. Report Sent to FDA		12. Location	Where Event	Occurred	
l _ '	•	Location			tpatient
Yes(mm/dd.	/уууу)	Home			agnostic Facility
Ŭ NO]	g Home	☐ år	nbulatory irgical Facility
13. Report Sent to Mar	nufacturer'		tient Treatme		irgical Facility
Yes(mm/dd.	· · · · ·	Facilit			
No (mm/dd.	(YYYY)	Other	 	(Specif	
14. Manufacturer Name	o/Address			(Specii)	77
14. Mailulacturer Haisi					
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

	FDA USE ONLY			
_				
f <u>5</u>				
H. DEVICE MANUFACTURERS ONLY				
1. Type of Reportable Event	2. If Follow-up, What Typ-e?			
Death	Correction			
Serious Injury	Additional Information			
Malfunction	Response to FDA Request			
_	Device Evaluation			
3. Device Evaluated by Manufacturer?	4. Device Manufacture Date			
Not Returned to Manufacturer	(mm/yyyy)			
Yes Evaluation Summary Attached				
No (Attach page to explain why not) or	5. Labeled for Single Use ?			
provide code:				
	Yes No			
6. Event Problem and Evaluation Codes (Refer to	coding manual)			
Patient				
Code				
Device Code	-			
COME				
Method				
Results				
results				
Conclusions -	- - -			
7. If Remedial Action Initiated, Check Type	3. Usage of Device			
	☐ Initial Use of Device			
Recall Notification	Reuse			
Repair Inspection Replace Patient Monitoring	Unknown			
	9. If action reported to FDA under 21 USC 360i(f), list correction/			
Adjustment	21 USC 360i(f), list correction/ removal reporting number:			
Other:				
10. Additional Manufacturer Narrative	and / or 11. Corrected Data			
	•			
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	DSS			
	APR = 9 2015			
	F # 17			
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CUSTOMER COMPLAINT RECORD

	OPATHIC -	CUSTOMER COMPLAINT RECORD			thylands 7000		
SECTION I:	COMPLAINT		501A-505			5243	
		a description of the		AINT #:	2614	2013	
AKEN BY:	482 115 115	EDYTA FRACKIEWICZ	DATE OF COMP		03/23/2015		
PRODUCT: SIZE:		BY TEETHING TABLETS	S TABLETS ITEM CODE:				
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DDRESS:	>						
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cc: QA/QC Packaging

Production Shipping / Receiving

APR - 2015

CaseID: 11008869



Serious Adverse Event SAE-0013-2015

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 units have been distributed.

Review of Records:

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

The Quality Control analysis was reviewed and indicated all results, including microbial, were within specification for Hyland's Baby Teething Tablets lot # A08815. The Baby Teething bulk lot # 124034 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

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

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

Other investigations:

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

Prepared by

Data

128/15

Individual Case Safety Report

11008869-01-00-04

DSS APR - 9 2015

APR - 8 2015





SERIOUS ADVERSE EVENT DATA FORM

#:160	04	COMPLAINT #:				
CTION I:	PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)					
ME:	(b) (6)					
DRESS:						
r¥;		STATE: (b)(6)				
UNTRY:	USA	ZIP CODE:				
ONE #:	(b) (6)					
CTION II:	PACKAGING INFORMATION:					
	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)				
Individualism Immunity with Information and Information Individual Information Individual Individua	and subtract of the control of the c	Teething Tablets Total Transmission of the Control				
CTION III:	CORRECTIVE ACTION:					
RRECTIVE A	ACTION(S) COMPLETED BY:	DATE:				
CTION IV:	Vo.	APR -9:				
VIEWED BY	MANAGEMENT BY:	UUUT DATE: 03-30-15				
		DATE: 03-27-15				

ISTRIBUTION: FDA ADVERSE EVENT FIL

Individual Case Safety Report

11008869-01-00-05

FORM SAE01

11012669-01-00-01 A. PATIENT INFURINATION Patient Identifier 2. Age at Time 4. Weight of Event: Months Female OF Date Male of Birth: kgs B. ADVERSE EVENT OR PRODUCT PROBLEM ✓ Adverse Event and/or Product Problem (e.g., defects/malfunctions) Outcomes Attributed to Adverse Event (Check all Ihat apply) Death: Disability or Permanent Damage ✓ Life-threatening Congenital Anomaly/Birth Defect Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd/yyyy) 03/19/2015 03/24/2015 5. Describe Event or Problem MOTHER POSTED ON (b) (6) THAT HYLAND'S BABY TEETHING TABLETS DID NOT DISSOLVE, CHILD WAS CHOKING ON THEM, AND MOTHER HAD TO PERFORM THE HEIMLICH MANEUVER. PLEASE TYPE OR USE BLACK INK

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

RECEIVED

APR 0 9 2015

(Continue on page 3)

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

(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.

aser-facilities, ors and manufacturers

ORY reporting

CaseID: 11012660
Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse. Mfr Report # 54973 UF/Importer Report #

f 5		\cap	FDA Use On
C. SUSPECT		يعنب	
	led strength & mfr/labeler) BABY TEETHING TAB	FETTE	
	DIDY INDITING TAB	DELO	
#2			
2. Dose, Frequenc	y & Route Used 3	from/to (or best	(If unknown, give duration) estimate)
#1 UNKNOWN		#1	
#2	11	#2	
4. Diagnosis for Us	Marie Carlo Carlo and Carlo	Stone	Abated After Use bed or Dose Reduced?
#1 TEMP RELI	EF OF TEETHING PAI	N _	Yes No Doesn
#2		#2 🗆	Yes No Doesn
6. Lot #	7. Exp. Date	-	Apply
#1	#1		Reappeared After roduction?
#2	#2	#1 🔲	Yes No Doesn
54973-3127		#2 🗔	Vac Dala Doesn
400000000000000000000000000000000000000	edical Products and Therap		- Apply
D SUSPECT N	MEDICAL DEVICE	(0	Continue on page 3)
I. Brand Name	ALDICAL DEVICE		
2. Common Device	Nama	126.8	Procode
Common Device	Name	20.1	rocode
3. Manufacturer Na	me, City and State		
. Model#	Lot#		5. Operator of Device
Catalan II	5.1.2.5	160	Health Professional
Catalog #	Expiration Date	te (mm/dd/yyyy)	Lay User/Patient
Serial #	Unique Identif	ier (UDI) #	Other:
. If Implanted, Giv	e Date (mm/dd/yyyy) 7.	If Explanted, Gi	ve Date (mm/dd/yyyy)
3,000,000,000	0.127,000,004,0	0.000	*****
	se Device that was Reproce	ssed and Reuse	d on a Patient?
	No 8, Enter Name and Address	s of Reprocesso	,
			DSS
0. Device Available	e for Evaluation? (Do not see	nd to FDA)	APR 1 0 2015
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1 Concomitant II			(mm/dd/yyyy)
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. Health Profession	man de la		nitial Reporter Also Sent Report to FDA
Yes V No	NA NA		Yes No V Unk.

CaseID: 11012660

Individual Case Safety Report

11012660-01-00-02

3. User Facility or Imp	norter Nam				
5. Oser racinty or mi	porter mair	ie/Address			

4. Contact Person			5. Phone N	Number	
6 Data Haar Facility		T			
Date User Facility of Importer Became		7. Type of Repor	rt	8. Date	of This Report
Aware of Event (mn	n/aa/yyyy)	☐ Initial			
		Follow-up#		.]	
Approximate Age of Device	10. Event	Problem Codes (/	Refer to cod	ing manua	a/)
Age of Bevice	Patient [Γ		
	Code		<u> </u>		
	Device Code]-	-	-	
11. Report Sent to FDA		12. Location W	here Event	Occurred	
Yes		Hospital			utpatient
No (mm/dd/	(уууу)	Home		Di	agnostic Facility
13. Report Sent to Man	ufacturer'		Home		mbulatory urgical Facility
_ `		Outpatie	ent Treatmer		
Yes	<i>(YYYY</i>)	Facility			
I 🗀 😘		Other: _		(Specif	(y)
	Address				
14. Manufacturer Name					
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This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

		FDA USE ONLY
: 5		
H. DEVICE MANUFA	CTUDEDS ONL	V
Type of Reportable Ever		
Death		2. If Follow-up, What Type?
Serious Injury		Correction
Malfunction		Additional Information
- Wallanction		Response to FDA Request
		Device Evaluation
3. Device Evaluated by Mar		Device Manufacture Date
Not Returned to Mar		(mm/yyyy)
Yes Evaluation	on Summary Attached	
No (Attach page to e	əxplain why not) or	5. Labeled for Single Use?
provide code.		☐Yes ☐No
C F		
6. Event Problem and Evalu	uation Codes (Refer to	coding manual)
Patient Code	-	-
Device		
Code		
Method	_	
_		
Results		- -
Conclusions		
7. If Remedial Action Initiate	ed, Check Type	8. Usage of Device
Recall	Notification	Initial Use of Device
Repair Ir	nspection	Reuse
Replace P	Patient Monitoring	Unknown
	Modification/	9. If action reported to FDA under 21 USC 360i(f), list correction/
Other:	ujostilient	removal reporting number:
10. Additional Manufacto	urer Narrative	and / or 11. Corrected Data
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@rda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

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

HOMEOPATHIC -

CUSTOMER COMPLAINT RECORD



SECTION I:	COMP					COMPLAINT #:	2613	
TAKEN BY:	_1	EDYTA FRACKIE	WICZ		DAT	E OF COMPLAINT	_2610 D	3/19/15/
PRODUCT:	N	HYLAND'S BABY	TEETHING TABLETS	3		ITEM CODE:	BTET	63-3
SIZE:		NOT PROVIDED			_	LOT NO.:	NOT PROVID	DED
REPORTER:	(b) (6)							
ADDRESS:	-							
CITY:					s	TATE:		
COUNTRY:	USA							
PHONE #:								
E-MAIL;			R POSTED THE FOLL				A. E. 17	
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		FOR ADDITIO	NAL SPACE PLEASE	USE REVERSE OF	RATTACH	A SEPARATE SH	EET	
PRODUCT RECE	EIVED FOR	Y	(N)	PRODU	JCT BEING	RETURNED FOR	INSPECTION	Y (N)
INSPECTION:		(C	IRCLE ONE					(CIRCLE ONE)
				DAT	E REQUES	STED PRODUCT B	E RETURNED;	
						UPS CALL	TAG ISSUED:	Y (CIRCLE ONE)
						DATE BRODU	T DECEMEN	
SECTION II:	INVEST	IGATION				DATE PRODUC	T RECEIVED;	
INVESTIGATION:	PLE	ASE SEE ATTAC	CHED INVESTIGATION	N REPORT.				
ADVERSE EVENT	T FORWARDED	TO PHARMACIS	ST / NURSE FOR EVA	LUATION ON		024045		
			ST / NURSE FOR EVA			03/19/15 EDVTA E	RACKIEWICZ	
SECTION III;		RECTIVE ACTIO		LOATIONET		EDITAL	KACKIEWICZ	
	-							
CORRECTIVE AC	CTION(S) COMPL	ETED BY:				DATE:		DSS
SECTION IV:		E EVENT REPO	IRTS				1603	APR 1 0 201
ADVERSE EVENT			(v), N			AL II.	1000	MEN A V ZUI
ADVERSE EVENT		v:	03/19/15		BY:	EDYTA FRACKI	FWIC7	
SECTION V:			0	1,//		- DEFEATING		APR - 9 2015
REVIEWED BY MA	ANAGEMENT BY	t:	FW.	dell		DATE:	03-31	
DV:	6	4/1 /	Bours.			-	03-30	
BY:		Ind	ividual Cas	e Safetor T)ana	DATE: _	0000	
cc: QA/QC				Saracy P	(eport	100		
Packaging			8			1/11/11		Form # VD1

CaseID: 11012660



Serious Adverse Event SAE-0012-2015

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. 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 Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\stackrel{(b)}{=}$ ppm.

Conclusion:

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

Prepared by

3/30/15

Date

Individual Case Safety Report 11012660-01-00-04 DSS APR 1 0 2015





SERIOUS ADVERSE EVENT DATA FORM

CTION I:	PATIENT INFORMATION (IF DIFFERE	ENT FROM REPORTER ON FORM VD1)
ME:	(b) (6)	THE SALE ON TOWN FOR
ORESS:		
t :		STATE:
NTRY: NE #:	USA	ZIP CODE:
AIL:		
TION II:	PACKAGING INFORMATION:	
AF	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
Allestines in the control of the con	MONEY TENERS AND TENER	Teething labels Raby Leethins Labels
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FION III:	CORRECTIVE ACTION:	Individual Case Safety Report 11012660-01-00-05
	CORRECTIVE ACTION: CTION(S) COMPLETED BY:	11012660-01-00-05 DS
RECTIVE AC		11012660-01-00-05 DS DATE: APR 1 0
RECTIVE ACTION IV:		11012660-01-00-05 DS

APR - 9 2015



by user-facilities, sutors and manufacturers ATORY reporting

CaseID: 11061630
rm Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.
The state of the s

Mfr Report # UF/Importer Report #

FORM FDA 3500A (2/13)

Page 1 of 5

1. Patient Identifier (b) (6) 2. Age at Time of Event: 1 or	3. Sex 4. Weight Years Female Ibs	Charles a la contrata de contrata del contrata de la contrata del la contrata de la contrata de la contrata d	ed strength & mfr/labele BABY TEETHING '			
or	Female lbs	#1 HYLAND'S E	BABY TEETHING	TABLETS		
In confidence of Birth:						
	☑ Male	#2				
D. ADVERGE EVENT ON TROOP	ngs	2. Dose, Frequency	& Route Used	3. Therapy Date	es (If unknown, giv st estimate)	ve duration
	A PART OF THE PROPERTY.	#1		from/to (or be	st estimate)	
Adverse Event and/or Outcomes Attributed to Adverse Event	Product Problem (e.g., defects/malfunctions)	#2				
(Check all that apply)	Ta = 3 / 4 Ta Ta = 1	4. Diagnosis for Use	(Indication)	#2	ent Abated After	Dien
Death: (mm/dd/yyyy)	Disability or Permanent Damage		F TEETHING PAI	IN Sto	pped or Dose Re	educed?
✓ Life-threatening	Congenital Anomaly/Birth Defect	#2		#1 [_	Yes No	Doesn Apply
Hospitalization - Initial or prolonged	Other Serious (Important Medical Events)	6. Lot#	7. Exp. Date	#2	Yes No	Doesn Apply
3. Date of Event (mm/dd/yyyy)	rmanent Impairment/Damage (Devices)	#1	#1		ent Reappeared A	
03/29/2015	4. Date of This Report (mm/dd/yyyy) 04/07/2015	#2	#2		ntroduction? Yes No	Doesn Anniv
5. Describe Event or Problem		9. NDC# or Unique II	- total		Ties Tivo	- PPJ
MOTHER AND AUNT POSTED ON	b)(6) THAT SHORTLY AFTER	54973-3127-	1	#2	Yes No	☐ Doesn
RECEIVING HYLAND'S BABY TE SEIZURE AND HAD TO BE ADMII	ETHING TABLETS CHILD HAD A NISTERED CPR.	10, Concomitant Med	dical Products and Th	erapy Dates (Exclude	de treatment of ev	ent)
					(Continue on ,	page 3)
		D. SUSPECT MI	EDICAL DEVICE			
	1807.	1. Brand Name				
	Received	2. Common Device N	lame	2b	Procode	
		3. Manufacturer Nam	e, City and State			-
	APR 2 2 2015					
		4. Model#	Lot#		5. Operator o	of Device
	some bridge forms	Catalage		S	Health P	rofessional
	CDM	Catalog #	Expiration	n Date (mm/dd/yyyy	Lay Use	r/Patient
		Serial#	Unique Id	lentifier (UDI) #	Other.	
		6. If Implanted, Give	Date (mm/dd/vvvv)	7. If Explanted, 0	Sive Date (mm/de	dhanad
Ballon T. H. W. L	(Continue on page 3)	o. II III planted, Give	Date (minute yyyy)	in Explained,	Sive Date (minute	u yyyy)
Relevant Tests/Laboratory Data, Includ	ing Dates		e Device that was Rep	processed and Reu	sed on a Patient	?
	1	9. If Yes to Item No. 8		dress of Reprocess	or	
		13.47	,	ar ass or reproduct	.0,	
		10 Device Available	for Evaluation? (Do no	of seed to EDA)):ee
		Yes No		Manufacturer on:	Ann	00
				2 - 25 - 55 -	(milited/ y y)	23 21
Other Polavent History Including Prop	(Continue on page 3)	11. Concomitant Med	ical Products and The	erapy Dates (Exclud	de trealment of ev	rent)
	cisting Medical Conditions (e.g., allergies, e, hepalic/renal dysfunction, etc.)					
NKNOWN		E. INITIAL REPO	NOTER		(Continue on p	age 3)
		Name and Address		00		
	1	(b) (6)	6/1			
			L.	SA_{AP}	R 2 2 20	15
		Phone #	l Em-	ail Address	THE.	
			1210	- r 100 COO		
	(Continue on page 3)		(b) (6)		

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Facility

Other: _

Outpatient Treatment

Home

12. Location Where Event Occurred

Initial Follow-up #

Importer

3. User Facility or Importer Name/Address

2. UF/Importer Report Number

Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Literature √ Consumer

User Facility

Distributor

Other:

Company Representative

Study

3. Report Source (Check all that apply)

Health Professional

1. Check One

User Facility

4. Contact Person

Approximate Age of Device

Yes

☐ No

Yes

☐ No

Address

6. Date User Facility or

11. Report Sent to FDA?

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

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

04/03/2015

30-day

Initial

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

54973 AE # 1605

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

7. Type of Report

5-day

7-day

10-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

je 2 d

		FDA USE ONLY
of ⁵		
H. DEVICE MANUFAC	TURERS ONLY	
Type of Reportable Event		2. If Follow-up, What Type?
Death		Correction
Serious Injury		Additional Information
Malfunction		Response to FDA Request
		Device Evaluation
3. Device Evaluated by Manu	facturer?	4. Device Manufacture Date
Not Returned to Manu	facturer	(mm/yyyy)
Yes Evaluation	Summary Attached	
No (Attach page to ex	plain why not) or	5. Labeled for Single Use?
provide code:		☐ Yes ☐ No
6. Event Problem and Evalua	tion Codes (Refer to c	oding manual)
Patient Code	-	-
Device		
Code]-[
Method]_[
Results	-	- -
—		
Conclusions		J ⁻ L
7. If Remedial Action Initiated	I, Check Type 8.	Usage of Device
Recall No	dification	Initial Use of Device
Repair Ins	spection	Reuse
Replace Pa	tient Monitoring	Unknown -
	odification/ 9. justment	If action reported to FDA under 21 USC 360i(f), list correction/
Other:	justinent	removal reporting number:
10. Additional Manufactu	rer Narrative an	d / or 11. Corrected Data
		D -
		DSS
		ADD
		DSS APR 23 20
		- 20
		APR 2 2 2015

CaseID: 11061630

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

(A)NDA#

IND#

BLA# PMA/

510(k)#

Combination Product

OTC Product Yes

8. Adverse Event Term(s)

Pre-1938

SEIZURE

Yes

Yes Yes

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

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Individual Case Safety Report

MPLAINT RECORD



Carparet at Tarrens of		COMPLAINT #	2615	
11061	1630-01-00-03	DATE OF COMPLAINT	T: 04/03/15	
PRODUCT	HYLAND'S BABY TEETHING TABLETS	ITEM CODE	BTETT135	
SIZE:	135 TABLETS	LOT NO.	: A41614	
REPORTER: (b)	0 (6)			
ADDRESS:				
CITY		STATE:		
COUNTRY:	USA	ZIP CODE:		3
PHONE #:	(b) (6)			
E-MAIL:		COMMENT ON HYLAND'S BABY TEETHIN		
OLD NEPHEW HAD A UNTIL WE DID A SYM OK, AND WITHOUT KI TO MOTHER OVER TI EDYTA FRACKIEWICZ: THE ER. DOCTOR'S NO AND NO FAMILY HISTO	OF YOU HAVE TEETHING BABIES OR HAVE USED THI SEIZURE RIGHT AFTER HE WAS GIVEN THESE TABL PTOM RESEARCH))!! PLEASE STOP THE USE, IT WA NOWING IT WAS A SEIZURE, THAT MY MOM WAS THI HE PHONE BECAUSE SHE DID NOT CALL OR PROVID SPOKE WITH MOTHER AND CHILD IS CURRETLY DOING W OT SURE WHY THE CHILD HAD A SEIZURE AND THEY WIL SRY OF SEIZURES. CHILD BECAME STIFF AND STOPPED D. SHE REQUESTED THAT HYLAND'S BABY TEETHING TAI FOR ADDITIONAL SPACE PLEASE USE IT	LETS (ONE OF THE SYMPTONS OF USIN S. THE SCARIEST THING EVER IN OUR LE ERE TO GIVE HIM CPRIII. PLEASE DO NI DE A NUMBER WHERE SHE COULD BE RE VELL. ON THE DAY OF THE SEIZURE THEY L. DO FOLLOW-UP TESTS. NO FEVER OR I BREATHING FOR 3 MINUTES DURING THE BLETS BE REMOVED FROM THE MARKET.	. (b) (6) WY 1 YEAR (G THIS PRODUCT, WAS UNAWARE LIVESIII THANK GOD HE WAS AND IS OT USEII WAS UNABLE TO SPEAK REACHED. 04/10/15 FOLLOW-UP: Y CALLED PARAMEDICS AND WENT TO ILLNESS AT THE TIME OF THE SEIZURE SEIZURE. OFFERED A REFUND AND	
PRODUCT RECEIVED		PRODUCT BEING RETURNED FOR	R INSPECTION: Y)
INSPECTION:	(CIRCLE ONE)		(CIRCLE ONE)	
		DATE REQUESTED PRODUCT B	BE RETURNED;	4.1
		UPS CAL	L TAG ISSUED: (CIRCLE ONE)	
		DATE PRODU	CT RECEIVED:	
SECTION II:	INVESTIGATION			_
Consideration of contracts		Pag.		
INVESTIGATION:	PLEASE SEE ATTACHED INVESTIGATION REPO	DRT.		-
				_
ADVERSE EVENT FOR	RWARDED TO PHARMACIST / NURSE FOR EVALUATION	ON ON: 04/03/15	i	-
ADVERSE EVENT FOR	RWARDED TO PHARMACIST / NURSE FOR EVALUATION	ON BY: EDYTA F	FRACKIEWICZ	_
SECTION III;	CORRECTIVE ACTION:			
				-
				-
CORRECTIVE ACTION	i(S) COMPLETED BY:	DATE:		
CORRECTIVE ACTION				Dec
	N(S) COMPLETED BY: ADVERSE EVENT REPORTS		1605	DSS
SECTION IV:	ADVERSE EVENT REPORTS RIOUS: Y N	AE #:	1605 AP	W.J. F -
SECTION IV:	ADVERSE EVENT REPORTS RIOUS: Y N		1605 AP	W.J. F -
SECTION IV:	ADVERSE EVENT REPORTS RIOUS: Y N	BY: EDYTA FRACK	1605 AP	W.J. F -
SECTION IV: ADVERSE EVENT SEF ADVERSE EVENT REF	ADVERSE EVENT REPORTS RIOUS: PORTED ON: 04/03/15	BY: EDYTA FRACK	1605 AP	W.J. F -
SECTION IV: ADVERSE EVENT SEF ADVERSE EVENT REF SECTION V:	ADVERSE EVENT REPORTS RIOUS: PORTED ON: 04/03/15	BY: EDYTA FRACK	1605 AP	DSS R 2 3 2015

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1

Individual Case Safety Report





rerse Event SAE-0014-2015

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 (b) (4) 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 with in specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

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

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

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured one other 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

4/16/15

APR 23 2015

APR 2 2 2015

CaseID: 11061630



EVENT DATA FORM



AE #: 16	505	COMPLAINT #: _2615	
SECTION I:	PATIENT INFORMATION (IF DIFFER	ENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:	·		_
CITY:		OTATE.	_
COUNTRY:	USA	STATE: ZIP CODE:	
PHONE #:	NA 105		
E-MAIL:	(b) (6)		
SECTION II:	PACKAGING INFORMATION:		
А	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
series y and congruent of the series of the programme of	However the Company of the Company o	Teethers lablets Jeetharia Teatharia Tabeta	
SECTION III:	CORRECTIVE ACTION:		
CORRECTIVE /	ACTION(S) COMPLETED BY:	DATE:	DSS APR 23 2018
SECTION IV:	0		ALK 23 501
	MANAGEMENT BY:	Alla DATE: 04-16-18	
BY;	Pur Ban	DATE: 04-16-15 DATE: 04-16-15	
	QA / QC DIRECTOR		

iser-OR OR

Yes V No

NA

of

	For	m Appor	Semon: 011028,8037.6/30/2015
facilities,	Mfr Report #	54973	
and manufacturers Y reporting	UF/Importer R	eport #	~
6			FI LLE CONTY
C. SUSPECT PROD	UCT(S)		T. Section,
#1 HYLAND'S BABY #2 HYLAND'S BABY	TEETHING T	ABLETS	
2. Dose, Frequency & Roo #1 2 TABS Q1HR X	2 DOSES	#1	apy Dates (If unknown, give duration) No (or best estimate)
#2 APPLIED TO GUN		#2	
#1 TEMP RELIEF TE	EETHING PAIN		5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Poesn't Apply
#2 FEMP RELIEF S)	7. Exp. Date	NESS	#2 Yes No Doesn't
#1B37614	#1		8 Event Reappeared After Reintroduction?
#2124181	#2		#1 Yes No Poesn't
54973-3127-1 //	54973-7521	1-2	#2 Yes No Doesn't
0. Concomitant Medical	Products and The	erapy Dat	es (Exclude treatment of event)

D. SUSPECT ME	DICAL DEVICE		Continue on page 3)
1. Brand Name			
2. Common Device N	ame	2b.	Procode
3. Manufacturer Nam	e, City and State		
6.7			
4. Model#	Lot#		5. Operator of Device
4. Model# Catalog#		n Date (mm/dd/yyyy)	5. Operator of Device Health Profession Lay User/Patient
	Expiratio	n Date <i>(mm/dd/yyyy)</i> lentifier (UDI) #	Health Profession

1. Patient Identifier 2. Age (b) (6) of E	at Time vent: 3	Months	3. Sex	4. Weight	1. Name (Give labeled #4 HYLAND'S BA			
or _ Date		(10/4191	Female	or lbs	#2 HYLAND'S BA			
In confidence of B	or PRODU	CT PROBLE	✓ Male	kgs	2. Dose, Frequency & #1 2 TABS Q1HR		3. Therapy Date from/to (or be	es (If unknown, give do st estimate)
1. Adverse Event and		oduct Problem (e	.g., defects/malfi.	unctions)	#2 APPLIED TO	GUMSBIDX1DAY	#2	
✓ Life-threatening	dd/yyyy)	Congenital	r Permanent Dar Anomaly/Birth D ous (Important M	Pefect	4. Diagnosis for Use (#1 TEMP RELIEF #2 TEMP RELIEF	Indication) TEETHING PAI	NESS 5. Eve	ent Abated After Use pped or Dose Reduc Yes No
Hospitalization - initial Required Intervention	Colored Section				6. Lot#	7. Exp. Date		Yes No
3. Date of Event (mm/dd/yyy 04/11/20	y)	4. Date of This	Report (mm/dd) 04/16/2015	(yyyy)	#1B37614 #2124181	- #1 #2	Rei	ent Reappeared After introduction? Yes No 🔽
5. Describe Event or Problem CUSTOMER SENT AN E AND TEETHING GEL T MADE HIM CHOKE. 04/16/15 FOLLOW-UP DIFFICULTY SWALLOW	-MAIL STATHICKENED THE MOTHER ING AND THE	REPORTED THE	OF HER BAB HAT CHILD WHICH CAU	Y AND HAD SED	9. NDC# or Unique ID 54973-3127-1 10. Concomitant Medi		-56	Yes No Continue on pag
SEVERE CHOKING AND THE CHILD ON HIS S AIRWAY AND ALMOST	IDE ON THE	E FLOOR IN		A COLUMN TO SECURE	SOSPECT WE Brand Name	DICAL DEVICE		
				1	2. Common Device Na	ime	21	. Procode
			Rece	eived	3. Manufacturer Name	e, City and State		
					4. Model#	Lot#		5. Operator of De
			APR 2	9 2015	Catalog #	Expiration	Date (mm/dd/yyy)	Lay User/Pa
					Serial #		entifier (UDI) #	Other:
			(Continue on	page 3)	6. If Implanted, Give D	ate (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yy)
6 Relevant Tests/Laborator	y Data, Includin	ng Dates		777	8. Is this a Single-use	Device that was Rep	rocessed and Reu	sed on a Patient?
					9. If Yes to Item No. 8,	Enter Name and Ad	dress of Reproces	sor
					10. Device Available fo	or Evaluation? (Do no		(mm/dd/yyyy)
7 Other Relevant History, In race, pregnancy, smoking a				lergies.	11. Concomitant Medic	cal Products and The	erapy Dates (Exclu	A STATE OF THE STA
NO KNOWN ALLERGIES FEVER, NOT PREMATU		AL ISSUES,	NO 11LNESS	S, NO	E, INITIAL REPO	PTEP		(Continue on page
				İ	Name and Address	C. C.		DSS
					(b) (6) (b) (6) USA			MAY -1
			(Cartieres		Phone # (b) (6)	(b) (6	ail Address	
ubmission of a sona-t-	door not ass	potituto an od-	(Continue on		2. Health Professional	100	<u> </u>	Initial Reporter Als
Submission of a report of a report of the submission of a report of the submission o					Yes V No	NA Occupation		Report to FDA

(Continue on page 3)

DSS

MAY -1 2015

Initial Reporter Also Sent Report to FDA

Yes No V Unk.

Individual Case Safety Report



11088037-01-00-02

User Facility	∐ lmp	porter	
3. User Facility or Imp	orter Nam	e/Address	
4. Contact Person		5. Phone	Number
C. Date Hear Facilities	_	17. To a 4 B a s 4	O Pote of This Person
Date User Facility o Importer Became Aware of Event (mg		7. Type of Report	Date of This Report (mm/dd/yyyy)
Aware of Event (mn	vaaryyyy)	initial initial	
	Lea	Follow-up#	-]
Approximate Age of Device	10. Event	Problem Codes (Refer to cod	ding manual)
	Patient Code	-	-
	Device [
	Code		
11. Report Sent to FDA	17	12. Location Where Event	t Occurred Cutpatient
Yes(mm/dd	/уууу)	Hospital Home	Diagnostic Facility
∐ No		D Numina Hama	Ambulatory Surgical Facility
13. Report Sent to Mar	idiacturer	Outpatient Treatme	
Yes(mm/dd/	уууу)	Facility	
l No		Other:	(Specify)
14. Manufacturer Name	e/Address		
14. Manufacturer Name	e/Address		
14. Manufacturer Name	e/Address		
14. Manufacturer Namo	e/Address		
14. Manufacturer Namo	e/Address		
G. ALL MANUFA	CTURE		
G. ALL MANUFA 1. Contact Office (and	CTURE		2. Phone Number
G. ALL MANUFA	CTURE! Manufactu		310-768-0700
G. ALL MANUFA 1. Contact Office (and Name	CTURE! Manufactu		_
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI	CTURE! Manufactu		310-768-0700 3. Report Source
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST	CTUREI Manufacto CZ	aring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC.	CTUREI Manufacto CZ	aring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature
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G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND	CTUREF Manufacto	ring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional
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G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d/	CTUREF Manufactu CZ CREET A 9006 DS.COM d/yyyy) D15	5. (A)NDA # IND # BLA # PMA/ 510(k) #	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor
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G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d/	CTUREF Manufacto CCZ CREET A 9006 DS.COM d/yyyy) D15	5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Product Yes Pre-1938 Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/di	CTUREI Manufacto CZ FREET 9006 05.COM d/yyyy) 015 #	5. (A)NDA# IND# BLA# PMA/ 510(k)# Combination Product Yes Pre-1938 Yes OTC Product Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:
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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:

	CaseID: 11088037
	FDA USE ONLY
6	
H. DEVICE MANUFACTURERS ONLY	
. Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
3. Device Evaluated by Manufacturer?	Device Manufacture Date (mm/yyyy)
Not Returned to Manufacturer	(27373)
Yes Evaluation Summary Attached	
No (Attach page to explain why not) or provide code:	5. Labeled for Single Use?
	Yes No
6. Event Problem and Evaluation Codes (Refer to	o coding granuel)
Patient Patient	o ocong mandar)
Code	
Device Code	-
Code	
Method -	
Results	
Results	
Conclusions -	<u> - - </u>
7. If Remedial Action Initiated, Check Type	8. Usage of Device
Recall Notification	Initial Use of Device
Repair Inspection	Reuse
Replace Patient Monitoring	Unknown
Relabeling Modification/	9. If action reported to FDA under
Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:	
10. Additional Manufacturer Narrative	and / or 11. Corrected Data
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer

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

Paperwork Reduction Act (PRA) Staff information unless it dis PRAStaff@fda.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

Individual Case Safety

CUSTOMER COMPLAINT RECORD

Cale	A 802 3037
Caso	0001

Individual C		
DI BUTUUN BURUN	TURA MITA	

		COMPLAINT #:	2616	
11088037-01-00-03	-	DATE OF COMPLAINT:	04/11/15	
11000007-01-00-05	3EL_	ITEM CODE:	BTET-T135	/ TGELU0.5Z
SIZE: 135 TABLETS / 0.5 OZ.		LOT NO.	B37614 // 124	181
(b) (6) REPORTER:				
ADDRESS:				
circ		STATE: (b) (6)		
COUNTRY: USA		ZIP CODE:		
PHONE #:				
E-MAIL:				
CUSTOMER SENT THE FOLLOWING NATURE OF COMPLAINT: MADE HIM CHOKE! THESE SHOULD COME WITH A WARNING ON THEMI THAT CHILD HAD TROUBLE SWALLOWING AFTER USING BOTH TEETHIN STARTED CHOKING ON BOTH TIMES. CHOKING WAS SEVERE, SHE HAD TO LE BREATHING. ALMOST HAD TO PERFORM CPR. WILL RETURN THE PRODUCT NO ILLNESS, NO FEVER. HAS AN APPOINTMENT TO SEE THE DOCTOR NEXT	THEY ARE DANG 04/16/15 FOLLOV IG GEL AND BABY AY HIM ON HIS SID TO THE STORE. N WEEK.	SEROUS! THEY THICKEN W-UP: SPOKE WITH CUS Y TEETHING TABLETS DU E ON THE FLOOR AND OPI O MEDICAL ISSUES, NOT F	IED THE SALIVA TOMER AND SH DE TO THICK SAL EN HIS AIRWAY D PREMATURE, NO	OF MY BABY AND IE INFORMED ME LIVA WHICH HE IUE TO DIFFICULTY
FOR ADDITIONAL SPACE PLEASE USE	REVERSE OR AT	TACH A SEPARATE SHE	E)	
			MODEOTION	v (N)
PRODUCT RECEIVED FOR Y N INSPECTION: (CIRCLE ONE)	PRODUCT	BEING RETURNED FOR	INSPECTION:	(CIRCLE ONE)
	DATE R	EQUESTED PRODUCT BE	E RETURNED:	
		UPS CALL	TAG ISSUED:	Y (CIRCLE ONE)
		DATE PRODUC	T RECEIVED:	
SECTION II: INVESTIGATION				
INVESTIGATION: PLEASE SEE ATTACHED INVESTIGATION RE	PORT			
TELASE SEE AT TACHED INVESTIGATION AS	Citi			
			-	
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUAT	TION ON:	04/11/15		
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUAT	TION BY:	EDYTA F	RACKIEWICZ	
SECTION III: CORRECTIVE ACTION:				
<u>German</u>				
A LASTATURE PROCESS IN A RESIDENCE OF THE PROCESS O		000		
CORRECTIVE ACTION(S) COMPLETED BY:		DATE:		
SECTION IV: ADVERSE EVENT REPORTS		AE #:	1606	DSS
ADVERSE EVENT SERIOUS: V				MAY -1 201
ADVERSE EVENT REPORTED ON: 04/11/15	1	BY: EDYTA FRACK	IEWICZ	
SECTION V:	1.14			
DEMONES BY MANAGEMENT BY	MAI	DATE	04-7	3-15
REVIEWED BY MANAGEMENT BY:	~ W	DATE:		3-15 3-15
BY: 19cm		DATE:	04-23	3 15
QA / QC DIRECTOR				

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

APR 3 0 2015

CaseID: 11088037



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 $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

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

Prepaked by

4116115

Date

DSS MAY -1 2015







T DATA FORM

#: 1606	COMPLAINT #:
ECTION I: PATIENT INFORMA	ION (IF DIFFERENT FROM REPORTER ON FORM VD1)
AME: (b) (6)	
DDRESS:	
	(b) (6)
тү:	STATE:
OUNTRY: USA (6) (6)	ZIP CODE:
ONE #:	
MAIL:	
ECTION II: PACKAGING INFOR	MATION:
AFFIX PACKAGING LABEL H	ERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
The major have part the first printed mainty in the major have part to the major have part	Toblets Toblets
CTION III: CORRECTIVE ACT	ON:
RRECTIVE ACTION(S) COMPLETED BY	DSS MAY - 1 2
na mangana nagarakan kabang balang bi	DATE: MAY -1 2
CTION IV:	
VIEWED BY MANAGEMENT BY:	Walt DATE: 04-23-15
	Boun DATE: 04-23-15
Duc	1201111





T DATA FORM

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1.1	(088037-01-00-08	COMPLAINT #: 2616	_
SECTION 1:	PATIENT INFORMATION (IF DIFFERE	ENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:			
CITY:		(b) (d) STATE:	-
OUNTRY:	USA	ZIP CODE:	-
HONE #:	(b) (6)		
-MAIL:			
SECTION II:	PACKAGING INFORMATION:		
AFF	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
SX (HINS, Seldmont Claims Fernigurarily that to incring small Meritalings: De and chistosis to whether on this could be a small fewer sharelogs are Range and of vessel couldness are small couldness are age, stock 1/3 for necessary mileses often lating office produced for common and the small couldness are small produced for common and the small couldness are small produced for common and the small for common and for common for	Teething Gel Gel para la dentición FAST RELIEF OF PAIN AND IRRITABILITY FROM TEETHING Allvin rápido para al dolor y la OS FL. OZ. "Irritabilidad debrido a la dentición No HAS IDUDOSCIOS altabilidad. Cibralidad BHAS. Colhec Chuly no QN HAS IDUDOSCIOS altabilidad. Cibralidad BHAS. Colhec Chuly no QN HAS IDUDOSCIOS altabilidad. Cibralidad provinción del MAS IDUDOSCIOS altabilidad. In debrido del vina discondi afor more hara 7 deses in a low anticis in destruta del vina del ha la servina dellary to rim impatient in ribs provinci a decider de segmentando de not inscribe al 7 deses inventes; todo as international, per en anticisa de not inscribe al 7 deses inventes in al inches a desas in ancienta del per en ancie	Teething Gel ger value of Annahum ger valu	
ECTION COR	RECTIVE ACTION:		
			DS
ORRECTIVE AC	TION(S) COMPLETED BY:	DATE;	MAY -1
ECTION IV:		1	

DISTRIBUTION: FDA

BY:

REVIEWED BY MANAGEMENT BY:

ADVERSE EVENT FILE

APR 3 0 2015

DATE: 04-23-15

red: OMB No. 0910-0294 Edires: 12/31/2011 Individual Case Safety Report Internet Consumer Report eporting of FDA USE ONLY Triage unit sequence # problems and Trors 11090548-01-00-01 Dose or Amount Frequency Route Patient Identifier 2. Age at Time or Evens or Date of Birth: Three times 2-3 tablets 4x a Taken by mouth daily 21 lb day ✓ Female 1 Years #2 (b) (6) kg In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Dates of Use (If unknown, give duration) from/to (or best estimate) 5. Event Abated After Use Stopped or Dose Reduced? Check all that apply: #1 04/28/2015 - 04/30/2015 #1 Ves No Doesn't Product Problem (e.g., defects/malfunctions) 1. Adverse Event Apply #2 Product Use Error Problem with Different Manufacturer of Same Medicine #2 Yes No Doesn't 2. Outcomes Attributed to Adverse Event. 4. Diagnosis or Reason for Use (Indication) (Check all that apply) #1 Testhing 8. Event Reappeared After Reintroduction? Death: Disability or Permanent Damage Doesn't #1 Yes V No (mm/dd/yyyy) Apply Life-threatening Congenital Anomaly/Birth Defect #2 Yes No Doesn't Hospitalization - initial or prolonged Dother Serious (Important Medical Events) 6. Lot# 7. Expiration Date #1 A24314 #1 Required Intervention to Prevent Permanent Impairment/Damage (Devices) 9. NDC # or Unique ID #2 #2 A24314 3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 05/01/2015 E. SUSPECT MEDICAL DEVICE 05/01/2015 1. Brand Name 5. Describe Event, Problem or Product Use Error See additional page(s) for complete text. 2. Common Device Name MAY - 4 2015 3. Manufacturer Name, City and State 4. Model # Lot # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: 6. Relevant Tests/Laboratory Data, Including Dates Serial # Other # 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 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. F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) G. REPORTER (See confidentiality section on back) 1. Name and Address C. PRODUCT AVAILABILITY Name: (b) (6) Product Available for Evaluation? (Do not send product to FDA) MAY -4 2015 Address: ✓ Yes No Returned to Manufacturer on: (mm/dd/yyyy) State (b) (6) ZIP City: D. SUSPECT PRODUCT(S) Phone # E-mail 1. Name, Strength, Manufacturer (from product label) (b) (6) Name: Hylands teething tablets Strength: 250 quick dissolve tablets Manufacturer: Hylands 2. Health Professional? 3. Occupation 4. Also Reported to:

CaseID: 11090548

Manufacturer

User Facility

Distributor/Importe/

Name:

Strength:

Manufacturer:

ž

USE BLACK

QR.

TYPE

PLEASE

5. If you do NOT want your identity disclosed

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

Yes No

B.5. Describe Event or Problem (continued)

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

Individual Case Safety Report

11090548-01-00-02

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

Individual Case Safety Report

11090548-01-00-03



isumer Report	9 (
ARY reporting	
oduct problems and use errors	Tria
use citors	

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

	FDA USE ONLY	
Triage unit sequence #		_
	598075	

ise errors	sequence #	
inc circus	59	8075
2. Dose or Amount	Frequency	Route
#1 2 PILLS	As needed	Taken by mouth
	wn, give duration) from/to	5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't
		Apply
4. Diagnosis or Reason f #1 EASE TEETHING D		#2 Yes No Doesn't Apply 8. Event Reappeared After Reintroduction?
		#1 Yes No Doesn't Apply
6. Lot# #1	7, Expiration Date #1 05/22/2015	#2 Yes No Doesn't Apply 9. NDC # or Unique ID
#2	#2	
E. SUSPECT MED	ICAL DEVICE	
	•	СТИ
3. Manufacturer Name, C	ity and State	MAY 2 6 2015
4. Model #	Lot#	5. Operator of Device Health Professional
Catalog #	Expiration Date (mr	n/dd/yyyy) Lay User/Patient Other:
Serial#	Other#	
T. W. C. P. S. C. S.		planted, Give Date (mm/dd/yyyy)
Yes No		
Product names and thera	py dates (exclude treatme	ent of event)
G. REPORTER (See 1. Name and Address Name: (b) (6)	confidentiality secti	
Address:		DS
Phone #	E-mail (b) (6)	e: ZIP; MAY 2
2. Health Professional? 3	3. Occupation	4. Also Reported to:
	#1 2 PILLS #2 3. Dates of Use (If unknown (or best estimate)) #1 #2 4. Diagnosis or Reason #1 EASE TEETHING D #2 6. Lot # #1 #2 E. SUSPECT MED 1. Brand Name 2. Common Device Name 3. Manufacturer Name, C 4. Model # Catalog # Serial # 6. If Implanted, Give Date 8. Is this a Single-use De Yes No 9. If Yes to Item No. 8, Enter F. OTHER (CONCO Product names and thera See additional G. REPORTER (See 1. Name and Address Name: (b) (6) Address: City:	2. Dose or Amount #1 2 PILLS #2 3. Dates of Use (If unknown, give duration) from/to (or best estimate) #1 #2 4. Diagnosis or Reason for Use (Indication) #1 EASE TEETHING DISCOMFORT #2 6. Lot # #1 05/22/2015 #2 E. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Catalog # Expiration Date (mm/dd/yyyy) 7. If Expiration Date (mm/



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.

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

n/a

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: 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

DSS MAY 2 6 2015



by user-facilities, butors and manufacturers DATORY reporting

Form Approace OMD	ND in 1910-122 3 Source 6/30/201 See OMB statement on revers				
Mfr Report # 54973	OCT				

UF/Importer Report #

PLEASE TYPE OR USE BLACK INK

FORM FDA 350	0A (2/13)			rage				FDA Use Only
A. PATIENT INF	ORMATION				C. SUSPECT PR			
1. Patient Identifier (b) (6)	and Property	ADV.	3. Sex	4. Weight	1. Name (Give labeled	ABY TEETHING T		- 1
(2)(5)	or 1 1/	2 Years	✓ Female	lbs	#1 HILAND'S BE	abi issiiiing ii	100010	
	Date		Male Male	or kgs	#2		1	DF
In confidence B. ADVERSE EV	of Birth:	ICT PROBLE	М		2. Dose, Frequency &	Route Used	from/to (or bes	(If unknown, give duration) estimate)
170			1 t A	The Same	#12 TABS SL B	ID PRN X2DAYS	#1	
1. Adverse Even		roduct Problem (e.g., derects/mairu	ncuons)	#2		#2	
2. Outcomes Attribut (Check all that appl	ted to Adverse Event y)	-		- 1	4. Diagnosis for Use	(Indication)		nt Abated After Use ped or Dose Reduced?
Death:		Disability	or Permanent Dan	nage	#1 TEMP RELIEF	TEETHING PAIN		Ves I No I Doesn't
Life-threatenin	(mm/dd/yyyy) ng		Anomaly/Birth D		#2			Apply Doesn't
Hospitalization	- initial or prolonged	Other Ser	ious (Important M	edical Events)	6. Lot#	7 Exp. Date	#2	Yes No Apply
Required Inter	rvention to Prevent Per	manen! Impairmer	nt/Damage (Device	es)	#1	#1		nt Reappeared After
3. Date of Event (mn	n/dd/yyyy)	4. Date of This	s Report (mm/dd/	40 10 11 11 11	#2	#2		Yes No Doesn't
04/0	00/2014		05/21/2015		9. NDC# or Unique ID	1 17.17		
5. Describe Event or MOTHER REPOR	Problem TED THAT CHIL	HAD BEEN	ISING THE P	RODUCT	54973-3127-3		#2	Yes No Doesn't
FOR A COUPLE GIVEN 1 TAB C - 1 HOUR PRIO SEIZURE LASTE CHILDREN'S HO STOPPED BREAT SEIZURE, HIT BACK. CHILD H DOCTORS AS FE	OUPLE OF HOUR. R TO THE SEIZ! D 15 MINUTES . SPITAL. HE F. HING, ALSO VO. HIS HEAD WHEN AD NO FEVER,	URE GAVE SEC AND HE WAS T ELL OVER DUI MITED AND AS HE FELL, AN BUT SEIZURE	SEIZURE. TI COND TABLET FRANSPORTED RING THE SE SPIRATED DU ND EYES ROL	HEN 1/2 . THE TO IZURE, RING THE	D. SUSPECT ME	EDICAL DEVICE		e treatment of event) (Continue on page 3)
125000000		447.6			2. Common Device N	lame	26	Procode
	R	ECEN	/En			02 d 01-t-		
		And Desire E			3. Manufacturer Nam	le, City and State		
	4.5	JUN 05 20	115		4. Model #	Lot#	-	5. Operator of Device
			. 1.0		4. MODELE			Health Professional
		CDR	ii l		Catalog #	Expiration	Date (mm/dd/yyyy	Lay Usen Patient
					Serial #	Unique Id	entifier (UDI) #	Other:
			(Continue or	nade 3)	6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
6. Relevant Tests/La	boratory Data, Includ	ding Dates	(ooriands or	, page of	8 is this a Single-us	e Device that was Rep	rocessed and Reu	sed on a Patient?
The same of the sa					Yes N	0		
						8, Enter Name and Ad		sor
						for Evaluation? (Do n	Manufacturer on:	
							The Policy of	(mm/dd/yyyy)
			(Continue or	n page 3)	11. Concomitant Med	dical Products and Th	erapy Dates (Exclu	de treatment of event)
7. Other Relevant Hi race, pregnancy, s. NO FAMILY HIS	TORY OF SEIZU	RES. HAS H	ISTORY OF F	<i>llergies,</i> LUID IN				(Continue on page 3)
THE EARS AND	HAD TUBES PLA	CED IN 2014			E. INITIAL REP			200 1 (-19)
					1. Name and Addres	s	9	LA
				2.777.78	Phone # (b) (6)	En	all Address	
		244.2	(Continue of		2. Health Profession	al2 3 Decumation		4. Initial Reporter Also Sent
Submission of a personnel, user f caused or contrib	acility, importer.	distributor, m	amission that anufacturer o	product	Yes V)S\$		Report to FDA Yes No V Unk.



e 2 of ⁵

Case	D: '	111	738	07

					H. DEVICE MANUF	ACTURERS ONLY	Y .
. Check One			2. UF/Importer I	Report Number	1. Type of Reportable Ev	ent	2. If Follow-up, What Type?
User Facility	[] Impo	orter			Death		Correction
3. User Facility or Imp	orter Name	/Address			Serious Injury		Additional Information
					Malfunction		Response to FDA Request
							Device Evaluation
					3. Device Evaluated by N	lanufacturer?	4. Device Manufacture Date (mm/yyyy)
					Not Returned to N	fanufacturer	(111111)
. Contact Person			5. Phone N	lumber	Yes Evalua	ation Summary Attached	
					No (Attach page)	to explain why not) or	5. Labeled for Single Use?
. Date User Facility or	r	7. Type of R	eport	8. Date of This Report	provide code:	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	☐ Yes ☐ No
Importer Became Aware of Event (mm	- 1		•	(mm/dd/yyyy)			∐ Yes ∐ No
Audio of Event (initial	,,,,,,	Initial			6. Event Problem and Ev	aluation Codes (Refer to	o coding manual)
		Follow-u	ıp#		Patient		
. Approximate	10. Event I	Problem Cod	es (Refer to code	ing manual)	Code		
Age of Device	Patient [7		Device]_
	Code				Code		
	Device		7-	_	Method	-	- -
	Code	,					
1. Report Sent to FDA	\?	12. Locatio	on Where Event		Results	-	- -
Yes		□Ho	spital	Outpatient Diagnostic Facility			
No (mm/dd/	<i>'</i> yyyy)	☐ Ho	me	Ambulatory	Conclusions		
3. Report Sent to Man	ufacturer?	☐ Nu	rsing Home	Surgical Facility	7. If Remedial Action Init	iated, Check Type	8. Usage of Device
			tpatient Treatme	nt			Initial Use of Device
Yes(mm/dd/	(уууу)		cility		Recall	Notification	Reuse
□ No			ner:	(Specify)	Repair	Inspection	Unknown
4. Manufacturer Name	e/Address	<u> </u>			Replace	Patient Monitoring	
					Relabeling	Modification/ Adjustment	If action reported to FDA under 21 USC 360i(f), list correction/
					7000	riajastinent	removal reporting number:
					Other:		
					· · · · · · · · · · · · · · · · · · ·		
					10. Additional Manuf	acturer Narrative	and / or 11. Corrected Data
G. ALL MANUFA	CTURER	S					_
. Contact Office (and			Davices)	2. Phone Number			
Name	wanusactus	ing Site for t	Devices,	310-768-0700			
DYTA FRACKIEWI	CZ			3. Report Source			
Address				(Check all that apply)			
				Foreign			
YLAND'S, INC.	need			Study			
54 W. 131ST ST OS ANGELES, CA				Literature			
OU AMGELES, CA	. 50001	•		1-			
Email Address				Consumer Health Professional			
TANDARD@HYLAND	S.COM			1			
Date Received by		5.		User Facility			
Manufacturer (mm/de	d/yyyy)	(A)NDA#		Company			
05/21/20	15	1		Representative Distributor			
If IND, Give Protocol	#	- IND#	.	19			
		BLA#		Other:			
		PMA/					
Type of Report		510(k) #					
(Check all that apply)		Combinati					
5-day 30-day	-	Product	Yes				
7-day Period	IIC .	Pre-1938	Yes				
10-day 🗸 Initial		OTC Prod	uct 🗸 Yes				
✓ 15-day Follow	v-up #		التا			ח	22
Manufacturer Report	Number	,	Event Term(s)				SS -8 2015
4973 AE # 160	18	SEIZURE	5			IIIN -	- Q 2015
					1	3014	0 ZUIJ
This section applies	only to rea	quirements o	of the Paperworf	k Reduction Act of 1995.	Department of Health and H	luman Services	OMB Statement: "An agency may not

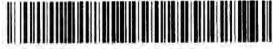
The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.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

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

			CaseID: 111738					
111720	07-01-00-03		DATE OF COMPLAINT	W. artist of the				
	A T A TABLE OF THE		ITEM CODE	5.100				
IZE:	NOT PROVIDED	10 Hereig	LOT NO.	AND THE OWNER	D			
EPORTER: (0) (
DDRESS: N/	Δ							
N/	V							
TY: N			(b) (6) STATE:					
			ZIP CODE: N/A					
(b)								
HONE#								
MAIL: N								
AYS PRIOR (WAS USING HILDREN'S HOSPITAL. F DLLED BACK. WAS GIVE DT WANT A REFUND. RODUCT RECEIVED FO		IT A NEW BOTTLE FOR THE CHIL RE, STOPPED BREATHING, ALSO OR TO SEIZURE. THEN 1/2 TO 1	O VOMITED AND ASPIRATED.	MINUTES AND HE W HIT HIS HEAD WHEN E GAVE SECOND TA	HE FELL AND EYES			
ISPECTION:	(CIRCLE d	0	E REQUESTED PRODUCT	DE DETLIDNED:	(CINOLE GLE)			
		DA.	E REQUESTED PRODUCT	-				
			T. 477	o tell al tale tale t	(CIRCLE ONE)			
			LIDS CAL	I TAG ISSUED				
			UPS CAL	L TAG ISSUED:	(GINGEL GIVE)			
				L TAG ISSUED:	(SINGLE GILL)			
SECTION II:	INVESTIGATION PLEASE SEE ATTACHED INV	VESTIGATION REPORT			(onder one)			
		VESTIGATION REPORT			(onder one)			
IVESTIGATION:				UCT RECEIVED: _	(onder one)			
OVERSE EVENT FORW	PLEASE SEE ATTACHED INV	SE FOR EVALUATION ON:	DATE PRODU	UCT RECEIVED: _	(OINGEL ONL)			
DVERSE EVENT FORW	PLEASE SEE ATTACHED INV	SE FOR EVALUATION ON:	DATE PRODU	UCT RECEIVED: _				
DVERSE EVENT FORW	PLEASE SEE ATTACHED INV /ARDED TO PHARMACIST / NUR /ARDED TO PHARMACIST / NUR	SE FOR EVALUATION ON:	DATE PRODU	UCT RECEIVED: _	(OINGLE ONL)			
NVESTIGATION: DVERSE EVENT FORW DVERSE EVENT FORW ECTION III:	PLEASE SEE ATTACHED INV /ARDED TO PHARMACIST / NUR /ARDED TO PHARMACIST / NUR CORRECTIVE ACTION:	SE FOR EVALUATION ON:	DATE PRODU	OT RECEIVED: _				
OVERSE EVENT FORM DVERSE EVENT FORM ECTION III:	PLEASE SEE ATTACHED INV /ARDED TO PHARMACIST / NUR /ARDED TO PHARMACIST / NUR CORRECTIVE ACTION:	SE FOR EVALUATION ON:	DATE PRODU	OCT RECEIVED: _				
DVERSE EVENT FORW DVERSE EVENT FORW ECTION III: ORRECTIVE ACTION(S	PLEASE SEE ATTACHED INV ARDED TO PHARMACIST / NUR CORRECTIVE ACTION: COMPLETED BY: ADVERSE EVENT REPORTS	SE FOR EVALUATION ON:	DATE PRODU	OCT RECEIVED: _				
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DVERSE EVENT FORW DVERSE EVENT FORW ECTION III: ORRECTIVE ACTION(S ECTION IV: DVERSE EVENT SERIO	PLEASE SEE ATTACHED INV VARDED TO PHARMACIST / NUR CORRECTIVE ACTION: COMPLETED BY: ADVERSE EVENT REPORTS OUS:	SE FOR EVALUATION ON:	DATE PRODU	OCT RECEIVED:	JUN			
NVESTIGATION:	PLEASE SEE ATTACHED INV ARDED TO PHARMACIST / NUR CORRECTIVE ACTION: COMPLETED BY: ADVERSE EVENT REPORTS DUS. RTED ON: 05/21	SE FOR EVALUATION ON:	DATE PRODU	OCT RECEIVED: _	JUN 8-15			
DVERSE EVENT FORM DVERSE EVENT FORM ECTION III: CORRECTIVE ACTION(S ECTION IV: DVERSE EVENT SERIO	PLEASE SEE ATTACHED INV ARDED TO PHARMACIST / NUR CORRECTIVE ACTION: COMPLETED BY: ADVERSE EVENT REPORTS DUS. RTED ON: 05/21	SE FOR EVALUATION ON:	DATE PRODU	OCT RECEIVED:	JUN			

cc: QA / QC Packaging

Production Shipping / Receiving JUN Ports V9015





CaseID: 11173807

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 $\leq_{(4)}^{(6)}$ 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

USS JUN -8 201



SE EVENT DATA FORM



SECTION I:		FFERENT FROM REPORTER ON FORM	1 VD1)	
NAME:	(b) (6)			
ADDRESS:				
CITY:		STATE:	(b) (6)	
COUNTRY:	USA	ZIP CODE:		
PHONE #:	(b) (6)			
E-MAIL:				
SECTION II:	PACKAGING INFORMATION:			
A	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OU (INCLUDE DRUG FACTS PAN	ITER CARTON HE AND PRINCIPAL L IELS)	RE DISPLAY
		Teethin	3 m	
				*
	Control of the special control of the special			
SECTION III:	CORRECTIVE ACTION:		*	
ORRECTIVE A	CTION(S) COMPLETED BY:		ATE:	
	CTION(S) COMPLETED BY:		ATE:	_
CORRECTIVE A	CTION(S) COMPLETED BY:	14	ATE:	2. 16



by user-facilities, ibutors and manufacturers DATORY reporting

	CaselD. 111/00/9
Form	Approved: DMB No. 0910-0291, Expires: 8/30/2015
	See OMB statement on reverse

	See OMB statement on reve
Mfr Report # 54973	1,000

UF/Importer Report #

3	70		2	
Jana	1	of	5	

FORM	FDA	3500A	(2/13)
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(b) (6)	ORMATION			
	1. Patient Identifier 2. Age at Time of Event: INFANT		3. Sex	4. Weight
	orINFAN	T	Female	
	Date			10
In confidence	of Birth:		Male	
B. ADVERSE EV	ENT OR PRODU	JCT PROBLEM	1	
1. Adverse Even	and/or P	roduct Problem (e.	g., defects/malf	unctions)
2. Outcomes Attribut				
(Check all that apply	()	6-2		
Death:	(mm/dd/yyyy)	Disability or	Permanent Da	mage
Life-threatening		Congenital	Anomaly/Birth D	Defect
Hospitalization	- initial or prolonged	✓ Other Serio	us (Important M	ledical Eve
Required Inter	vention to Prevent Pen	nanent Impairment/	Damage (Devic	es)
3. Date of Event (mm	/dd/yyyy)	4. Date of This	Report (mm/dd	(yyyy)
05/0	0/2015		05/19/2015	i
UNSTEADY WHEN	RECE JUN 08	2015		
6, Relevant Tests/Lab	oratory Data, includi	ng Dates	(Continue on	page 3)
		ng Dates	(Continue on	page 3)
	oratory Data, Including ory, Including Preexicular ory, Including Preexicular organization of the control of th	ng Dates	(Continue on	page 3)

C. SUSPECT PRODUCT(S) Name (Give labeled strength & mfr/labeler) #1 HYLAND'S BABY TEETHING TABLETS Therapy Dates (If unknown, give duration) from/to (or best estimate) 2. Dose, Frequency & Route Used #1 2 TABS SL X 1 DOSE #1 4. Diagnosis for Use (Indication) 5. Event Abated After Use Stopped or Dose Reduced? #1 TEMP RELIEF TEETHING PAIN #1 Yes No Doesn't Doesn' Apply #2 Yes No 6. Lot # 7. Exp. Date 8. Event Reappeared After #1 #1 Reintroduction? #2 #1 Yes No Doesn't #2 9. NDC# or Unique ID Doesn't #2 Yes No 54973-3127-3 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) D, SUSPECT MEDICAL DEVICE Brand Name 2. Common Device Name 2b. Procode 3. Manufacturer Name, City and State 4. Model # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Serial # Unique Identifier (UDI) # Other: 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of the (Continue on page 3) E. INITIAL REPORTER 1. Name and Address Phone # Email Address (b) (6) 2. Health Professional? 3. Occupation 4. Initial Reporter Also Sent Report to FDA NA Yes V No Yes No V Unk

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



Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

9. Approximate Age of Device

No

Yes

☐ No

Address

11. Report Sent to FDA?

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

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

05/18/2015

30-day

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

☐ 10-day 🗸 Initial

54973 AE # 1607

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

7. Type of Report

5-day

7-day

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

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

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

2. UF/Importer Report Number

5. Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Literature ✓ Consumer

User Facility

Company

Distributor

Other:

Study

3. Report Source (Check all that apply)

Health Professional

Representative

e 2 of

					i F	DA USE	ONLY			
5										
H. DEVICE MANUFAC	TURE	RS	4O	ILY						
1. Type of Reportable Event						2. If Foll	ow-u	ıp,۱	What Type?	?
Death							Corre	ecti	on	
Serious Injury							Addi	tion	al Informatio	on
Malfunction							Resp	ons	se to FDA R	equest
							Devi	ce E	Evaluation	
3. Device Evaluated by Manu	facturer	,			\dashv	4 Devic	e Ma	muf	facture Date	
Not Returned to Manu						(mm/y			uotore Date	•
Yes Evaluation		, At	tach	ha						
				eu	}	5. Label	ed fo	r S	ingle Use?	
No (Attach page to ex provide code:	pain wny	rioi) Or						_	
							Yes		☐ No	
6. Event Problem and Evalua	tion Cod	es /	Ref	er to		ling manu	ıai}			
Patient			1	C, 10		mig man	.с., 1 г			٦
Code			-	L			J-[
Device	· · · ·]_				1-1			٦
Code		,		<u> </u>	_		J L			
Method].	-			-	-		-		
					7			וו		l
Results		-[- [
Conclusions		_[٦.			1_[1
						L		J L		
7. If Remedial Action Initiate	d, Check	Тур	e	- 1	8. U	sage of				
Recall	otification							e o	f Device	
Repair In	spection					Re				
Replace	atient Mor	itor	ing			<u> </u>	cnow			
	odification			- [9. If 2	action re 1 USC 36	epor 50i(f)	ted , lis	to FDA und t correction	ier n/
Other:	ujustinent				r	emoval r	epòr	ting	number:	
Other.				-						
10. Additional Manufacti	ırer Narra	tive	3	i	and	/ or	11.	. [Correcte	d Data
									-	_
									DS	5
								J	UN - 9) 201
								_		
							JU	N	-82) N1E

CaseID: 11176579

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

(A)NDA#

IND#

BLA#

510(k)#

Product

Pre-1938

Combination

OTC Product

8. Adverse Event Term(s)

Yes

Yes

✓ Yes

BELLADONNA TOX, WRITHING, ALTERED

STATE, CRYING, DILATED PUPILS, CONFUSION, STAGGERING, UNSTEADY

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

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Please DO NOT RETURN this form to the above PRA Staff email address.



CIVIL		

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Cas	THE RESERVE	14765	19

3111	76579-01-00-03				
		DATE OF CO	MPLAINT:	05/18/2015	
PRODUCT:	HYLAND'S BABY TEETHING TABLETS	IT	EM CODE:	BTET	
SIZE:	NOT PROVIDED		LOT NO.	NOT PROVIDE	ED
REPORTER:	(6) (6)				
ADDRESS:	N/A				
CITY:	N/A	STATE:	N/A		
COUNTRY:	USA	ZIP CODE:	N/A		
PHONE #:	NOT PROVIDED				
E-MAIL:	(b) (6)				
PACE WHEN TRY COULD HAVE DON	(CIRCLE ONE)	TRYING TO STAND. 1) AND I WILL PURSUE THI COMPANY SHOULD BE I	AM LIVID AN S BY OTHER BANNED FRO ARATE SHE	ID NOW VERY F MEANS AS WELL DM PRODUCING A SET	RIGHTENED THIS
			UPS CALL	TAG ISSUED:	(CIRCLE ONE)
		DAT	TE PRODUC	T RECEIVED:	
SECTION II:	INVESTIGATION				
INVESTIGATION:	PLEASE SEE ATTACHED INSPECTION REPORT.				
ADVERSE EVENT	FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:		05/18/201	5	
ADVERSE EVENT	FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:		EDYTA FI	RACKIEWICZ	
SECTION III:	CORRECTIVE ACTION:				
CORRECTIVE AC	TION(S) COMPLETED BY:		DATE		DSS
CORRECTIVE AC	TION(S) COMPLETED BY: ADVERSE EVENT REPORTS			1607	DSS JUN - 9 2015
SECTION IV:	ADVERSE EVENT REPORTS			1607	
SECTION IV: ADVERSE EVENT	ADVERSE EVENT REPORTS SERIOUS: Y N	BV. PA	AE#:		
SECTION IV: ADVERSE EVENT ADVERSE EVENT	ADVERSE EVENT REPORTS SERIOUS: Y N	BY: ED			
SECTION IV: ADVERSE EVENT	ADVERSE EVENT REPORTS SERIOUS: (Y) N REPORTED ON: 05/18/2015	BY: EDY	AE #:		JUN - 9 2015

cc: QA / QC Packaging

Production Shipping / Receiving

JUN - 8 2595 #VD1





CaseID: 11176579

SAE-0016-2015

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 Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(6)}$ 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

JUN - 9 2015



SE EVENT DATA FORM



AE #: 1607		COMPLAINT#: 2617	
SECTION I:	PATIENT INFORMATION (IF DIF	FERENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:			
CITY:	3.64	STATE:	
COUNTRY: PHONE #:	USA	ZIP CODE:	
E-MAIL:	(b) (d)		
SECTION II:	PACKAGING INFORMATION:		
(w)	Treething Dabets Address of the Control of the Con	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Teething Tablets MAN TO BE AND THE TOWN THE TO	
SECTION III;	CORRECTIVE ACTION:		
			SS
			-9 2015
CORRECTIVE AC	TION(S) COMPLETED BY:	DATE:	2.5.50
SECTION IV:	Qui	NH	
REVIEWED BY MA	10 1/2	DATE: 05- 77-15	
BY:	QA / QC DIRECTOR	DATE: 05-21-15	

JUN - 8 9915

by user-facilities, butors and manufacturers DATORY reporting

je 1 of 5

	age chie state herr an levelse
Mfr Report # 54973	
JF/Importer Report #	
	Enne

#1 HYLAND'S B #2 2. Dose, Frequency 6 #1 UNKNOWN #2 4. Diagnosis for Use	Route Head 3. The	erapy Dates (If unknown, give dun m/to (or pest estimate)
2. Dose, Frequency 6 #1 UNKNOWN #2	fron	m/to (or best estimate)
#1 UNKNOWN #2	fron	m/to (or best estimate)
#2		A CONTRACTOR OF THE CONTRACTOR
		Winn Hall
	#2	4
	(Indication) UN 0 9	2015. Event Abated After Use
#1 TEMP RELIE	F TEETHING PAIN	Stopped or Dose Reduce
#2		#1 Yes No V
(1)	Sant Book I	#2 Yes No A
	100000000000000000000000000000000000000	8. Event Reappeared After
		- Reintroduction?
		#1 Yes No A
		#2 Yes No A
10. Concomitant Med	ical Products and Therapy Da	ites (Exclude treatment of event)
	EDICAL DEVICE	(Continue on page
(5,220,235,27)		2b. Procode
2. Common Device N	distrib	2p. Procode
3. Manufacturer Nam	e, City and State	
4. Model #	Lot #	5. Operator of Dev
Catalog #	Expiration Date (m	mm/dd/yyyy) Health Profess Lay User/Patie
Serial #	Unique Identifier (L	UDI) # Other:
6. If implanted, Give I	Date (mm/dd/yyyy) 7 If Ex	xplanted, Give Date (mm/dd/yyyy)
		d and Reused on a Patient?
		Danmanear
Yes No	Returned to Manufactu	urer on:(mm/dd/yyyy)
11. Concomitant Med	cal Products and Therapy Dat	tes (Exclude treatment of event)
		(Continue on page .
	020025	
1. Name and Address (b) (6)	а	15A JU
Phone #	Email Addres	is .
1777	20000000	
	6. Lot # #1 #2 9. NDC# or Unique ID 54973-3127-3 10. Concomitant Med D. SUSPECT ME 1. Brand Name 2. Common Device N. 3. Manufacturer Name 4. Model # Catalog # Serial # 6. If Implanted, Give ID 8. Is this a Single-use Yes No 9. If Yes to Item No. 8 10. Device Available for Yes No 11. Concomitant Medi E. INITIAL REPO 1. Name and Address (b) (6)	6. Lot # 7. Exp. Date #1 #2 9. NDC# or Unique ID 54973-3127-3 10. Concomitant Medical Products and Therapy Date D. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name 3. Manufacturer Name, City and State 4. Model # Lot # Expiration Date (m Serial # Unique Identifier (t 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Expiration Date (m 9. If Yes to Item No. 8, Enter Name and Address of 10. Device Available for Evaluation? (Do not send to Yes No Returned to Manufacture) 11. Concomitant Medical Products and Therapy Date E. INITIAL REPORTER 1. Name and Address (b) (6)

									Casel FDA USE	D: 11179757
				e	2 of 5	_				
. CHECK ONE	_	:7-01-00-()2 			pe of Reportab	NUFACTURI le Event	ERS ONLY	2. If Fo	llow-up, What Type?
User Facility 3. User Facility or Impo	impor					Death Serious Injur Malfunction	у			Correction Additional Information Response to FDA Request Device Evaluation
					3. D e	_	by Manufacture to Manufacture			ce Manufacture Date (уууу)
. Contact Person			5. Phone N	umber			valuation Summ	•	5. Labe	led for Single Use?
Date User Facility or Importer Became Aware of Event (mm)		. Type of Repor		8. Date of This Report (mm/dd/yyyy)	6. Ev	provide code	e:			Yes No
. Approximate Age of Device	10. Event Properties Code Device Code	Follow-up # roblem Codes (I		ng menuel)		Pati Cod Dev Cod Meth	ient de la la la la la la la la la la la la la] - [] - []-[]-[
1. Report Sent to FDA Yes (mm/dd/) No 3. Report Sent to Man	(YYYY)	12. Location W Hospita Home Nursing	ı	Occurred Outpatient Diagnostic Facility Ambulatory Surgical Facility		Conclusion]-[]	B. Usage of]- []
Yes(mm/dd/ No	<i>'</i> 9999)	Outpating Facility Other:	ent Treatmer	(Specify)		Recall Repair Replace Relabeling Other:	Notification Inspection Patient M Modification Adjustme	on onitoring	Init	tial Use of Device use known reported to FDA under 60i(f), list correction/ reporting number:
G. ALL MANUFA			ces)	2. Phone Number	10.	Additional M	anufacturer Na	rative a	and / or	11. Corrected Data
Name DYTA FRACKIEWI			,	310-768-0700 3. Report Source						
Address YLAND'S, INC. 54 W. 131ST ST OS ANGELES, CA				(Check all that apply) Foreign Study Literature Consumer						
Email Address TANDARD@HYLAND	S.COM		-	Health Professional						
Date Received by Manufacturer (mm/do		5. (A)NDA#		User Facility Company						
05/21/20 If IND, Give Protocol		IND#		Representative Distributor Other:						
Type of Report (Check all that apply) 5-day 30-day 7-day Period 10-day ✓ Initial	_	PMA/ 510(k) # Combination Product Pre-1938	Yes Yes							
✓ 15-day ☐ Follow		OTC Product	✓ Yes							DSS
Manufacturer Report 4973 AE # 160		8. Adverse Eve SEIZURE	ent Term(s)							JUN 1 0 20

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54973 AE # 1609

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer required to respond to, a co
Paperwork Reduction Act (PRA) Staff

PRAStaff@fda.hhs.gov

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SECTION I:				CaseID. 11	, 0, 0,
SCOTION I.	COMPLAINT		COMPLAINT #:	2619	
TAKEN BY:	EDYTA	FRACKIEWICZ	DATE OF COMPLAINT:	05/21/2015	
PRODUCT:	HYLAN	ID'S BABY TEETHING TABLETS	ITEM CODE:	ВТЕТ	_
SIZE:	N/A		LOT NO.:	N/A	
REPORTER:	(b) (6)				
Individual	Case Safet	y Report		_	_
				*	_
tenenatitief fi	B. 12 B. 12 12 13 14 15 15		STATE: N/A	*	_
11	179757-01-00	0-03	ZIP CODE: N/A		_
PHUNE #	-				
E-MAIL:	N/A		- A		_
USE THESE WAR	T AFTER I USED THE RNING. NOT SHUR W SEIZURES OF THE N	/HAT I CAN REALLY SAY ALL I KNOV NEXT 24 HRS.	IRE HE WAS ONLY 4 MONTHS OLD STOPS VIS MY SON WAS TEETHING I PICKED UP REVERSE OR ATTACH A SEPARATE SHE	THE TEETHING TABLETS AND	MY
				1	7
PRODUCT RECE	IVED FOR	(CIRCLE ONE)	PRODUCT BEING RETURNED FOR	INSPECTION: Y (CIRCLE ON	N
2.4.22.42.4		4	DATE REQUESTED PRODUCT BE	E RETURNED:	
			UPS CALL	TAG ISSUED: (CIRCLE OF	N N
			DATE PRODUC	CT RECEIVED	
ecction II.	INVESTIGAT	ON.	DATE PRODUC	CT RECEIVED:	_
SECTION II:	INVESTIGAT	<u>ION</u>	DATE PRODUC	CT RECEIVED:	-
SECTION II:	TTANA	ION SEE ATTACHED INVESTIGATION REP		CT RECEIVED:	
	TTANA			CT RECEIVED:	
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INVESTIGATION:	PLEASE S	SEE ATTACHED INVESTIGATION REP	PORT		
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INVESTIGATION:	PLEASE S	SEE ATTACHED INVESTIGATION REI	PORT TION ON:	15	
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ADVERSE EVENT SECTION III: CORRECTIVE AC SECTION IV: ADVERSE EVENT ADVERSE EVENT	PLEASE S FORWARDED TO PI FORWARDED TO PI CORRECT CORRECT CORRECT ADVERSE EV	HARMACIST / NURSE FOR EVALUATIVE ACTION: D BY: ENT REPORTS	DATE: BY: EDYTA FRACK	1609	
ADVERSE EVENT SECTION III: CORRECTIVE AC SECTION IV: ADVERSE EVENT ADVERSE EVENT	PLEASE S FORWARDED TO PI FORWARDED TO PI CORRECT CORR	HARMACIST / NURSE FOR EVALUATIVE ACTION: D BY: ENT REPORTS	DATE: BY: EDYTA FRACK	1609	DSS
ADVERSE EVENT ADVERSE EVENT SECTION III: CORRECTIVE AC SECTION IV: ADVERSE EVENT	PLEASE S FORWARDED TO PI FORWARDED TO PI CORRECT CORRET	HARMACIST / NURSE FOR EVALUATIVE ACTION: D BY: ENT REPORTS	DATE: BY: EDYTA FRACK	15 RACKIEWICZ	DSS

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 11179757

SAE-0018-2015

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 Teetning Tablet lots for atropine, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤^(b)₍₄₎ ppm.

Conclusion:

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

Prepared by

5/28/2015

Date

DSS JUN 1 0 2015



RSE EVENT DATA FORM

Cas	611	1.11	79757
		3	10101

AE #:	1609	COMPLAINT #:
SECTION I	(b) (6)	DIFFERENT FROM REPORTER ON FORM VD1)
ADDRESS:	· -	
CITY:		STATE:
COUNTRY:	USA	ZIP CODE:
E-MAIL;		
SECTION II	PACKAGING INFORMATION:	
	AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	Teaching Tables	Commence of the second
		Teething Tablets Tablets Tablets
		Section of the Sectio
SECTION II	CORRECTIVE ACTION:	
CORRECTI	VE ACTION(S) COMPLETED BY:	DATE:
SECTION IN	<u> </u>	DSS
REVIEWED	BY MANAGEMENT BY:	DATE: 06-01-15 DSS MATE: 05-29-15 DATE: 05-29-15
BY:	Eur Ba	WWW DATE: 05-29-15
	QA / QC DÎRECTOR	

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAEDT

JUN - 9 2015



y user-facilities, itors and manufacturers aTORY reporting

	aseID: 11179760 d: OMB No 0910 0191, Expire / 6/30/2
Mfr Report # 54973	Jan Grand Her Grinder
UF/Importer Report #	

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

Page 1 of 5

A DATIENT IN				, age ,		ODIVETICA			FDA Use Onl
A. PATIENT IN Patient Identifier			3. Sex	4. Weight	C. SUSPECT PR 1. Name (Give labeled)		ngler)		
) (6)	of Event: 11	Months			#1 HYLAND'S BA				
	Of		✓ Female	or lbs	***************************************	3.103.11.303.40			-
In confidence	of Birth:		Male	kgs	#2	Davida Head	la Themas Da		when the matters
B. ADVERSE E	VENT OR PRODU	JCT PROBLE	M		2. Dose, Frequency &	Houte Used	from/to (or t	etes (if unknown, best estimate)	give duration
✓ Adverse Eve	nt and/or P	roduct Problem (e.g., defects/malf	unctions)	#1 UNKNOWN		#1		
Outcomes Attribu	uted to Adverse Event				#2		#2		
(Check all that app	oly)			215	4. Diagnosis for Use ((Indication)		vent Abated Aft	
Death:	(mm/dd/yyyy)		or Permanent Da		#1 TEMP RELIEF	TEETHING E	PAIN	Yes No	Doesn
Life-threateni			al Anomaly/Birth [#2			L) 4 L)	— Арріу
	on - initial or prolonged	the state of the state of	ious (Important N	ALL THE PARTY	6. Lot#	7. Exp. Dat	#2	Yes No	Doesn Apply
	ervention to Prevent Pen		7,100		#1	#1	8.E	vent Reappeare	d After
Date of Event (m	25/2015	4. Date of The	05/27/2015	3324	#2	#2	#1	eintroduction?	Doesn
Describe Event o		-			9. NDC# or Unique ID		JUN 0.9	7015	Libbia
	EPORTS THEY HAV				54973-3127-3		#2	Yes No	Doesn Apply
					D SUSPECT ME 1, Brand Name	DICAL DEVI	CE	(Continue d	
					2. Common Device Na	ame		2b. Procode	
				100	3. Manufacturer Name	. City and State			
					4. Model #	Lot #	7.47	5. Operate	or of Device
					Catalog #	Expira	ation Date (mm/dd/yy	av)	tn Professiona User/Patient
					Serial #	Uniqu	e Identifier (UDI) #	Othe	
			(Continue or	n page 3)	6. If implanted, Give D	ate (mm/dd/yyyy)	7. If Explanted	d, Give Date (mn	n/dd/yyyy)
Relevant Tests/La	aboratory Data, Includi	ng Dates			8. Is this a Single-use	Device that was	Reprocessed and R	eused on a Pati	ent?
					Yes No				
					9. If Yes to Item No. 8,	Enter Name and	Address of Reproc	essor	
					10. Device Available for	or Evaluation? (C	o not send to FDA)		
					Yes No	Returned	I to Manufacturer on:	(mm/dd/	(VVV)
			(Continue or	page 3)	11. Concomitant Medi	cal Products and	Therapy Dates (Exc		
Other Relevant Hi race, pregnancy, s	istory, including Preex moking and alcohol use	isting Medical Co , hepatic/renal dys	nditions /e a						
					E. INITIAL REPO	RTFR		(Continue o	n page 3)
					1. Name and Address (b) (6)	ALC: UNITED STREET			220
					101 (0)				DSS
								JUI	102
			Manual	anna ana	Phone # (b) (6)		Email Address		
hmission of a	report does not co	netitudo en ca	(Continue or			19 2 0		IA Initial Descri	dos Alex O
rsonnel, user f	acility, importer, d	istributor, ma	nufacturer or	product	2. Health Professional Yes No	Pharmacis		4. Initial Repo Report to F	DA
used or contrib	outed to the event.	A			Y Yes No	r namaci:	ж.	Yes	No V Unk



e 2 of 5

Case	ID:	11	17	97	60

				_				JIN L. T		
1. Check One	-	2. U	F/Importer R	Report Number	_	e of Reportable E	JFACTURERS (Event		2. If Follow-up	p, What Type?
User Facility	mpoi	rter				Death			☐ Corre	ection
3. User Facility or Impor	orter Name/	Address] [Serious Injury			Additi	onal Information
						Malfunction			Respo	onse to FDA Request
									Devic	e Evaluation
					3. Devi	ice Evaluated by	Manufacturer?			rufacture Date
						Not Returned to	Manufacturer		(mm/yyyy)	
4. Contact Person			5. Phone N	umber	11 =	Yes Eval	uation Summary Atta	ched		
			L] [No (Attach page provide code:	e to explain why not)	or	5. Labeled for	Single Use?
6. Date User Facility or Importer Became	i i	7. Type of Repor	rt	8. Date of This Report (mm/dd/yyyy)		provide code.			Yes	☐ No
Aware of Event (mm/d	(dd/yyyy)	Initial			6 Eva	at Oroblom and E	Evaluation Codes (F	ofor to or	ding manual)	
		Follow-up #			O. Ever	Patient		reiei io co	oung mandan	
9. Approximate 1 Age of Device	10. Event P	roblem Codes (Refer to codir	ng manual)]	Code				
F	Patient	-	-	-	1	Device Code		-	7-	
	Code Device									
	Code		<u> </u>]	Method			<u> </u>	-
11. Report Sent to FDA?	?	12. Location W	here Event (] [Results	-		-	-
Yes	0004	Hospita	al .	Outpatient Diagnostic Facility		_				
☐ No (mm/dd/y)		Home	Homo	Ambulatory		Conclusions			<u>- </u>	
13. Report Sent to Manua	ufacturer?	☐ Nursing ☐ Outpatie	r Home ent Treatmen	Surgical Facility	7. If Re	medial Action In	itiated, Check Type	8.	Usage of Devic	
Yes(mm/dd/yy	ariar)	Facility				Recall	Notification		Initial Use	e of Device
☐ No	""	Other:				Repair	Inspection		Reuse	
	ı			(Specify)	1 1 1					
4. Manufacturer Name/A	/Address			(Specify)		Replace	Patient Monitorin	_	Unknown	
14. Manufacturer Name/A	/Address			(Specify)		Replace Relabeling	Patient Monitorin Modification/ Adjustment	9.	If action reporte 21 USC 360i(f),	ed to FDA under list correction/
14. Manufacturer Name/	/Address			(Specify)			Modification/	9.	If action reporte	ed to FDA under list correction/
 14. Manufacturer Name/i	/Address			(Specify)		Relabeling	Modification/	9.	If action reporte 21 USC 360i(f),	ed to FDA under list correction/
4. Manufacturer Namel	/Address			(Specify)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
		3		(Specify)	10.	Relabeling Other:	Modification/	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/
G. ALL MANUFAC	CTURERS		ces)	(Specify) 2. Phone Number	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name	CTURERS Manufacturi		ces)		10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name EDYTA FRACKIEWIC	CTURERS Manufacturi		ces)	2. Phone Number 310-768-0700 3. Report Source	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name EDYTA FRACKIEWIC Address	CTURERS Manufacturi		ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name EDYTA FRACKIEWIC Address HYLAND'S, INC.	CTURERS Manufacturi CZ		ces)	2. Phone Number 310-768-0700 3. Report Source	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name CDYTA FRACKIEWIC Address HYLAND'S, INC.	CTURERS Manufacturi CZ REET		ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name CDYTA FRACKIEWIC Address AYLAND'S, INC. LS4 W. 131ST STR LOS ANGELES, CA	CTURERS Manufacturi CZ REET		ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC I. Contact Office (and M. Name DYTA FRACKIEWIC Address HYLAND'S, INC. L54 W. 131ST STR LOS ANGELES, CA Email Address	CTURERS Manufacturi CZ REET 90061		ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name CDYTA FRACKIEWIC Address AYLAND'S, INC. 154 W. 131ST STR OS ANGELES, CA Email Address STANDARD@HYLANDS	CTURERS Manufacturi CZ REET 90061		ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and Manue) DYTA FRACKIEWIC Address IYLAND'S, INC. 54 W. 131ST STR OS ANGELES, CA Email Address TANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y	CZ REET 90061 S.COM	ng Site for Devi	ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC Contact Office (and M. Name DYTA FRACKIEWIC Address IYLAND'S, INC54 W. 131ST STR .OS ANGELES, CA Email Address TANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201	CZ REET 90061 S.COM	ng Site for Devid	ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number:
G. ALL MANUFAC J. Contact Office (and M. Name DYTA FRACKIEWIC Address HYLAND'S, INC. L54 W. 131ST STR LOS ANGELES, CA Email Address STANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201	CZ REET 90061 S.COM	5. (A)NDA #	ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number: Corrected Data
G. ALL MANUFAC Contact Office (and M. Name DYTA FRACKIEWIC Address IYLAND'S, INC. 54 W. 131ST STR OS ANGELES, CA Email Address TANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201	CZ REET 90061 S.COM	5. (A)NDA # IND # BLA #	ces)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number: Corrected Data
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G. ALL MANUFAC Contact Office (and M. Name DYTA FRACKIEWIC Address IYLAND'S, INC. 54 W. 131ST STR. OS ANGELES, CA Email Address ITANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201 If IND, Give Protocol #	CTURERS Manufacturi CZ REET 90061 S.COM Myyyy) 15	5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination		2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	ed to FDA under list correction/ ng number: Corrected Data
G. ALL MANUFAC Contact Office (and M. Name DYTA FRACKIEWIC Address IYLAND'S, INC. 54 W. 131ST STR OS ANGELES, CA Email Address TANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201 If IND, Give Protocol #	CTURERS Manufacturi CZ REET 90061 S.COM Myyyy) 15	5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product	Yes	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	DSS
G. ALL MANUFAC Contact Office (and M. Name DYTA FRACKIEWIC Address IYLAND'S, INC. 54 W. 131ST STR. OS ANGELES, CA Email Address ITANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201 If IND, Give Protocol # Type of Report (Check all that apply) 5-day 30-day 7-day Periodic	CTURERS Manufacturi CZ REET 90061 S.COM Myyyy) 15	5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Pre-1938	Yes Yes	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	DSS
G. ALL MANUFAC Contact Office (and M. Name DYTA FRACKIEWIC Address HYLAND'S, INC. 54 W. 131ST STR. OS ANGELES, CA Email Address STANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201 If IND, Give Protocol # Type of Report (Check all that apply) 5-day 30-day 7-day Periodic 10-day / Initial	CTURERS Manufacturi CZ REET 90061 S.COM Myyyy) 15	5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product	Yes	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	9.	If action reports 21 USC 360i(f), removal reporti	DSS
G. ALL MANUFAC I. Contact Office (and M. Name EDYTA FRACKIEWIC Address HYLAND'S, INC. 154 W. 131ST STR LOS ANGELES, CA Email Address ETANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201 6. If IND, Give Protocol # Type of Report (Check all that apply) 5-day 30-day 7-day Periodic 10-day Initial	CTURERS Manufacturi CZ REET 90061 S.COM Myyyy) 15	5. (A)NDA #	☐ Yes ☐ Yes ☑ Yes ☑ Yes	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:	10.	Relabeling Other:	Modification/ Adjustment	and	If action reports 21 USC 360i(f), removal reporti d / or 11.	DSS JUN 10 2
G. ALL MANUFAC I. Contact Office (and M. Name DYTA FRACKIEWIC Address HYLAND'S, INC. L54 W. 131ST STR LOS ANGELES, CA Email Address STANDARD@HYLANDS Date Received by Manufacturer (mm/dd/y 05/25/201 i. If IND, Give Protocol # 'Type of Report (Check all that apply) 5-day 7-day Periodic 10-day Initial 115-day Follow-u	CZ REET 90061 S.COM (Vyyy) 15 #	5. (A)NDA #	☐ Yes ☐ Yes ☑ Yes ☑ Yes	2. Phone Number 310-768-0700 3. Report Source (Check all that apply)	10.	Relabeling Other:	Modification/ Adjustment	and	If action reports 21 USC 360i(f), removal reporti	DSS JUN 10 2

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.

MADE IN TH	HE USA SINCE 1903	Ca	36100
SECTION I:	COMPLAINT	COMPLAINT #: 2622	
TAKEN BY:	(6) (6)	DATE OF COMPLAINT: 05/25/2015	
PRODUCT:	HYLAND'S BABY TEETHING TABL	ETS ITEM CODE: BTET	
SIZE:	NOT PROVIDED	LOT NO.: NOT PROVIE	DED
REPORTER:	(b) (6)		
ADDRESS:			
CITY:		STATE: (b) (6)	
COUNTRY:	USA	ZIP CODE: N/A	
PHONE #:	(b) (6)		
E-MAIL:	N/A	ST CALLING FROM THE ER DEPT AT ^(b) (6)	V (p) (g)
PROVIDE ANY F	N THE PRODUCT ASSOCIATED WITH HEMOLYTIC FURTHER INFORMATION REGARDING THE CHILD PROVIDE ADDITIONAL INFORMATION.	D RED SPOTS ON SKIN. REPORTER WOULD LIKE TO KNOW IF THE ANEMIA OR SOME SORT OF THROMBOCYTOPENIA. REPORTER OF SYMPTOMS, HISTORY, OR USE OF THE PRODUCT. HE WILL AS USE REVERSE OR ATTACH A SEPARATE SHEET	WOULD NOT
PRODUCT RECEINSPECTION:	EIVED FOR Y (CIRCLE ONE)	PRODUCT BEING RETURNED FOR INSPECTION:	Y (CIRCLE ONE)
	ase Safety Report	DATE REQUESTED PRODUCT BE RETURNED:	3500000000
		UPS CALL TAG ISSUED:	Y (CIRCLE ONE)
1117	79760-01-00-03	SI S SALE INSISSES.	(GINGLE GIAL)
3,111	, 5, 55 5 , 55 5 5	DATE PRODUCT RECEIVED:	
SECTION II:	INVESTIGATION		
INVESTIGATION	PLEASE SEE ATTACHED INSPECTION	N REPORT.	
	IT FORWARDED TO PHARMACIST / NURSE FOR E IT FORWARDED TO PHARMACIST / NURSE FOR E CORRECTIVE ACTION:	(b) (6)	
CORRECTIVE AC	CTION(S) COMPLETED BY:	DATE:	
SECTION IV:	ADVERSE EVENT REPORTS	AE #:1612	DOC
ADVERSE EVEN	T SERIOUS: (Y) N		DSS
	T REPORTED ON: 05/25/2015	£ BY: (b) (6)	JUN 1 0 201
SECTION V:		\ 1/	
REVIEWED BY M	IANAGEMENT BY:	DATE: 05-29-	15
BY:	GA/QC DIRECTOR	DATE: 05-29-	15
	MA / GO DINECTOR		
cc: QA/QC	Production		





.dverse Event SAE-0022-2015

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-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 $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

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

Prepared by

Date

5/28/2015

DSS JUN 1 0 2015

CaseID: 11179760



SE EVENT DATA FORM



16	12	COMPLAINT#: 2622
TION I:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)
E:	UNKNOWN	
RESS:	(b) (6)	
NE33.	-	- Marie
2		STATE:
NTRY:	USA	ZIP CODE:
NE #:	(b) (6)	
dL:		
TON II:	PACKAGING INFORMATION:	
	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE
6	der ten der service state de desenviers et	(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	- 🔊	PARLES
	Teething Tablets	
3	dissertation and the second and the	and the same of th
	Section Section	
		Teething Tablets an increase and office.
1		Statement of the Automorphism (articles)
,		Security and the security of t
	A second	
	The second secon	
		Comp Page
		the manufacture of the first and the first a
ON III:	CORRECTIVE ACTION:	
		DATE:
	CORRECTIVE ACTION: CTION(S) COMPLETED BY:	DATE:
ECTIVE A		
		DSS
ECTIVE A		DSS
ECTIVE A	CTION(S) COMPLETED BY:	DATE: 06-01-199N 10 :



by user-facilities, rutors and manufacturers ATORY reporting

Form Appendice	م الم	1.1.1.7.5 e OMB stat	Apires 36/30/2015 ement on reverse.
Mfr Report # 54973			
UF/Importer Report #		10	
		1	FDA Use Only
T(S)			

je 1 of 6

Patient Identifier (b) (6)	of Event: 5	Months	Female	4. Weight	#1 HYLAND'S BAB	Y TEETHING	TABLETS	
la anafolossa	Date		Male	or tree	#2 HYLAND'S BAB	Y NIGHTTIME	TEETHING TAB	LETS
In confidence B. ADVERSE E	of Birth: VENT OR PRODU	JCT PROBLEM		kgs	2. Dose, Frequency & R.	oute Used	3. Therapy Date from/to (or bes	s (If unknown, give duration st estimate)
. Adverse Ever	nt and/or Pr	roduct Problem (e.g.	, defects/mailu	nctions)	#1 UNKNOWN		#1	
Outcomes Attribu	ted to Adverse Event	4			#2 UNKNOWN			2 (25)
Death:		Disability or F	Permanent Dan	nage	4. Diagnosis for Use (inc		Stor	nt Abated After Use pped or Dose Reduced?
✓ Life-threatening	(mm/dd/yyyy)	Congenital Ar	nomaly/Birth De	efect	#1 TEMP RELIEF T	100	#1	Yes No Does
✓ Hospitalization	- initial or prolonged	Other Serious	s (Important Me	edical Events)	#2 TEMP RELIEF 1	7. Exp. Date	N U 9 4013	Yes No Does
	vention to Prevent Perm		The second second		#1	#1 s	8. Eve	nt Reappeared After
Date of Event (mr	n/dd/yyyy) 10/0000	4. Date of This Re	port (mm/dd/) 5/26/2015	(vyy)	#2	#2	The same of the	res No Does
Describe Event or	WE STATE OF		3/20/2013		9. NDC# or Unique ID	1,4		Apply
HILD DEVELOP MONTHS.	ED INFANT BOTU	LISM AND WAS	HOSPITALI	ZED FOR	54973-3127-3,	54973-3197-	1 #2	Yes No V Apply
					D. SUSPECT MEDI	CAL DEVICE		(Continue on page 3)
					2. Common Device Name		2b.	Procode
					3. Manufacturer Name, C	ity and State		
					4. Model #	Lot #		5. Operator of Device
					Catalog #	Expiration	Date (mm/dd/yyyy)	Health Professiona Lay User/Patient
					Serial #	Unique Ide	entifier (UDI) #	Other:
Palavant Tastell at	oratory Data, Includin		Continue on p	oage 3)	6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Explanted, G	ive Date (mm/dd/yyyy)
THE PARTY OF THE P	oratory Date, moluum	y oates			8. Is this a Single-use De	vice that was Rep	rocessed and Reus	ed on a Patient?
					9. If Yes to Item No. 8, En	ter Name and Add	iress of Reprocess	or
					10. Device Available for E	valuation? (Do no	t send to FDA)	-
					Yes No	Returned to M	fanufacturer on:	(mm/dd/yyyy)
			Continue on p		11. Concomitant Medical	Products and The	rapy Dates (Exclude	
Other Relevant Hist ace, pregnancy, sm	tory, including Preexis oking and alcohol use, t	sting Medical Condit hepatic/renal dysfunc	tions (e.g., allei tion, etc.)	rgies,				
							(Continue on page 3)
					E. INITIAL REPORT 1. Name and Address	ER	- 4 A	MES
					(0) (6)		715	JUSS
							W.	JUN 10 201
								AU 201
			andtan e ee	O	Phone #	Ema	il Address	
mission of a re	port does not con		ontinue on p		2. Health Professional?	Occupation	TA:	Initial Reporter Also Sent
sonnel, user fac	ility, importer, dis ted to the event.	tributor, manufa	cturer or p	roduct		NA		Report to FDA Yes No V Unk.

											SEID: "	111797	73
1 1 3 3 4 5 5 6 6 6 6 6 6 6 6			#		•	2 of 6	;						
1	11797	73-01-00	-02		ì			/ANII	FACTURERS ONL	Υ			
1. Check One		12.	UF/Importer F	Report No	amber		Type of Repor			_	f Follow-up	, What Type	?
User Facility	impo	orter					Death				Corre	ction	
3. User Facility or Imp	orter Name	Address				11	Serious I	Injury			Addition	onal Informati	ion
							Malfuncti	ion			Respo	onse to FDA F	Reques
							_				Device	e Evaluation	
						3.1	Device Evalua	ated by I	Manufacturer?	4.	Device Man	ufacture Dat	te
							_	_	Manufacturer		(mm/yyyy)		
4. Contact Person			5. Phone N	lumber		11	= -	_	ation Summary Attached				
								_	to explain why not) or		Labeled for	Single Use?	?
6. Date User Facility o	r	7. Type of Rep	ort	8. Date	of This Report	11	provide		,,,,		Yes	☐ No	
Importer Became Aware of Event (mm	n/dd/yyyy)	☐ Initial		(mm/	dd/yyyy)					_			
		_		1		6. 1	Event Problem	n and E	valuation Codes (Refer	o coding	manual)		
9. Approximate	10 Event I	Follow-up		ina menus	aD	-		Patient]-[7
Age of Device	l _	riobielli Codes	(Neier to cook	ny manue				Code Device					=
	Patient Code		-]-				Code					
	Device		1-	=				Method				-	7
	Code _	Teo : .	J			4		,,,,,,,,,					
11. Report Sent to FDA	4?	_	Where Event				F	Results				-	
Yes(mm/dd/	/vvvv)	Hosp			utpatient iagnostic Facility		Const	luciana				_	7
No		Home	e ing Home		mbulatory	١L		lusions				<u>'</u>	
13. Report Sent to Man	nufacturer?	1 =	atient Treatmer		urgical Facility	7.1	f Remedial Ad	ction Ini	tiated, Check Type	8. Usag	ge of Device		
Yes(mm/dd/	Acan	Facili					Recall		Notification		Initial Use	of Device	
☐ No	97977	Other	r:	(Speci	fv)	-	Repair		Inspection	▎▕ੂ	Reuse		
14. Manufacturer Name	e/Address	L		(Opour	***	11	Replace		Patient Monitoring	L	Unknown		
						Π	Relabelin	ig [Modification/ Adjustment	21 U	SC 360i(f), I	ed to FDA un list correctio	on/
							Other:		,	remo	oval reporti	ng number:	
						1		-1 14	factures New Mary		. 44 !	Correcte	-d P-4-
C ALL MANUEL	CTUDER	10				10.	Addition	ai Manu	facturer Narrative	and / or	11.	Larrecte	n Data
G. ALL MANUFA		· -	wiese)	2 Pho	ne Number	¶							
Name	manuractu	uly site for De	wices)	4	68-0700								
EDYTA FRACKIEWI	CZ				ort Source	+ $+$							
Address					ck all that apply)								
HYLAND'S, INC.				Fon	-								
154 W. 131ST ST				Stu	-								
LOS ANGELES, CA	90061	_			rature								
Email Address				✓ Cor									
STANDARD@HYLAND	S.COM			ഥ	Ith Professional								
Date Received by Manufacturer (mm/de	d/www)	5.		1=	r Facility								
05/21/20		(A)NDA # _			npany resentative								
		IND#_			ributor								
3. If IND, Give Protocol	#	BLA#		Oth	er:								
		PMA/											
'. Type of Report (Check all that apply)		510(k) #											
5-day 30-da		Combination	Yes			11							
7-day Period		Product											
10-day / Initial	-	Pre-1938	∐ Yes										
	v-up #	OTC Produc	Yes Yes									-	_
. Manufacturer Report	t Number	8. Adverse E	Event Term(s)			1						DSS	3
		1	OMITT TOL									_	_

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:

8. Adverse Event Term(s) INFANT BOTULISM

54973 AE # 1611

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PRAStaff@fda.hhs.gov
valid OMB control numb
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JUN 1 0 2015



OMPLAINT RECORD

Code	Dana 2 773
Case	11111111111
	a was all

111	79773-0	01-00-03	COME	DI A/A/T #-	2821			
		EDYTA FRACKIEWICZ	DATE OF COM	PLAINT #:	2621 05/21/2015	05/21/2015		
PRODUCT:		HYLAND'S BABY TEETHING TABLETS; HYLAND'S BABY NIGHTTIME TEETHING TABLET.	ITE	M CODE:	. 100			
SIZE:		UNKNOWN; 135 TABS		LOT NO.:	NOT PROVIDE	ED .		
REPORTER:	(b) (6)			-0.00				
ADDRESS:	N/A							
	N/A							
CITY:	N/A		STATE:	N/A				
COUNTRY:	USA		ZIP CODE:	N/A				
PHONE #	N/A	and the second s						
E-MAIL:	N/A			TOT ILE	THE NET OF THE	WILESTIED OUE		
NATURE OF CO	MPLAINT:	MOTHER POSTED THE FOLLOWING COMM WAS REFERRING TO THE BABY TEETHING CONTACT HYLAND'S TO PROVIDE MORE I BOTULISM AT 5 MONTHS OLD, SHE WAS H LONGER TRUST THIS BRAND.	TABLETS OR BABY NIGH INFORMATION. THEY MAI	TTIME TE	ETHING TABLET: UGHTER SICK W	S. SHE DID NOT ITH INFANT		
		FOR ADDITIONAL SPACE PLEASE USE REVE	RSE OR ATTACH A SEPA	RATE SHI	EET			
PRODUCT RECEINSPECTION:	EIVED FOR	(CIRCLE ONE)	PRODUCT BEING RETUR			Y (CIRCLE ONE)		
			DATE REQUESTED PR	ODUCTB	E RETURNED:			
			i i	UPS CALL	TAG ISSUED:	(CIRCLE ONE)		
			DATE	E PRODUC	CT RECEIVED:			
SECTION II:	INV	ESTIGATION						
INVESTIGATION		PLEASE SEE ATTACHED INVESTIGATION REPORT						
					-			
ADVERSE EVEN	IT FORWARI	DED TO PHARMACIST / NURSE FOR EVALUATION O	ON:	05/21/20	15			
ADVERSE EVEN	T FORWARI	DED TO PHARMACIST / NURSE FOR EVALUATION B	ay:	EDYTA F	RACKIEWICZ			
SECTION III:		CORRECTIVE ACTION:						
CORRECTIVE A	CTION(S) CC	OMPLETED BY:		DATE:				
SECTION IV:	ADV	ERSE EVENT REPORTS		AE #:	1611			
ADVEDGE EVE					-			
ADVERSE EVEN		\circ	av. For	TA EDACH	TEMIC Z	Doc		
ADVERSE EVEN	REPURIE	D ON: 05/21/2015	BY: EDY	TA FRACK		DSS		
SECTION V:		27.11			48.00	JUN 10 2015		
REVIEWED BY N	MANAGEMEN	VTBY:		DATE:	06-0	10 2015 الكلج) - ان 19-15		
ву:		QA/QC DIRECTOR	7	DATE:	05-2	19-15		

cc: QA / QC Packaging

Production Shipping / Receiving

JUN - 9 2015





CaseID: 11179773

SAE-0021-2015

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 Scopolamine levels and was found to meet the specification of ≤^(t)₍₄₎ ppm.

Conclusion:

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

Prepared by

Date

5/28/15

DSS JUN 1 0 2015



SE EVENT DATA FORM



AE #: 1611		COMPLAINT#: 2621
SECTION I:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)
NAME:	(6) (6)	
ADDRESS:		
CITY:	with at	STATE:
COUNTRY:	USA	ZIP CODE:
PHONE #:		
E-MAIL;		
SECTION II:	PACKAGING INFORMATION:	
AFFD	X PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	Texture Tables	
	me stran	Color Michigan Color (Calabu) Lat and Project (Video Color (Calabu) Lat and Project (Video Color (Calabu) Color
		Teething Tablets
	· · · · · · · · · · · · · · · · · · ·	
*		
100	The state of the s	
1	See Auto (1990)	
ECTION III:	CORRECTIVE ACTION:	
ORRECTIVE ACT	ON(S) COMPLETED BY:	DATE:
3.0.00	On(0) OOM 22 / 25 0 / .	DAIL.
ECTION IV:		. 1
EVIEWED BY MAN	MAGENTEN EN MAJOR	DATE: 06-01-15 JUN 1
E VIEWED BY WAL	NAGEMENT BY:	DATE: UG-UI 13 JUN 1
	/ 1/	

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUN - 9 2015



E EVENT DATA FORM



#: 1611	1	COMPLAINT#: 2621
CTION I:	PATIENT INFORMATION (IF DIFFE	RENT FROM REPORTER ON FORM VD1)
DRESS:		STATE:
UNTRY; DNE #; AIL:	USA	ZIP CODE:
TION II:	PACKAGING INFORMATION:	AFFIX COPY OF OUTER CARTON HERE
Similar States 2016. Committee States and Administration of Committee States and Administration	The control of the co	The state of the s
TION III:	CORRECTIVE ACTION:	
CTION III:	CORRECTIVE ACTION: TION(S) COMPLETED BY:	DATE:

DISTRIBUTION: FOA ADVERSE EVENT FILE

FORM SAE01

by user-facilities, butors and manufacturers OATORY reporting

	ved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.
Afr Report # - 34973	

	See OMB statement on re
Mfr Report # 54973	1
UF/Importer Report #	OTO
	CH

na 1 of 6

A. PATIENT INF					C. SUSPECT PROD			225
Patient Identifier (b) (6)	of Event	(a)- V	3. Sex	4. Weight	1. Name (Give labeled stren		Southern	
100000000000000000000000000000000000000	or1	Years		lbs	#1 HYLAND'S BABY	TEETHING TA	BLETS	
In confidence	Date of Birth:		☐ Male	or	#2			
B. ADVERSE EV		JCT PROBLE	M	kgs	2. Dose, Frequency & Rou	e Used	3. Therapy Dates	(If unknown, give duration
		37.00 TO THE	SET CHIPTE	Thursday = -1	#1 2 TABS EVERY T	NO HRS X2	from/to (or best #1	estimate)
1. Adverse Event 2. Outcomes Attribute	and/or P	roduct Problem (e.g., defects/mail	unctions)	#2		#2	
(Check all that apply)				4. Diagnosis for Use (Indica	tion)		t Abated After Use
Death:	(mm/dd/yyyy)	Disability	or Permanent Dar	mage	#1 TEMP RELIEF TE			ped or Dose Reduced?
Life-threatening		Congenita	Anomaly/Birth D	Defect		,	#1 <u></u>	Yes No Doe Appl
	- initial or prolonged		ous (Important M	Charles Control Control	#2 6. Lot #	7. Exp. Date	#2 🗍	Yes No Doe
	ention to Prevent Pen	manent Impairmen	/Damage (Device	es)	#1 50		HE I	Reappeared After
Date of Event (mm/		4. Date of This	Report (mm/dd.			The Comp III has	Reint	roduction?
. Describe Event or P	3/2015	-	05/26/2015		#2 9. NDC# or Unique ID	#2	115 #1 □	Yes ☐ No ☑ Doe App
THE REPORTER S	TATED THAT CH	ILD WAS GIV	EN A 2 TAB	LET DOSE	54973-3141-1	UN 0 9 21	J1.J #2 🗍	Yes No Does
AND THEN WAS G	IVEN A SECOND	2 TABLET D	OSE "A COU	PLE OF	10. Concomitant Medical Pr	oducts and The		_ App
EPORTER STATES ECONDS. FOLLOS HILD'S TEMPERS 03 DEGREES FAI XPERIENCED AND ASTED FOR ABOS OCTORS IN THE F THESE EPISOS S FEBRILE SEIZ AUSED BY BABY	WING THIS EPI: ATURE AND FOUR HRENHEIT. SOMM OTHER EPISODE JOT ONE MINUTE EMERGENCY DEI LES WERE SEIZE GURES POSSIBLY	SODE, THE R ND THAT SHE E TIME LATE: SIMILAR TO CHILD TAKE PARTMENT WE! URES. F/U 5,	EPORTER TOO HAD A FEVE R, THE CHII THE FIRST, EN TO THE E RE "NOT SUR '24/15: DIF	OK THE ER OF LD THAT ER. RE YET" AGNOSED	D. SUSPECT MEDIC. 1. Brand Name 2. Common Device Name 3. Manufacturer Name, City 4. Model #			Continue on page 3) Procode 5. Operator of Device
					Catalog #		ate (mm/dd/yyyy)	Health Profession
					Serial #	Unique Ident	ifier (UDI) #	Other:
			(Continue on	page 3)	6. If implanted, Give Date (m	m/dd/yyyy)	. If Explanted, Giv	e Date (mm/dd/yyyy)
Relevant Tests/Labor	ratory Data, Includin	g Dates			8. Is this a Single-use Device	that was Reproc	essed and Reused	on a Patient?
					Yes No 9. If Yes to Item No. 8, Enter			
				J.	10. Device Available for Eval	uation? (Do not se Returned to Man	end to FDA) ulacturer on:	DS:
			Continue on p	page 3)	11. Concomitant Medical Pro	ducts and Therap	y Dates (Exclude t	reatment of eventy
Other Relevant Historace, pregnancy, smok MPERATURE OF I IZURE F/U 05/ GREES FAHRENHE	103 DEGREES FA 24/15: FEVER	AHRENHEIT FO	DLLOWING 19	rgies, ST	E. INITIAL REPORTER		(Co	ontinue on page 3)
CHESO FARRENTE	all.				1. Name and Address (b) (6)		71.	CA.
							Us)) [
		,	Continue on p	nage 3)	Phone # (b) (6)	Email A	~) d &

8. Date of This Report

Outpatient
Diagnostic Facility

Ambulatory
Surgical Facility

(Specify)

2. Phone Number

310-768-0700

Foreign

Literature ✓ Consumer

User Facility

Distributor

Other:

Study

3. Report Source (Check all that apply)

Health Professional

Representative

(mm/dd/yyyy)

2. UF/Importer Report Number

5. Phone Number

11179851-01-00-02

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

☐ Home

Other:

12. Location Where Event Occurred

| Initial Follow-up #

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

9. Approximate

Yes Yes

☐ No

Yes

No

Name

Address

6. Date User Facility or

11. Report Sent to FDA?

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

Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

LOS ANGELES, CA 90061

STANDARD@HYLANDS.COM

05/23/2015

30-day

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol #

(Check all that apply)

10-day 🗸 Initial

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

7. Type of Report

5-day

7-day

EDYTA FRACKIEWICZ

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

Email Address

1. Contact Office (and Manufacturing Site for Devices)

e 2

of <u>6</u>		
H. DEVICE MANUF		LY
Type of Reportable Ev Death Serious Injury Malfunction	ent	If Follow-up, What Type? Correction Additional Information Response to FDA Request
3. Device Evaluated by M	anufacturer?	Device Evaluation 4. Device Manufacture Date
Not Returned to M		(mm/yyyy)
No (Attach page to provide code:	o explain why not) or	5. Labeled for Single Use?
6. Event Problem and Eva	luation Codes (Refer	to coding manual)
Patient Code Device Code		-
Method]-[
Results		
Conclusions		
7. If Remedial Action Initia		8. Usage of Device
Recall	Notification	Initial Use of Device Reuse
Repair Replace	Inspection Patient Monitoring	Unknown
Relabeling	Modification/	9. If action reported to FDA under
	Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:		
10. Additional Manufac	turer Narrative	and / or 11. Corrected Data
		DSS
		JUN 1 0 2015

CaseID: 11179851

FDA USE ONLY

SEIZURE, FEVER 54973 AE # 1610 This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

(A)NDA#

IND#

BLA# PMA/

510(k)#

Product

Pre-1938

Combination

OTC Product

8. Adverse Event Term(s)

Yes

Yes

✓ Yes

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SECTION I:			COMO MATERIA	2000	
TAKEN BY:		LILIANA GLUBISZ	COMPLAINT #		
PRODUCT:		HYLAND'S BABY TEETHING TABLETS	ITEM CODE	1222211	
SIZE:		T6	LOT NO.	65.172	
REPORTER:	(b) (6)		201110	12001	
ADDRESS:	N/A				
	N/A			-	
CITY	N/A		STATE: (b) (6)		
COUNTRY:	USA		ZIP CODE; N/A		
PHONE #:	(b) (6)		2,110		
E-MAIL:	N/A				
103 DEGREES FA EPISODE LASTED	ECONDS. FO THRENHEIT. FOR ABOL STATED THA	DLLOWING THIS EPISODE, THE REPORTS SOME TIME LATER, THE CHILD EXPERIE IT ONE MINUTE. AT THE TIME OF THE CA AT THE DOCTORS IN THE EMERGENCY D	NG BACK IN HER HEAD. THE REPORTER ST ER TOOK THE CHILD'S TEMPERATURE AND NCED ANOTHER EPISODE SIMILAR TO THE LL, THE REPORTER HAD BEEN IN THE EME IEPARTMENT WERE NOT "NOT SURE YET" I	FOUND THAT SH FIRST, THOUGH RGENCY DEPAR F THESE EPISOD	HE HAD A FEVER OF THIS SECOND TMENT FOR ABOUT
		FOR ADDITIONAL SPACE PLEASE U	SE REVERSE OR ATTACH A SEPARATE SH	EET	
PRODUCT RECEIVINSPECTION:	VED FOR	(CIRCLE ONE)	PRODUCT BEING RETURNED FOR	INSPECTION:	(CIRCLE ONE)
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INSPECTION: ividual Ca	ase Sai	(CIRCLE ONE)	DATE REQUESTED PRODUCT 8		
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INSPECTION: ividual Ca	ase Sai	(CIRCLE ONE)	DATE REQUESTED PRODUCT B	E RETURNED: - TAG ISSUED:	(CIRCLE ONE)
ividual Ca	3851-01	(CIRCLEONE) Sety Report -00-03	DATE REQUESTED PRODUCT B	E RETURNED: - TAG ISSUED:	(CIRCLE ONE)
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INSPECTION: ividual Ca 11179 \$ECTION II: INVESTIGATION:	ase Sat 3851-01 inve	(CIRCLE ONE) Sety Report -00-03 STIGATION BASE SEE ATTACHED INVESTIGATION F	DATE REQUESTED PRODUCT B UPS CALL DATE PRODUCT REPORT ATION ON:05/23/201	E RETURNED: TAG ISSUED: ET RECEIVED:	(CIRCLE ONE)
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INSPECTION: ividual Ca 11179 \$ECTION II: INVESTIGATION:	ASE SAL BASSI-01 INVE FORWARDS	(CIRCLE ONE) Sety Report -00-03 STIGATION BASE SEE ATTACHED INVESTIGATION F	DATE REQUESTED PRODUCT B UPS CALL DATE PRODUCT REPORT ATION ON:05/23/201	E RETURNED: TAG ISSUED: CT RECEIVED: 5	(CIRCLE ONE)
INSPECTION: ividual Ca 11179 SECTION II: INVESTIGATION: ADVERSE EVENT	ASE SAL BENEFORWARDS	(CIRCLE ONE) Sety Report -00-03 STIGATION BEASE SEE ATTACHED INVESTIGATION FOR EVALUATION PHARMACIST / NURSE FOR EVALUATION PRECTIVE ACTION:	DATE REQUESTED PRODUCT B UPS CALL DATE PRODUCT REPORT ATION ON:05/23/201	E RETURNED: TAG ISSUED: CT RECEIVED: 5	(CIRCLE ONE)
INSPECTION: ividual Ca i11179 SECTION III: INVESTIGATION: ADVERSE EVENT I ADVERSE EVENT I SECTION III:	FORWARDS SON(S) COM	(CIRCLE ONE) Sety Report -00-03 STIGATION BEASE SEE ATTACHED INVESTIGATION FOR EVALUATION PHARMACIST / NURSE FOR EVALUATION PRECTIVE ACTION:	DATE REQUESTED PRODUCT B UPS CALL DATE PRODUCT REPORT ATION ON: 05/23/201 ATION BY: LILIANA C	E RETURNED: TAG ISSUED: CT RECEIVED: Substituting the substitution of the substitut	(CIRCLE ONE)
INSPECTION: i vidual Ca section III: CORRECTIVE ACTI CO	FORWARDS FORWARDS FORWARDS ADVE	(CIRCLE ONE) Sety Report OU-03 STIGATION LEASE SEE ATTACHED INVESTIGATION F TO PHARMACIST / NURSE FOR EVALU DITO PHARMACIST / NURSE FOR EVALU DRECTIVE ACTION:	DATE REQUESTED PRODUCT B UPS CALL DATE PRODUCT REPORT ATION ON: 05/23/201 ATION BY: LILIANA C	E RETURNED: TAG ISSUED: CT RECEIVED: Substituting the substitution of the substitut	(CIRCLE ONE)

REVIEWED BY MANAGEMENT BY:

770

.....

DATE: 06-01-15

CaseID: 11179851

REPORTER:

(b) (6)

COMPLAINT # 1620

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.

F/U 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 OFFERRED HER A REFUND, WHICH SHE SAID WOULD NOT BE NECESSARY.

Individual Case Safety Report



11179851-01-00-04

DSS JUN 1 0 2015

Jverse Event

SAE-0019-2015

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 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 with in specification of ≤(4) opm.

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-0654-2014, 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.

7.8/2015

JUN 1 0 2015

CaseID: 11179851



RSE EVENT DATA FORM



CTION I:	PATIENT INFORMAT	TION (IF DIFFERENT	FROM REPORTER ON	FORM VD1)		
ME:	(b) (6)					
DRESS:						3
Y:			ST	ATE: (b) (6)		_
UNTRY:	USA		ZIP C	ODE:		
ONE #:	(b) (6)					2
IAIL:						=
CTION II:	PACKAGING INFOR	MATION:				
AF	FIX PACKAGING LABEL HE	ERE	AFFIX COPY (INCLUDE DRUG F	OF OUTER CARTO ACTS AND PRINCIP PANELS)		
State I March 100 per l'en procession de l'entre de l'e	I considerative with the considerative with t	andi aby				
dises investore on revenues of the second of	on its settlementation the settlement of the set	CLYSSI FARSHS				
Buddenburk Weit (1984) The second of the sec	Sen di sell'orientamination Silvingia di Sentino Silvingia di Se	CLYSSI FARSHS		DATE:		
TION III:	CORRECTIVE ACTIO	CLYSSI FARSHS			b0(-15	DS Jun 1



by user-facilities, butors and manufacturers DATORY reporting

	CaseID: 11188555
Fort	Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.
Mfr Report #	4973

UF/Importer Report #

RM FDA	4 3500A	(2/13)		
KM FDA	4 3500A	(2/13)		

A. PATIENT INF	ORMATION		
	2. Age at Time	3. Sex	4. Weigh
(b) (6)	of Event: 7	Months	
	or		maleor
In confidence	Date of Birth:	✓ M	ale
B. ADVERSE EV	So in a serie	ICT PROBLEM	
		LINE WAY OF ALL ALL	
 Adverse Event Outcomes Attribut 		roduct Problem (e.g., defect	s/mairunctions)
(Check all that apply			
Death:		Disability or Permane	ent Damage
Ufe-threatening	(mm/dd/yyyy)	Congenital Anomaly/	Birth Defect
	- initial or prolonged	Other Serious (Impor	
A CONTRACTOR OF THE SECOND		manant Impairment/Damage	
3. Date of Event (mm	/dd/yyyy) 4/2015	4. Date of This Report (40.00
5. Describe Event or	Ne beach App	05/28/	2012
TABLETS 5/27/1 HE DISCONTINUE	and company of the same of	HAD A SEIZURE 5/20 ETHING TABLETS.	8/15 AFTER
		Receive	d
		JUN 1120	15
		CDR	
6. Relevant Tests/Lab			ue on page 3)
	1222	(Continu	ie on page 3)
FATHER HAS SELL	BURE DISORDER	sting Medical Conditions (e hepaticirenal dysfunction, et R AND ON MEDICATIO EXCEEDING 101 DEGR	N. CHILD
		Continu	ie on page 3)

5			FDA Use Only
C. SUSPECT I	PRODUCT(S) led strength & mfr/labele	r)	
	BABY TEETHING		
#2			
2. Dose, Frequency	v & Route Used	3 Therany Date	s (If unknown, give duration)
	BID X 1 MONTH	from/to (or be	st estimate)
		-	
#2 4. Diagnosis for Us	an (Indication)	#2 15 Sw	ent Abated After Use
	EF TEETHING PAI	Sto	pped or Dose Reduced?
#2		#1	Yes V No Doesn'
3. Lot#	7. Exp. Date	#2	Yes No Doesn'
#1A36714	#1		ent Reappeared After
#2	#2		ntroduction?
NDC# or Unique		#1.[Yes No ✓ Doesn' Apply
54973-3127-		#2	Yes No Doesn't
0. Concomitant M	edical Products and Th	erapy Dates (Exclu	de treatment of event)
D. SUSPECT A Brand Name	MEDICAL DEVICE		(Continue on page 3)
. Common Device		To.	
Common Device	name	20	. Procode
. Manufacturer Na	me, City and State		
. Model #	Lot #		5. Operator of Device
Catalog #	Expiration	n Date (mm/dd/yyyy	Health Professional
4444997	- Lapinos	n Date (minimum)yyy	Lay User/Patient
Serial #	Unique Id	lentifier (UDI) #	Other:
If Implanted, Give	e Date (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
Is this a Single-u	se Device that was Rep	processed and Reu	sed on a Patient?
Yes	No		
. If Yes to Item No.	. 8, Enter Name and Ad	dress of Reprocess	sor
	e for Evaluation? (Do no		
Yes N	Returned to	Manufacturer on:	(mm/dd/yyyy)
1. Concomitant Me	edical Products and Th	erapy Dates (Exclu	
			(Continue on page 3)
E INITIAL REP	AND DESIGNATION OF THE PERSON		
Name and Address (6)	65		Dec
			200
			DSS JUN 12 2
hone #	Em	ail Address	
b) (6)			47
_	nal? 3. Occupation	4	Initial Reporter Also Sent Report to FDA
Yes V No	NA NA		TYPE TINE THE

e 2 of 5

CaseID:	11188555
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FDA USE ONLY

1. FOR USE BT				lovucas Ambul	T DEMOCE MAN	EACTUDEDS ONLY	· · · · · · · · · · · · · · · · · · ·
. Check One	USEK FA			Report Number	DEVICE MANU Type of Reportable E	FACTURERS ONLY	2. If Follow-up, What Type?
User Facility	Impo	I		,	Death		Correction
. User Facility or Imp	orter Name/	Address			Serious Injury		Additional Information
_				ļ	Malfunction		Response to FDA Request
							Device Evaluation
					3. Device Evaluated by		4. Device Manufacture Date (mm/yyyy)
Contrat Barrer			ć 51 N		Not Returned to		
Contact Person		l	5. Phone N	umber	Yes Evalu	ation Summary Attached	
Date User Facility or	<u>. r</u>	7. Type of Bases		0 Date of This Danes	No (Attach page provide code:	to explain why not) or	5. Labeled for Single Use?
Importer Became Aware of Event (mm	- 1	7. Type of Repor	•	8. Date of This Report (mm/dd/yyyy)			Yes No
Aware or Event (min	//du/yyyy)	Initial			6. Event Problem and E	valuation Codes (Pofor t	n coding manuall
		Follow-up #			Patient	valuation codes (Neier I	coding manual)
Approximate Age of Device	10. Event P	roblem Codes (F	Refer to codi	ng manual)	Code	<u> </u>	
	Patient				Device	—	
	Code _				Code		
	Device Code		·		Method	-	- -
. Report Sent to FDA	17	12. Location W	here Event	Occurred			
Yes		Hospita		Outpatient	Results		
No (mm/dd/	/yyyy)	Home		Diagnostic Facility	Conclusions	-	
Report Sent to Man	rufacturer?	Nursing	Home	Ambulatory Surgical Facility		Hated Charle Town	
			ent Treatmer	nt	7. If Remedial Action Ini	патес, Спеск Туре	8. Usage of Device
Yes(mm/dd/	/yyyy)	Facility			Recall	Notification	Initial Use of Device
No		Other:		(Specify)	Repair	Inspection	Reuse
. Manufacturer Name	e/Address				Replace	Patient Monitoring	9. If action reported to FDA under
					Relabeling [Modification/ Adjustment	21 USC 360i(f), list correction/
					Other:		removal reporting number:
					10. Additional Manu	facturer Nametive	and / or 11. Corrected Data
G. ALL MANUFA	CTURER	s			To Carabina mana	TWO CONTROLLED TO	and / or 11. Corrected Data
Contact Office (and			ces)	2. Phone Number			
lame				310-768-0700			
YTA FRACKIEWI	CZ			3. Report Source			
ddress				(Check all that apply)			
YLAND'S, INC.				Foreign			
54 W. 131ST ST				Study			
S ANGELES, CA	30001			Literature			
mail Address				Consumer Health Professional			
ANDARD@HYLAND	OS.COM			User Facility			
Date Received by Manufacturer (mm/do	d/yyyy)	5.		Company			
05/28/20		(A)NDA #	····	Representative			
f IND, Give Protocol		IND#		Distributor			
, = 1010001		BLA#		Other:			
		PMA/					
		510(k) #					
		Combination	□ Vae				
(Check all that apply)		Product	Yes				
Type of Report (Check all that apply) 5-day 30-day 7-day Period	у	Product					
(Check all that apply) 5-day 30-day	y dic	Pre-1938	Yes				
(Check all that apply)] 5-day ☐ 30-day] 7-day ☐ Period] 10-day ☑ Initial	y dic	1	☐ Yes				Dec
(Check all that apply)] 5-day	v-up#	Pre-1938	✓ Yes				DS
(Check all that apply) 5-day 30-day 7-day Period 10-day Initial 15-day Follow Manufacturer Report	y dic v-up # t Number	Pre-1938 OTC Product	✓ Yes				DS:
(Check all that apply) ☐ 5-day ☐ 30-day ☐ 7-day ☐ Period ☐ 10-day ☑ Initial	y dic v-up # t Number	Pre-1938 OTC Product 8. Adverse Eve	✓ Yes				DS: JUN 12

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 or relatin and runnian Services

Food and Drug Administration

Office of Chief Information Officer

Paperwork Reduction Act (PRA) Staff

PRAStaff@/da.hhs.gov

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

111006	555-01-00-03	COI	MPLAINT #:	2624	÷
111005	733-01-00-03	DATE OF CO	OMPLAINT:	05/28/2015	
RODUCT:	BABY TEETHING TABLETS		EM CODE:	BTET-T40	
IZE:	40 TABS		LOT NO.:	A36714	
EPORTER: (b)	(6)				
ODRESS:	-				
TY:		STATE:	(b) (6)		
100 To 10	ISA	ZIP CODE:	1		
	0) (6)				
MAIL: N	WA				
ETHING TABLETS YE SORDER AND IS ON EN ONE AND ONLY I		VEN AFTER HE STOPPED THE TEETH	HING TABLE ME WHEN T	HEY HAPPEN A	SSEIZURE
ETHING TABLETS YE SORDER AND IS ON	STERDAY. CHILD HAD A SEIZURE TODAY EV MEDICATION. FATHER CANNOT DESCRIBE HIS WIFE HAS SEEN THEM. FOR ADDITIONAL SPACE PLEASE	/EN AFTER HE STOPPED THE TEETH SEIZURES BECAUSE HE IS NOT HO	HING TABLE ME WHEN T	HEY HAPPEN A	SSEIZURE
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ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:

EDYTA FRACKIEWICZ

SECTION III:

CORRECTIVE ACTION:

DATE:

SECTION IV:

ADVERSE EVENT REPORTS

AE #: 1614

ADVERSE EVENT SERIOUS:

(A) N

ADVERSE EVENT REPORTED ON:

REVIEWED BY MANAGEMENT BY:

05/28/2015

BY: EDYTA FRACKIEWICZ

DSS

SECTION V:

Relit

DATE: 06-03-15 JUN

BY:

DATE:

96-03-15

cc: QA / QC Packaging Production Shipping / Receiving

JUN 1501 2015





CaseID: 11188555

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 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 with in specification of $\leq_{(4)}^{(b)}$ ppm.

Retention Samples:

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

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

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured one other complaint (CC-0654-2014) 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 1 2 2015



SE EVENT DATA FORM



#: _1614	COMPLAINT #: 2624	
CTION I: PATIENT INFORMATION (IF DIFFER	RENT FROM REPORTER ON FORM VD1)	
ME: (b) (6)		
DRESS:		
	(b) (6).	S
6	STATE:	-
NTRY: USA (b) (6)	ZIP CODE:	-
NE #:		
AIL:		2
TION II: PACKAGING INFORMATION:		
AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE	
Section of the sections	(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
Testium laties	water name.	
The second secon	(Halamaria	
CHIMINIO	F. Montage is a montage of Paul Conference of the Conference of th	
	Teething 3 (mitano)	
	and developed the second of th	
	Service Control of the	
The state of the s		
The state of the s		
ON III: CORRECTIVE ACTION:		
RECTIVE ACTION(S) COMPLETED BY:	Wint.	
ACTIVE ACTION(S) COMPLETED BY:	DATE:	S
TON DA		
ION IV:	JUN	12
EWED BY MANAGEMENT BY:	DATE: 06-03-15	
(1) . m	00/	_
7 MIN TANIL	1 11 12 12	

essional Report

(Dase(D: 11254142) Form Approved: OMB No. 0910-0291, Expires: 12/31/2011

	- 9	and Olyna Statement St.
porting of		FDA USE ONLY
roblems and	Triage unit sequence #	604369
000		

11254142-01-00-01			product us	ct probler e errors	ne andl	Triage unit sequence #	604369
A. PATIENT IN	PORMATION 2. Age at Time of Event or Date of Birth: 15. Months	3. Sex	4. Weight	2. Dose #1	or Amount	Frequency	Route
in confidence	(b) (6)	✓ Male	arkg	3. Dates o	f Use (If unknown	n, give duration) from/t	5. Event Abated After Us

A. PATIENTI Patient Identifier	2. Age at Time of Event or Date of Birth: 15 Months (b) (6)	3. Sex Female	4. Weight	#1			
heck all that apply		OBLEM OR E	RROR	3. Dates of Use (If u (or best estimate) #1 1 month	inknown, give duration) fi	Stopped	Abated After Use or Dose Reduced?
Adverse Ever	nt Product Problem (e. Error Problem with Differ	.g., derects/manun ent Manufacturer	of Same Medicine	#2		#2 🗆 Ye	es TNo TDoesn's
Outcomes Attrit (Check all that ap	buted to Adverse Event pply) Disa	ability or Permaner		4. Diagnosis or Real #1 reething #2	ason for Use (Indication)	8. Event Reintr	Reappeared After oduction?
Life-threatenin	on - initial or prolonged 🗸 Othe	ngenital Anomaly/B er Serious (Importa	ant Medical Events)	6. Lot# #1	7. Expiration I	75.0	es No Doesn't Apply
Required Inte	ervention to Prevent Permanent	t Impairment/Dama	age (Devices)	#2	#2	9. NDC X	of orinque to
B. Date of Event (r	(minute))))))	ate of this Report	(mm/dd/yyyy)	(192)	MEDICAL DEVICE		
06/30/201! . Describe Event	t, Problem or Product Use Err	CL 2 P. N. C. P. P. S. C.		1. Brand Name			
				2. Common Device	e Name		CTU
See addit	cional page(s)	for compl	ete text.	3. Manufacturer N	ame, City and State		UL - 8 2015
				4. Model #	Lot#		5. Operator of Device Health Professional
				Catalog #	Expiration	Date (mm/dd/yyyy)	Lay User/Patient
6. Relevant Tests	s/Laboratory Data, Including	Dates		Serial #	Other#		
				27274072 27 2	ive Date (mm/dd/yyyy)		Give Date (mm/dd/yyyy)
				Yes No			
				9. If Yes to Item No	o. 9, Enter Name and Add	ress of Reprocesso	
	nt History, Including Preexisti pregnancy, smoking and alcoh tional page(s)			Product names a	ONCOMITANT) Mind therapy dates (exclu	ide treatment of eve	nt)
See addi	Clonal page (5)	101 00	-255 (510)	See addit	tional page(s) for co	mplete text.
				1 Name and Add	R (See confidentia	lity section on l	back)
C. PRODUC	T AVAILABILITY ble for Evaluation? (Do not ser	nd product to FDA		Name: (b) (6) Address:		Ĺ	15 DSS
The second secon	No Returned to Manufac	turer on:	(mm/dd/yyyy)	City:		State:	ZIP: JUL 8

D. SUSPECT PRODUCT(S) E-mail Phone # 1 Name, Strength, Manufacturer (from product label) #1 Name: Hyland's teething tablets Strength: 4. Also Reported to: 2. Health Professional? 3. Occupation Manufacturer: Manufacturer V Yes No User Facility #2 Name: 5. If you do NOT want your identity disclosed Strength: Distributor/Importer to the manufacturer, place an "X" in this box: Manufacturer. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 11254142

likely brief seizure

none

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)

DSS JUL 8 2015

y user-facilities, utors and manufacturers ATORY reporting

Form Approved	MB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse,
Mfr Report # 54973	
UF/Importer Report #	10

A. PATIENT INF	ORMATION		C. SUSPECT	PRODUCT(S)		
	2. Age at Time	3. Sex 4. Weight	1. Name (Give lat	eled strength & mfr/labe	eler)	
(b) (6)	of Event: Month	15 Female	#1 HYLAND'S	BABY TEETHING	TABLETS	
le (Street	Date	Male or	#2 HYLAND'S	TEETHING TABL	ETS	
In confidence	of Birth:		2. Dose, Frequen	cy & Route Used	3. Therapy Dates	(If unknown, give duration,
B. ADVERSE EV	ENT OR PRODUCT PR	OBLEM	#1 UNKNOWN		from/to (or best	t estimate)
. Adverse Event		blem (e.g., defects/malfunctions)	- D	ECHIV	ED	
Check all that apply			#2 UNKNOWN	las (Indication)	#2	nt Abated After Use
Death:	☐ Di	sability or Permanent Damage	100000000000000000000000000000000000000	regulation		ped or Dose Reduced?
Life-threatening	(mm/dd/yyyy)	ongenital Anomaly/Birth Defect			#1	Yes No Doesn
Hospitalization		her Serious (Important Medical Even	s)	IEF TEETHING PA		Yes No Doesn
Required Interv	vention to Prevent Permanent Im	pairment/Damage (Devices)	6. Lot #	CDK		— — Арріу
3. Date of Event (mm	/dd/yyyy) 4. Date	of This Report (mrn/dd/yyyy)	#1	#1		nt Reappeared After troduction?
06/1	8/2015	06/18/2015	#2	#2	#1 🗀	Yes No Doesn
Describe Event or	Problem	UP CAUD MADE THE ME	9. NDC# or Uniqu		* • •	— — Doesn
	HAD SEIZURES THAT W	HE GAVE TABLETS TO HER ERE ATTRIBUTED TO		7-3; 54973-7504	4-1 #2 L Therapy Dates (Exclud	TES NO Apply
			D. SUSPECT	MEDICAL DEVIC		(Continue on page 3)
			2. Common Devi	e Name	26.	Procode
			3. Manufacturer I	lame, City and State		
			4. Model #	Lot#		5. Operator of Device
			Catalog #	Expirat	tion Date (mm/dd/yyyy)	Health Professiona Lay User/Patient
			Serial #	Unique	Identifier (UDI) #	Other:
Relevant Tacts (I sh	oratory Data, Including Dates	(Continue on page 3)	6. If Implanted, G	ve Date (mm/dd/yyyy)	7. If Explanted, G	live Date (mm/dd/yyyy)
. Helevant Tests/Lau	oratory Data, including Dates		Yes	No	Reprocessed and Reus	A District Services
			9. If Yes to Item I	o. 8, Enter Name and .	Address of Reprocess	or .
			10. Device Availa	ole for Evaluation? (Do	not send to FDA)	-
			Yes		to Manufacturer on:	(mm/dd/yyyy)
Other Relevant His	tory, Including Preexisting Med	(Continue on page 3)	11. Concomitant	Medical Products and	Therapy Dates (Exclud	le treatment of event)
race, pregnancy, sm	oking and alcohol use, hepatic/re	mai vysiunction, etc.)		DORVER	(ContinuDS (3)
			E, INITIAL RI 1. Name and Add (b) (6)	The state of the s		JUL 9 2015
			6			
		(Continue on page 3)	Phone #		Email Address	
ibmission of a re	port does not constitute	an admission that medical	2. Health Profess	onal? 3. Occupation	[4.	Initial Reporter Also Sen
ersonnel, user fac-	cility, importer, distribute ited to the event.	r, manufacturer or product	☐ Yes 🗸	272		Report to FDA Yes No V Unk

CaseID:	1	125	82	15
FDA USE ONL	Υ			

1.1	125821	5-01-00-	02		e 2 o	of <u>o</u>		
1,1 ON 002 D						H. DEVICE MANUE	ACTURERS ONLY	1
1. Check One		2. (JF/Importer F	leport Number		1. Type of Reportable Ex	vent	2. If Follow-up, What Type?
User Facility	Impo	orter				Death		Correction
3. User Facility or Imp	orter Name	Address				Serious Injury		Additional Information
					- 1	Maifunction		Response to FDA Request
					- 1	_		Device Evaluation
					- 1			
					- 1	3. Device Evaluated by I	Manufacturer?	4. Device Manufacture Date (mm/yyyy)
						Not Returned to I	Manufacturer	(
4. Contact Person			5. Phone N	umber	- 1	Yes Evalu	ation Summary Attached	
						No (Attach page	to explain why not) or	5. Labeled for Single Use?
Date User Facility of Importer Became	r	7. Type of Repo	ort	8. Date of This Rep (mm/dd/yyyy)	ort	provide code:		Yes No
Aware of Event (mm	n/dd/yyyy)	Initial		(1111111100179797)	- 1			
		Follow-up #				6. Event Problem and Ev	valuation Codes (Refer to	o coding manual)
9. Approximate	10 Event F	Problem Codes		na manual)		Patient		1-[
Age of Device	l _	. John Cours	(,,0,0,10,000)	ng manual)		Code		
	Patient Code		-]-[][Device Code	-	-
	Device [≕			
	Code	j	-			Method		
11. Report Sent to FDA	A?	12. Location	Where Event	Occurred		Results		¬-[
Yes		Hospi	tal	Outpatient		Kesuits		
No (mm/dd.	l/yyyy)	Home	1	Diagnostic Fa	CIIITY	Conclusions	-	- -
13. Report Sent to Mar	nufacturer?	Nursir	ng Home	Ambulatory Surgical Faci	lity	7. If Remedial Action Ini	tisted Check Tune	8 Hearn of Davice
		Outpa	tient Treatme	•				8. Usage of Device
Yes(mm/dd.	/yyyy)	Facilit	•			Recall	Notification	Initial Use of Device
☐ No (Other		(Specify)		Repair	Inspection	Reuse
14. Manufacturer Name	e/Address	<u> </u>		1-6//		Replace	Patient Monitoring	Unknown
						Relabeling	Modification/ Adjustment	If action reported to FDA under 21 USC 360i(f), list correction/
						Other:	najoumen	removal reporting number:
					i			
						10. Additional Manu	facturer Narrative	and / or 11. Corrected Data
G. ALL MANUFA	CTURER	S						
1. Contact Office (and	Manufactu	ring Site for De	vices)	2. Phone Number				
Name				310-768-0700				
EDYTA FRACKIEWI	ICZ	···		3. Report Source	natu)			
Address				(Check all that a	(Kirk)			
HYLAND'S, INC.				Foreign	1	}		
154 W. 131ST ST				Study				
LOS ANGELES, CA	W 30061	L		Literature				.
Email Address				Consumer Health Profess				
STANDARD@HYLANI	DS.COM			1 ===	Oilai			
4. Date Received by	ddanaa)	5.		User Facility				ļ
Manufacturer (mm/o		(A)NDA #		Company Representative				
06/18/20		IND#		Distributor				
6. If IND, Give Protoco	d#	_		Other:				·
		BLA # -						
7. Type of Report		PMA/ 510(k)#						
(Check all that apply)		Combination	l	<u> </u>				
5-day 30-da	-	Product	Yes					
7-day Perio		Pre-1938	Yes					Dec
10-day 🗸 Initial		OTC Produc	t 📝 Yes					D22
, ,	w-up #		<u> </u>					DSS Jul 9 2015
9. Manufacturer Repoi	rt Number		vent Term(s)					JUL 9 2015
54973 AE # 16	16	SEIZURES						
							Uhman Bandara	

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

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

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."

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 11258215

Jverse Event SAE-0025-2015

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 $\leq_{(4)}^{(5)}$ ppm.

Conclusion:

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

Prepared by

Date

6/26/2015

DSS JUL 9 2015



EVENT DATA FORM



161	6	COMPLAINT #: _2626
TION I:	PATIENT INFORMATION (IF DIFF	ERENT FROM REPORTER ON FORM VD1)
E:	(b) (6)	
RESS:		
ī.		STATE:
NTRY:		ZIP CODE:
NE #:	A	
JL:		
TION II:	PACKAGING INFORMATION:	
AF	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY
(PANELS)
	Technical Toblets Technical Tob	(Internal)
	munimum (
		Tablets And Table
	mmmm	
(
ION III:	CORRECTIVE ACTION:	
Y		
RECTIVE A	CTION(S) COMPLETED BY:	DATE:
ION IV:		D8
	DAN	01-70-15
EWED BY N	MANAGEMENT BY:	DATE: 06-29-15
	/ / // // //	



VENT DATA FORM



Æ#: <u>161</u>		COMPLAINT #: 2626
CTION I:	PATIENT INFORMATION (IF DIFFER	RENT FROM REPORTER ON FORM VD1)
ME:	(b) (6)	
DRESS:		
Y:	1	STATE:
UNTRY:		ZIP CODE:
ONE #:		
MAIL:		
CTION II:	PACKAGING INFORMATION:	
AF	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
drug, if you site program or body, earli the addition of a I houth care professional the site product. Hough this and implication out of the relat- ditions. In case of accidio overlate, created a poisson cardiar terminationals, I'vi colo emopyrency, the manufacture contacted 24 hours a day. I want at 8009024-9809.	Access and on the property of	Teething Tablets Tabletas pura la Dentición - Gregoranto tené Transcerento - Chicama pura la Dentición - Chicama pura la Dentició
CTION III:	CORRECTIVE ACTION:	
	CTION(S) COMPLETED BY:	DATE:
RRECTIVE A		
CTION IV:	MANAGEMENT BY:	DATE:

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

JUL - 8 2015

vuser-facilities, itors and manufacturers LTORY reporting

Form Approved	SeID: 11275465 OMB No. 0910-0291, Expires: 6/30/201 See OMB statement on reverse

UF/Importer Report #

1. Patient Identifier	ORMATION			
	2. Age at Time		3. Sex	4. Weight
(b) (6)	of Event: 9	Months	☐ Female	lb:
	Date			or
In confidence	of Birth:		✓ Male	kg
B. ADVERSE EV	ENT OR PRO	DUCT PROBLE	M	
1. Adverse Event	t and/or	Product Problem	e.g., defects/malfe	unctions)
Outcomes Attribute (Check all that apply		nt		
Death:	(mm/dd/yyyy)	Disability	or Permanent Da	mage
Life-threatening		Congenit	ai Anomaly/Birth D	Defect
Hospitalization	- initial or prolonged	Other Se	rious (Important M	edical Events
Required Interv	vention to Prevent P	ermanent Impairme	nt/Damage (Devic	es)
3. Date of Event (mm.	/dd/yyyy)	4. Date of Thi	s Report (mm/dd	/yyyy)
06/1	2/2015		06/23/2015	
CHILD WAS PRES DOCTOR.	SCRIBED ANTIE		eceiv	
			ece, A	13
		12	JUL 1 4 2	015
			CDR	
		n==	(Continue on	page 3)
6, Relevant Tests/Labo	oratory Data, Inclu	ding Dates	(Continue on	page 3)
i, Relevant Tests/Labo	oratory Data, Inclu	ding Dates	(Continue on	page 3)
i, Relevant Tests/Lab	oratory Data, Inclu	ding Dates	(Continue on	page 3)
6, Rolevant Tests/Lab	oratory Data, Inclu	ding Dates	(Continue on	page 3)
ò, Relevant Tests/Lab	oratory Data, Inclu	ding Dates	(Continue on	page 3)
i, Relevant Tests/Lab	oratory Data, Inclu	ding Dates	(Continue on	page 3)
i, Relevant Tests/Lab	oratory Data, Inclu	ding Dates	(Continue on	page 3)
6, Relevant Tests/Lab	oratory Data, Inclu	ding Dates		
', Other Relevant Hist	ory, Including Pres	existing Medical Co	(Continue on	page 3)
	ory, Including Pres	existing Medical Co	(Continue on	page 3)
7. Other Relevant Hist race, pregnancy, smo	ory, Including Pree oking and alcohol us	existing Medical Co e, hepalichenal dys	(Continue on onditions (e.g., all function, etc.)	page 3) ergies,
. Other Relevant Hist race, pregnancy, smc	ory, Including Pree oking and alcohol us	existing Medical Co e, hepalichenal dys	(Continue on onditions (e.g., all function, etc.)	page 3) ergies,
. Other Relevant Hist race, pregnancy, smc	ory, Including Pree oking and alcohol us	existing Medical Co e, hepalichenal dys	(Continue on onditions (e.g., all function, etc.)	page 3) ergies,

PLEASE TYPE OR USE BLACK INK

(Continue on page 3) Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

f 5				A Use On
C. SUSPECT P	RODUCT(S)			- Augeor
	ed strength & mfr/labels			
#1 HYLAND'S E	BABY TEETHING	TABLETS		
#2				
2. Dose, Frequency	& Route Used	3. The	rapy Dates	(If unknown, give duration estimate)
#1 2 TABLETS,	ONCE, ORAL	#1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
#2		#2		
4. Diagnosis for Use	e (Indication)	-		Abated After Use
#1 TEMP RELIE	F TEETHING PAI	IN	37 -45	ves No Does
#2				Apply — Does
6. Lot#	7. Exp. Date		#2 \	Yes No Apply
#1B21514	#1			Reappeared After oduction?
#2	#2		#1 🔲	— — Dagg
9. NDC# or Unique I			# 17	- Does
54973-3127-	3 dical Products and Th			res No Apply
D. SUSPECT M I. Brand Name	EDICAL DEVICE			
2. Common Device I	Name		2b P	Procode
			1170	
3. Manufacturer Nan	ne, City and State			
4. Model #	Lot#	ot#		5. Operator of Device
Catalog #	Expiration	n Date (mi	m/dd/yyyy)	Health Professiona
				Lay User/Patient
Serial #	Unique Id	lentifier (U	DI) #	Other:
5. If Implanted, Give	Date (mm/dd/yyyy)	7. If Ex	planted, Giv	re Date (mm/dd/yyyy)
1.00	O B C C C C C C C C C C C C C C C C C C	6		
3. Is this a Single-us	e Device that was Rep	processed	and Reuse	d on a Patient?
	8, Enter Name and Ad			Dee
Yes No			2.	200
0-1				30E 201
. Concomitant Med	dical Products and The	erapy Date	s (⊏XClude	reatment or event)
			(C	ontinue on page 3)
E. INITIAL REPO	ORTER		,,,	- Fago 0)
Name and Address b) (6)	s			
(6) USA			JUL	1 4 2015
Phone # b) (6)	Em	all Address		
. Health Professions	al? 3. Occupation		[4. Ir	nitial Reporter Also Seni
Yes No			R	teport to FDA
E [] 140	10000			Yes No V Unk.



2 of ⁵

CaseID:	11275465
FDA USE ONL	Y

1. TON 00.					H. DEVICE			RS ONLY		
1. Check One		2. U	F/Importer i	Report Number	1. Type of Rep	ortable E	vent		2. If Follow-u	p, What Type?
User Facility	Imp	orter			☐ Death				Corre	ection
3. User Facility or Imp	orter Name	/Address			Serious	Injury			Addit	tional Information
					Malfund	ction			Resp	onse to FDA Request
									= '	ce Evaluation
										20 2141441011
					3. Device Evalu	ated by f	Manufacturer'	?		nufacture Date
					Not Re	turned to f	Manufacturer		(mm/yyyy)	
4. Contact Person			5. Phone N	umber	☐ Yes	☐ Evalu	ation Summan	y Attached		
					I I No (4"	ach nage	to explain why	not) or	5. Labeled fo	r Single Use?
6. Date User Facility of	,	7. Type of Repor	+	8. Date of This Report	provide		to explain willy	1100,01		
Importer Became	1	_	•	(mm/dd/yyyy)	1				☐ Yes	∐ No
Aware of Event (mm	i/da/yyyy)	Initial		İ	6. Event Proble	m and E	ratuation Cod	an /Defector	-]	
]	Follow-up#			O. EVENT FIODRE		raidation cou	(velet 10 c		
9. Approximate	10. Event	Problem Codes (Refer to codi	ing manual)	ľ	Patient Code		-	1-1	
Age of Device	Patient					Device				
	Code]-	-	-		Code	L			
	Device [
	Code		•			Method		-	J - L	
11. Report Sent to FDA	?	12. Location W	here Event	Occurred	1	Results		_	1_	_
Yes		Hospita	ıl	Outpatient		Results			J ⁻ L	
(mm/dd/	(yyyy)	Home		Diagnostic Facility	Con	clusions		-]_	-
∐ No		Nursing	Home	Ambulatory Surgical Facility					<u> </u>	
13. Report Sent to Man	utacturer?	1 = '	ent Treatmer	• .	7. If Remedial A	Action Init	tiated, Check	Type 8.	Usage of Device	
Yes		Facility			Recall		Notification	l	Initial Us	e of Device
No (mm/dd/	(YYYY)	Other:			Repair	ī	Inspection		Reuse	
				(Specify)	Replace	• [Patient Mor	nitoring	Unknown	1
14. Manufacturer Name	e/Address				Relabel	_	Modification	₁ 9.		ted to FDA under
								i	removal report	, list correction/ ting number:
					Other:				•	•
					40 🗆 44395		· · · · · · · · · · · · · · · · · · ·	M		
					10. Additio	nai Manui	facturer Narra	itive ar	nd / or 11.	Corrected Data
G. ALL MANUFA	CTURER	S								
Contact Office (and)	Manufactu	ring Site for Devi	ces)	2. Phone Number						
Name				310-768-0700						
EDYTA FRACKIEWI	.CZ			3. Report Source (Check all that apply)						
Address										
HYLAND'S, INC.				Foreign						
154 W. 131ST ST	REET			Study	1					
LOS ANGELES, CA	90061	-		Literature	1					
Email Address				Consumer Consumer						
STANDARD@HYLAND	S.COM			Health Professional						
Date Received by	3.300	5.		User Facility	1					
Manufacturer (mm/do	d/yyyy)	(A)NDA#		Company						
06/22/20	15	-		Representative						
6. If IND, Give Protocol	#	IND#		Distributor						
		BLA#		Other:						D00
		PMA/		i						DSS
Type of Report		510(k) #			1					
(Check all that apply)		Combination	_		1				J.	UL 1 5 2015
5-day 30-day		Product	Yes		1				•	
7-day Period	iic	Pre-1938	Yes		1					
10-day 📝 Initial		OTC Product	✓ Yes		j					
15-day Follow	/-up #				1					
. Manufacturer Report	Number	8. Adverse Eve	ent Term(s)		1					
54973 AE # 161	.8	SEIZURES			1				.1111	1 4 2015
		1			1				JUL	- 5414
This eaction applies	only to me	unicomante of the	Pananyari	Peduction Act of 1995	Department of He	alth and F	luman Service	s	OMR Statement	· "An agency may not

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

Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@ida.hhs.gov valid OMB control numb Please DO NOT RETURN this form to the above PRA Staff email address.

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

SECTION I:	COMPLAINT	COMPLAINT #: 26	328
TAKEN BY:	TUTTI GOULD	DATE OF COMPLAINT: 06	6/22/2015
PRODUCT:	BABY TEETHING TABLETS	ITEM CODE: B	TETT40
SIZE:	40 TABS	LOT NO.: B	21514
REPORTER:	(b) (6)		
ADDRESS:	N/A		
	N/A		
CITY:	N/A	STATE: (b) (6)	
COUNTRY:	USA	ZIP CODE: N/A	
PHONE #:	(b) (6)		
E-MAIL:	N/A		
CAR. AT THE HO SEIZURES AND THE EVENING, H ANTIBIOTICS, M AS OF YET THE	Y OR MAKE SOUNDS. MOTHER TOOK HIM TO THE HOSP OSPITAL, SHE DOES NOT REMEMBER IF THEY DID ANY TO PRESCRIBED ANTIBIOTICS, MOTRIN AND TYLENOL. THE HAD A FEVER OF 103-104, AND MOTHER TOOK HIM TO IOTRIN AND TYLENOL. THEY SAID IF HE HAS SEIZURES. IS CHILD HAS NO TEETH, BUT HAS SYMPTOMS OF TEETH SIVEN HIM MOTRIN AND TYLENOL PRIOR TO THIS EVENT FOR ADDITIONAL SPACE PLEASE USE	ESTS, BUT HE DID SEE 2 DOCTORS WHO DIA NEXT DAY, (B) (G) HE AGAIN D HE HOSPITAL WHERE THEY RECOMMENDED AGAIN, TO TAKE HIM TO THE CHILDREN'S HOS ING: RUBBING HIS GUMS AND INCREASED SA WITH NO REACTION. REVERSE OR ATTACH A SEPARATE SHEET	GNOSED IT AS PEBRILE EVELOPED SEIZURES IN THE SAME TREATMENT: SPITAL. ALIVATION.
PRODUCT RECEINSPECTION:	EIVED FOR Y (CIRCLE ONE)	PRODUCT BEING RETURNED FOR INS	PECTION: Y N (CIRCLE ONE)
		DATE REQUESTED PRODUCT BE RE	ETURNED:
SECTION II:	INVESTIGATION	UPS CALL TAG	
INVESTIGATION	PLEASE SEE ATTACHED INVESTIGATION RE	PORT	
AND THE PARTY OF	NT FORWARDED TO PHARMACIST / NURSE FOR EVALUA NT FORWARDED TO PHARMACIST / NURSE FOR EVALUA		D
SECTION III:	CORRECTIVE ACTION:	dividual Case Safety Rep	ort
		11275465-01-00-03	
CORRECTIVE A	CTION(S) COMPLETED BY:	DATE;	78
SECTION IV:	ADVERSE EVENT REPORTS	AE#1	JUL 1 5 2015
ADVERSE EVEN	NT SERIOUS: (Y) N NT REPORTED ON: 06/22/2015	BY: TUTTI GOULD	JUL 1 4 2015
SECTION V:	MANAGEMENT BY:	al A DATE	07-01-15
BY:	Que Bour	DATE:	07-01-15

cc: QA / QC Packaging

Production Shipping / Receiving

Individual Case Safety Report



CaseID: 11275465

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 (b) (4) units have been distributed.

JU27-2015

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 $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

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

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

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured one other complaint (CC-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

DSS JUL 1 5 2015

JUL 1 4 2015



E EVENT DATA FORM



	18				#: _2628		
TION I:	PATIENT INFORMATI	ON (IF DIFFEREN	T FROM REPORTER	ON FORE	N VD1)		
E:	(b) (6)						
RESS:							
			10-10-0				
				STATE:	(b) (6)		_
ITRY:	USA			IP CODE:			
IE #:	(b) (6)						_
IL:	(
AF	PACKAGING INFORM FFIX PACKAGING LABEL HEI FIX RE		UG FACTS	AND PRIN	TON HERE ICIPAL DISPLAY		
ON III:	CORRECTIVE ACTIO	DN:		The state of the s		DSS	
		DN:		The state of the s		DSS JUL 1 5 20	115
	CORRECTIVE ACTION	DN:		The state of the s	DATE:	JUL 1 5 20	
ECTIVE A		ON:		The state of the s	DATE:	JUL 1 5 20	
ECTIVE A	CTION(S) COMPLETED BY:	ON:				JUL 1 5 20	JUL 1 4
ECTIVE A	CTION(S) COMPLETED BY:	Service Berice	H		DATE:	JUL 1 5 20	JUL 1 4

by user-facilities, outors and manufacturers ATORY reporting

CaseID: 11275478
Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

Mfr Report # 54973
UF/Importer Report # OTC

Page 1 of 5

And the second of the second o	strength & mfr/labeler,			
#1 HYLAND'S B	ABY TEETHING T	ABLETS		
#2 N/A				
2. Dose, Frequency 8			py Dates o (or best e	(If unknown, give duration, estimate)
#1 3 TABS BID	PRN TEETHING	#1		
#2 N/A		#2		
4. Diagnosis for Use #1 TEMP RELIES		cei		Abated After Use ed or Dose Reduced?
#2 N/A	116		AGAC	es No Apply
6. Lot#	7. Exp. Date		#2 🔲	Yes No Doesn
#1A29815		L 15	2 Frent	Reappeared After
#2N/A	#2		#1 V	raduction? Yes No Doesn
9. NDC# or Unique ID		CDR		Apply
54973-3127-1	110	CDK	#2 🔲	res No Doesn
D. SUSPECT ME	EDICAL DEVICE		(0	Continue on page 3)
2. Common Device N	ame		2b. F	Procode
				14.4
3. Manufacturer Nam	e, City and State			
4. Model #	Lat#			5. Operator of Device
Catalog #	Expiration	Date (mm	/dd/yyyy)	Lay User/Patient
Serial #	Unique Ide	entifier (UD	11)#	Other:
6. If implanted, Give	Date (mm/dd/yyyy)	7. If Exp	lanted, Gi	ve Date (mm/dd/yyyy)
8. Is this a Single-use	Device that was Rep	rocessed a	ind Reuse	d on a Patient?
Yes No				
9. If Yes to Item No. 8	, Enter Name and Add	iress of Re	processo	
10 Davise Avellable	for Evaluation? (Do no	t cond in E	0.41	
Yes No				
	-			(mm/dd/yyyy)
11. Concomitant Med	ical Products and The	rapy Date:	s (Exclude	treatment of event)
E INITIAL DESC	22750		(0	Continue on page 3)
E. INITIAL REPO	131			
(b) (6)	DSS		71	A
	500	AE'	7 1	4 4 7015
	WL 15 20	162	L	97
Phone # (b) (6)	Ema	ail Address	1	
2. Health Professions	i? 3. Occupation			nitial Reporter Also Sen
☐ Yes ☑ No	NA			Report to FDA Yes No V Unk

FORM FDA 3500A (2/13) A. PATIENT INFORMATION 3. Sex 4. Weight 2. Age at Time 1. Patient Identifier of Event: (b) (6) Months Female or Date ✓ Male In confidence of Birth: kas B. ADVERSE EVENT OR PRODUCT PROBLEM Product Problem (e.g., defects/malfunctions) ✓ Adverse Event and/or Outcomes Attributed to Adverse Event (Check all that apply) Disability or Permanent Damage Death: (mm/dd/yyyy) Congenital Anomaly/Birth Defect Life-threatening Other Serious (Important Medical Events) Hospitalization - initial or prolonged Required Intervention to Prevent Permanent Impairment/Damage (Devices) 4. Date of This Report (mm/dd/yyyy) 3. Date of Event (mm/dd/yyyy) 06/16/2015 06/26/2015 5. 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 PLEASE TYPE OR USE BLACK INK SEIZURE WOULD BE. SHE STOPPED USING THE TABLETS AND CHILD HAS NOT HAD A TWITCHING EPISODE SINCE. (Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates (Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/henal dysfunction, etc.) IMMUNIZATIONS JUNE 10 (Continue on page 3) Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.



	CaseID: 11275478
•	FDA USE ONLY
. of <u>5</u>	
H. DEVICE MANUFACT	TURERS ONLY
Type of Reportable Event	2. If Follow-up, What Type?

E FOR HOE BY	1055 54	OU ITY/III.	5 (5) 6 ()		
	JSERFA	CILITY/IMPORTE		H. DEVICE MANUFACTURERS ONLY	
1. Check One	_		orter Report Number	Type of Reportable Event	2. If Follow-up, What Type?
User Facility	Impo	orter		Death	Correction
3. User Facility or Imp	orter Name	Address		Serious Injury	Additional Information
				Malfunction	Response to FDA Request
					1 = '
				1 1	Device Evaluation
				3. Device Evaluated by Manufacturer?	4. Device Manufacture Date
					(mm/yyyy)
4. Contact Person		Is Dh	N	Not Returned to Manufacturer	
4. Contact Person		5. PIK	one Number	Yes Evaluation Summary Attached	
				No (Attach page to explain why not) or	5. Labeled for Single Use?
Date User Facility or Importer Became	'	7. Type of Report	8. Date of This Report (mm/dd/yyyy)	provide code:	☐ Yes ☐ No
Aware of Event (mm	/dd/yyyy)	Initial	(mmod/yyyy)		_
				6. Event Problem and Evaluation Codes (Refer to c	oding manual)
		Follow-up #		Patient P	
9. Approximate Age of Device	10. Event P	Problem Codes (Refer to	o coding manual)	Code	
rigo or zonico	Patient [Device	
	Code _			Code	
	Device			Marked Company] []
	Code _			Method	J ⁻
11. Report Sent to FDA	?	12. Location Where E	ent Occurred	Bassille Company]_[
☐ Yes		Hospital	Outpatient	Results]-[]
(mm/dd/	уууу)	Home	Diagnostic Facility	Conclusions	1
No ,		Nursing Home	Ambulatory	Condusions	J-[]
13. Report Sent to Man	ufacturer?	Outpatient Tre	our grount womey	7. If Remedial Action Initiated, Check Type 8.	Usage of Device
Yes		Facility	aunent	Recall Notification	Initial Use of Device
□ No (mm/dd/	'yyyy)	Other:			Reuse
			(Specify)	Repair Inspection	<u> </u>
14. Manufacturer Name	/Address			Replace Patient Monitoring	Unknown
				Relabeling Modification/ 9. Adjustment	If action reported to FDA under 21 USC 360i(f), list correction/
					removal reporting number:
				Other:	
				10. Additional Manufacturer Narrative ar	nd / or 11. Corrected Data
C ALL MANUEA	CTUBER	c		Additional manufacturer Harrative al	nd / or 11. Corrected Data
G. ALL MANUFA					
Contact Office (and i	Manufactur	ing Site for Devices)	2. Phone Number		
Name			310-768-0700		
EDYTA FRACKIEWI	ÇZ		3. Report Source		
Address			(Check all that apply)	ł [
HYLAND'S, INC.			Foreign		
154 W. 131ST ST	REET		Study		
LOS ANGELES, CA	90061		Literature		
			✓ Consumer		
Email Address			Health Professional		
STANDARD@HYLAND	S.COM		_		
Date Received by	******	5.	User Facility		
Manufacturer (mm/do		(A)NDA #	Company		
06/26/20	15	100.4	Representative		
. If IND, Give Protocol	#	IND#	Distributor		
		BLA #	Other:		DSS
		PMA/			
7. Type of Report		510(k) #			JUL 1 0 2015
(Check all that apply)		Combination			JOE
5-day 30-day	4	Product Y	'es		
7-day Period	lic	Pre-1938 Y	.		
10-day 🗸 Initial			1		
✓ 15-day ☐ Follow	-up#	OTC Product 7 Y	es		
. Manufacturer Report	Number	8. Adverse Event Ter	·m(e)		
-		POSSIBLE SEIZO		15	215 4 4 000
54973 AE # 161	9			The H	JUL 1 4 2015
				1	302

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

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HOMEOPATHIC MADE IN THE USA SINCE 1903

Casalplanon 5478

SECTION I:	COMPLAINT	COM	IPLAINT#:	2629	
TAKEN BY:	EDYTA FRACKIEWICZ	DATE OF CO	MPLAINT:	06/26/2015	
PRODUCT:	BABY TEETHING TABLETS)))	EM CODE:	BTET-T135	
SIZE:	135 TABS		LOT NO.;	A29815	
REPORTER:	(b) (6)				
ADDRESS:	N/A				
	N/A		(b) (6)		
CITY:	N/A	STATE:	(0) (0)		
COUNTRY:	USA (b) (6)	ZIP CODE:	N/A		
PHONE #	and to a				
E-MAIL:	NA				
NATURE OF COM	ABOUT 10 MINUTES AFTER THIS DOSE HABOUT 15 MINUTES. HAPPENED A SEC MOTHER STATED "I WOULDN'T CALL IT ADRAMATIC OR VIOLENT AS A SEIZURE VIOLENT AS A SEIZURE VIOLENT AS A SEIZURE VIOLENT AS A SEIZURE VIOLENT AS A SEIZURE VIOLENT AS A SEIZURE VIOLENT AND AN INTERPRETATION OF THE PROPERTY	OND TIME THAT SAME DA' A SEIZURE". MOTHER STA YOULD BE. SHE STOPPED MMUNIZATION ON JUNE 10 ND OR REPLACEMENT.	Y AFTER SI ATES THAT USING THI ITH 4-5 DAY	HE GAVE THE TA THE TWITCHING E TABLETS AND 'S BEFORE GETT	BLETS AGAIN. WAS NOT AS HE HAS NOT HAD A
PRODUCT RECEINSPECTION:	EIVED FOR Y (CIRCLE ONE)	PRODUCT BEING RETU	RNED FOR	INSPECTION	(CIRCLE ONE)
		DATE REQUESTED P	RODUCT BI	E RETURNED:	
			UPS CALL	TAG ISSUED:	Y (CIRCLE ONE)
		DAT	TE PRODUC	T RECEIVED:	
SECTION II:	INVESTIGATION	-	6000000	0.00-000-1	
INVESTIGATION	PLEASE SEE ATTACHED INVESTIGATION REPOR	Т	-		
ADVERSE EVEN	IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION	ON:	06/26/201	5	
ADVERSE EVEN	IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION	BY:	EDYTA F	RACKIEWICZ	
SECTION III:	CORRECTIVE ACTION:	vidual Case Sa		Santa	
	1111111	Millia i Mil	lety R	eport	
		11.775.470.0	O HILL BRIEF		100
		11275478-0	1-00-03	3	188
CORRECTIVE AC	CTION(S) COMPLETED BY:		UMIL.		JUC . 0 (U15
SECTION IV:	ADVERSE EVENT REPORTS		AE #:	1619	
ADVERSE EVEN	rt serious:				JUL 1 4 2015
ADVERSE EVEN	T REPORTED ON: 06/26/2015	BY: ED	YTA FRACK	IEWICZ	JUL I T ZUIS
SECTION V:	-HC	T PM			
REVIEWED BY M	MANAGEMENT BY:	alle	DATE:	07-07	
BY:	Yur Ball	3576	DATE:	07-0	7-15 DS.
	QA / QC DIRECTOR				MIL 1 -

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 11275478

.dverse Event SAE-0028-2015

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 (b) (4) units have been distributed.

Review of Records:

The Hyland's Baby Teething Tablets lot # A29815associated 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 # 125264 was tested for total Atropine and Scopolamine and the results were with in specification of $\leq_{(4)}^{(6)}$ ppm.

Retention Samples:

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

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

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured one other complaint (CC-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.

Date

7/6/2015

JUL 1 4 2015



SE EVENT DATA FORM



AE #: 161	9	COMPLAINT#: 2629	-
SECTION I:		RENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:			
CITY:		STATE:	
COUNTRY:		ZIP CODE:	
PHONE #:			
E-MAIL:			
SECTION II:	PACKAGING INFORMATION:		
AF	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
indicadatatic record policy of our production of the production of	Select address BODY Select and the amount of the committee of the committe	WO A CARD AND A CARD A	
SECTION III:	CORRECTIVE ACTION:		
CORRECTIVE AC	CTION(S) COMPLETED BY:	- July Bate: The	1.52
SECTION IV:	-IR-	JUL 1	4 2015
REVIEWED BY M	MANAGEMENT BY:	HUTTLE DATE: 07-07-15	
BY:	Euc Bou	M DATE: 07-07-15	
	QA / QC DIRECTOR	W	

user-facilities, ors and manufacturers ORY reporting

1 of 5

Form Appropries	See OMB statement on reverse.
Mfr Report # 54973	
UF/Importer Report #	STC
	1.

Yes No V Unk

A. PATIENT INF				C. SUSPECT P	RODUCT(S)		
Patient Identifier (b) (6)	2 Age at Time of Event:	3. Sex	4. Weight		d strength & mfr/labele		
	or	Female	lbs	#1 HYLAND'S B	ABY TEETHING T	ABLETS	
In confidence	Date of Birth:	Male	or kgs	#2			
	ENT OR PRODUCT PR	ROBLEM		2. Dose, Frequency 8	& Route Used	3. Therapy Dates from/to (or best	(If unknown, give duration estimate)
✓ Adverse Even		roblem (e.g., defects/malf	functions)	#1 UNKNOWN		#1	
	ed to Adverse Event	objeti (e.g., objects man	Unational	#2		#2	
(Check all Ihat appl			200	4. Diagnosis for Use	(Indication)		nt Abated After Use
Death:	(mm/dd/yyyy)	Disability or Permanent Da		#1 TEMP RELIE	F TEETHING PAI	N	yes No Does
✓ Life-threatenin		Congenital Anomaly/Birth C		#2			— — Арріу
	- initial or prolonged	Other Serious (Important M	Dec of the	6. Lot#	7 Exp. Date	#2	Yes No Does
Date of Event (mn		e of This Report (mm/dd		#1	#1		t Reappeared After troduction?
	1/2015	07/01/2015	2.11.0	#2	#2	10.042.40	Ves No Does
Describe Event or	Problem _{(b) (B)}	Days J		9. NDC# or Unique ID)		Афру
ODI OF IDE LOCK	ED ON THAT SHE GAVE HER THE HYI	HER BABY WAS BO	7.77	54973-3127-3	3.	#2	Yes No Doesi
	Receive	2.2		D. SUSPECT ME	EDICAL DEVICE	(Continue on page 3)
	veceive	d		2. Common Device N	ame	2b.	Procode
	Trin .			3. Manufacturer Nam	e, City and State		
	JUL 1 5 2015	9					
				4. Model#	Lot#		5. Operator of Device
	CDR						Health Professiona
	-11		-0.11	Catalog #	Expiration	Date (mm/dd/yyyy)	Lay User/Patient
				Serial#	Unique ld	entifier (UDI)#	Other:
		(Continue or	page 3)	6. If Implanted, Give I	Date (mm/dd/yyyy)	7. If Explanted, G	ive Date (mm/dd/yyyy)
Relevant Tests/Lab	oratory Data, Including Dates			8. Is this a Single-use	Device that was Rep	rocessed and Reuse	ed on a Patient?
				Yes No. 8	, Enter Name and Ad	denna of Des	
				5. II 1 ES LO ITEM NO. 8	, citter waite and Ad	uress or Reprocesso	
							DSS
				10. Device Available f		ot send to FDA)	JUL 1 6 201
		Na Torritoria	700	E CONTRACTOR	Щ ступу		(mm/dd/yyyy)
Other Relevant Hist race, pregnancy, sm	ory, Including Preexisting Med	(Continue on dical Conditions (e.g., all enal dysfunction, etc.)		11. Concomitant Med	ical Products and The	erapy Dates (Exclude	a treatment of event)
	One and a said training					(0	Continue on page 3)
				E INITIAL REPO			
				1. Name and Address (b) (6)	q 1	SAIUL	1 5 2015
		(Continue on	page 3)	riidia #		Address	
mission of a re	port does not constitute	an admission that	medical	2 Health Professiona	l? 3. Occupation		Initial Reporter Also Sen
sonnei, user fac used or contribu	ility, importer, distribute ted to the event.	or, manufacturer or	product	Yes No	NA		Report to FDA Yes No V Unk



F. FOR USE BY	JSER FAC	ILH Y70V	IPUR	TEK (D	evices c	тту)
1. Check One			2. UF/	importer R	eport Num	ber
User Facility	Impor	ter				
3. User Facility or Imp	orter Name/A	Address				
3. User Facility or Importer Name/Address						
4. Contact Person			15	. Phone Nu	ımber	
4. Contact Person			ľ	. Filone ite	alline.	
6. Date User Facility o	. 17	. Type of R	Panort		8 Date of	This Report
Importer Became			Cepoit		(mm/dd/	
Aware of Event (mn	vaavyyyy)	Initial				
İ		Follow-	up#			
9. Approximate	10. Event P	roblem Cod	des (Re	efer to codin	ng manual)	
Age of Device	Patient					
	Code		_ -			
	Device		7.		7-	
	Code					
11. Report Sent to FD/	4?	_		ere Event C		-4'4
Yes		=	ospital		Diag	patient postic Facility
☐ No (mm/dd	'yyyy)	드	ome			oulatory
13. Report Sent to Mai	nufacturer?		ursing H			gical Facility
Yes			utpatier icility	nt Treatmen	τ	
No (mm/dd	YYYY)		her:			
14. Manufacturer Nam					(Specify)	
G. ALL MANUFA	CTURERS	3				
1. Contact Office (and	Manufacturi	ng Site for	Device	es)	2. Phone	Number
Name					310-768	8-0700
EDYTA FRACKIEW	ICZ				3. Report	Source
Address					1_	all that apply)
HYLAND'S, INC.					Foreig	jn
154 W. 131ST S					Study	
LOS ANGELES, C	A 90061				Literal	
Email Address					Consu	Professional
STANDARD@HYLAN	DS.COM				User F	
4. Date Received by Manufacturer (mm/c	id/ana/)	5.			Comp	-
07/01/2		(A)NDA #	<u> </u>			sentative
6. If IND, Give Protoco		IND≢	<u> </u>		Distrib	
6. If IND, GIVE PROTOCO	1 #	BLA#	:		Other:	:
		PMA/				
7. Type of Report (Check all that apply)		510(k) #	<u> </u>			
5-day 30-da		Combina Product	tion	Yes		
7-day Perio	•	Pre-1938	,			
10-day 🗸 Initial	ı			Yes		
15-day Follo	w-up #	OTC Pro	duct	√ Yes		
9. Manufacturer Repor	rt Number	8. Advers	e Ever	nt Term(s)		
54973 AE # 16	20			D, SEIZ		
		DEVELO	PMEN	TAL DEL	AY	

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

		FDA USE ONLY	
: 5			
H. DEVICE MANUFAC			.0
Type of Reportable Event		2. If Follow-up, What Typ	67
Death		Correction Additional Informa	ution
Serious Injury Malfunction		Response to FDA	j
Mandriction		Device Evaluation	
3. Device Evaluated by Manu		4. Device Manufacture Da (mm/yyyy)	ite
Not Returned to Manu			
	Summary Attached	5. Labeled for Single Use	2
No (Attach page to ex provide code:	plain why not) or		
		Yes No	
6. Event Problem and Evalua	ation Codes (Refer to	coding manual)	
Patient			\neg \Box
Code			
Device Code	-]-	
			7
Method			
Results]_]-	7
_			⊣
Conclusions			
7. If Remedial Action Initiate	d, Check Type	8. Usage of Device	
Recall N	lotification	Initial Use of Device	
Repair	spection	Reuse	
Replace P	atient Monitoring	Unknown	
	lodification/ djustment	if action reported to FDA u 21 USC 360i(f), list correct	ion/
Other:	ujusunem	removal reporting number	:
Oaler.			i
10. Additional Manufactor	urer Narrative	and / or 11. Correc	ted Data
			1
		_	200
		l) 55
			1 0 9015
		JUI	OSS L 1 6 2015
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		no 4 = 4	1045
		JUL 15 2	/U15

CaseID: 11279245

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PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

Information unless it displays a currently valid OMB control number."

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of



CUSTOMER COMPLAINT RECORD



			COM	MPLAINT #:	2630	
TAKEN BY:	EDYTA	FRACKIEWICZ	DATE OF CO	OMPLAINT:	07/01/2015	
PRODUCT:	BABY T	FEETHING TABLETS		EM CODE	BTET	
SIZE	N/A			LOT NO.:	N/A	
REPORTER:	(0) (6)					
ADDRESS:	NA					
	N/A					
CITY:	N/A		STATE	N/A		
COUNTRY	USA		ZIP CODE:	N/A		
PHONE #:	N/A					
E-MAIL:	N/A		(h) (f)	A AB 13	4.7.17.15.55	
NATURE OF COMPLA	G H	ATE UR COMPANY, U TOOK MY	DWING ON STATE OF THE SHE ENDED UP WIT ABLETS, THEN SHE ENDED UP WIT OF BADDIES LIFE FROM HER, SHE W YED, WITH SPEECH, WALKING, PLA	TH A BLEED VILL NEVER	IN HER BRAIN B NORMAL OR	DO NORMAL
	FOR	ADDITIONAL SPACE PLEASE	USE REVERSE OR ATTACH A SEP	ARATE SHE	ΕT	
PRODUCT RECEIVED	FOR	(CIRCLE ONE)	PRODUCT BEING RETU	RNED FOR	INSPECTION:	(CIRCLE ONE)
ndividual C	ase Safet		DATE REQUESTED P	RODUCT BE	RETURNED:	(divoice dive)
11111111111111111111					-	
	HIII KIM			UPS CALL	TAG ISSUED:	(CIRCLE ONE)
4450	22.2	THE PERSON NAMED IN COLUMN NAMED IN				
1128	9245-01-00	1-113		-		
	9245-01-00 INVESTIGATI		DAT	TE PRODUC	T RECEIVED: _	
SECTION II:	INVESTIGATI			TE PRODUC	T RECEIVED: _	
SECTION II: NVESTIGATION:	PLEASE SI	UN	PORT.	07/01/201		
SECTION II: INVESTIGATION: ADVERSE EVENT FO	PLEASE SI	EE ATTACHED INSPECTION RE	PORT.	07/01/201		
NVESTIGATION: ADVERSE EVENT FO	PLEASE SI RWARDED TO PH	EE ATTACHED INSPECTION RE	PORT.	07/01/201	5	
SECTION II: NVESTIGATION: ADVERSE EVENT FO	PLEASE SI RWARDED TO PH	EE ATTACHED INSPECTION RE HARMACIST / NURSE FOR EVAL	PORT.	07/01/201	5	DSS
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SECTION II: NVESTIGATION: ADVERSE EVENT FOR SECTION III: CORRECTIVE ACTION	PLEASE SI RWARDED TO PH CORRECT	EE ATTACHED INSPECTION RE HARMACIST / NURSE FOR EVAL HARMACIST / NURSE FOR EVAL IVE ACTION:	PORT.	07/01/201 EDYTA F	5	DSS JUL 16
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cc. QA/QC Packaging Production Shipping / Receiving JUL 1 5 2015

Form # VD1





Adverse Event

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 Closticia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of ≤(4) ∋pm.

Conclusion:

Prepared

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

Date

7/8/15

DSS

JUL 1 5 2015

CaseID: 11279245



SE EVENT DATA FORM



AE #:16	20	COMPLAINT #: 2630
SECTION 1:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:	-	
ADDITICOU.		
CITY:		STATE:
COUNTRY:	USA	ZIP CODE:
PHONE #:		
E-MAIL:		
SECTION II:	PACKAGING INFORMATION:	
Al	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE
1	The contraction of the contracti	(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	Teething Tables	A STATE OF THE PARTY OF THE PAR
1		Section 1
1		
		Tablets also plants are a second and a second and a second are a second and a second a second and a second and a second and a second and a second a
l		
1		
		Company of the Compan
(
ECTION III:	CORRECTIVE ACTION:	
		DSS
		JUL 16 2
ORRECTIVE A	CTION(S) COMPLETED BY:	DATE:
ECTION IV:	10 -	
		CARRO
EVIEWED BY N	MANAGEMENT BY:	DATE: 07-09-15
Y:	Eur Bau	DATE: 07-09-15
	QA / QC DIRECTOR	

PURMI FUA 3000A (2/13)

ser-facilities, rs and manufacturers DRY reporting

Form Approved: 35	5.00 OMB statement on reven
# 54073	

	See ONID statement on levelse
Mfr Report # 54973	
UF/Importer Report #	OTO
	UZ Luse Only

of 5 C. SUSPECT	PRODUCT(S)				1 L Laure On
1. Name (Give lab	THE REAL PROPERTY.				
#1 HYLAND'S	BABY TEETH	ING TA	BLETS		
#2 N/A					
2. Dose, Frequen	v & Route Used	-	3. Thera	py Dates (if unknown, give duration
	DOSE X 2 DAY	10	from/	o (or best e	estimate)
	7036 A 2 DA		#1	_	
#2 N/A			#2	Ta-	
4. Diagnosis for L	40.00				Abated After Use ed or Dose Reduced?
	EF TEETHING	PAIN		#1 🗸 Y	res No Does
#2 N/A	-			#2 🗆 Y	on Does
6. Lot#	7. Exp.	Date			— Афріу
#1N/A	#1				Reappeared After oduction?
#2N/A	#2			#1 🗸 Y	res No Does
9. NDC# or Uniqu				#2 🗆 Y	Does
54973-312					treatment of event)
				(0	Continue on page 3)
	MEDICAL DE	VICE			
1. Brand Name					
2. Common Device	e Name			2b. P	rocode
3. Manufacturer N	ame. City and Sta	ito		-1-	
	,,				
4. Model#	Lea	t#			5. Operator of Device
y. Middel ff	100				Health Profession
Catalog #	Ex	piration	Date (mm	/dd/yyyy)	Lay User/Patient
Carl-1#		ince 14	-416 11	W 4	Other:
Serial #	Un	idaa idei	ntifier (UD	n)#	
6. If Implanted, Gi	ve Date (mm/dd/y)	yy)	7. If Exp	lanted, Giv	e Date (mm/dd/yyyy)
L'Areb a			11		
8. Is this a Single-	use Device that w No	ras Repr	ocessed	and Reuse	d on a Patient?
9. If Yes to Item N	2.74	and Add	ress of Re	eprocessor	
		en de la companya de la companya de la companya de la companya de la companya de la companya de la companya de			
10. Device Availab	1			-	
Yes	No Retur	ned to M	anufacture	er on:	(mm/dd/yyyy)
11. Concomitant N	Medical Products	and Ther	apy Date	s (Exclude	treatment of event)
				(0	continue on page 3)
E. INITIAL RE				10	Jage 3)
1 Name and Addi					
ur (0)					DSS
					NL 23 2015
Phone #		Emai	Address		
(b) (6)					100
2. Health Professi		tion		4. h	nitial Reporter Also Ser Report to FDA
☐ Yes 🗸	NA O				Yes No 17 Uni

1. Patient Identifier (b) (6)	2. Age at Time of Event: 8 Months	3. Sex 4. Weight
	or	Female or
In confidence	Date of Birth:	☐ Male
B. ADVERSE EV	VENT OR PRODUCT PRO	BLEM
1. Adverse Even	t and/or Product Prob	lem (e.g., defects/malfunctions)
2. Outcomes Attribut		
(Check all that appl Death:	The second secon	ability or Permanent Damage
	(mm/dd/yyyy)	
Life-threatenin		genital Anomaly/Birth Defect er Serious (Important Medical Evel
THE CALL OF SAME	- initial or prolonged	
3. Date of Event (mm		of This Report (mm/dd/yyyy)
	07/01/15	07/08/15
5. Describe Event or CHILD HAD A S	Problem	204141774
LAST DOSE OF THEN CHILD HAS DIAGNOSED SEI HAD NO FEVER S CAUSED BY BAB	AFTER A DOSE OF BABY BABY TEETHING TABLETS S NOT HAD ANOTHER SEI ZURES AS FEBRILE INIT SO THEY CHANGED THE D	WAS ON ^{(b) (6)} AND SINCE ZURE. DOCTOR IALLY BUT THE CHILD IAGNOSIS TO SEIZURES CHILD WAS HOSPITALIZE
	Rece	eived
	JUL 2	2 2015
	CI	DR
		(Continue on name 3)
6 Relevant Tests/Lat	poratory Data, Including Dates	(Continue on page 3)
6. Relevant Tests/Lak	CI	(Continue on page 3
		(Continue on page 3)
Other Relevant His race, pregnancy, srr	tory, including Preexisting Medic loking and alcohol use, hepatic/ren	cal Conditions (e.g., allergies, al dysfunction, etc.)
1	and the same of th	A COMPANY OF A COMPANY

. Спеск опе О при протег кероп витое User Facility Importer 3. User Facility or Importer Name/Address 5. Phone Number 4. Contact Person 6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy) Date of This Report (mm/dd/yyyy) 7. Type of Report Initial Follow-up # 10. Event Problem Codes (Refer to coding manual) 9. Approximate Age of Device Patient Code Device Code 11. Report Sent to FDA? 12. Location Where Event Occurred Outpatient
Diagnostic Facility Hospital Yes (mm/dd/yyyy) Home No Ambulatory
Surgical Facility Nursing Home 13. Report Sent to Manufacturer? Outpatient Treatment Facility Yes Yes (mm/dd/yyyy) ☐ No Other: (Specify) 14. Manufacturer Name/Address G. ALL MANUFACTURERS 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number 310-768-0700 EDYTA FRACKIEWICZ Report Source (Check all that apply) Address Foreign HYLAND'S, INC. Study 154 W. 131ST STREET LOS ANGELES, CA 90061 Literature √ Consumer Fmail Address Health Professional STANDARD@HYLANDS.COM User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 07/07/15 Distributor IND# 6. If IND, Give Protocol# Other: BLA# PMA/ 7. Type of Report 510(k) # (Check all that apply) Combination 30-day 5-day Yes 7-day Periodic Pre-1938 Yes 10-day ✓ Initial OTC Product √ Yes ✓ 15-day Follow-up # 9. Manufacturer Report Number 8. Adverse Event Term(s) SEIZURES 54973 AE # 1621

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:

H. DEVICE MANUFACTURERS ONLY	
Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
3. Device Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
	E. I. ah alad fee Cinada Haa?
No (Attach page to explain why not) or provide code:	5. Labeled for Single Use?
provide south	Yes No
6. Event Problem and Evaluation Codes (Refer to co	ding manual)
Patient	
Code	
Device	_
Code	
Method -	_
Metriou	
Results -	
. Itesuris	
Conclusions	_
7. If Remedial Action Initiated, Check Type 8.	Jsage of Device
Recall Notification	Initial Use of Device
	Reuse
Repair Inspection	Unknown
Replace Patient Monitoring	
Relabeling Modification/ 9. Adjustment	f action reported to FDA under 21 USC 360i(f), list correction/
I ! '	removal reporting number:
Other:	
10. Additional Manufacturer Narrative and	1/or 11. Corrected Data
To La Production manufacture realization	
1	
l	

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 !

DSS

JUL 23 2015

HOMEOP		Case	301071
ECTION I:	COMPLAINT	COMPLAINT #: 2631	
AKEN BY:	EDYTA FRACKIEWICZ	DATE OF COMPLAINT: 07/07/2015	
RODUCT:	HYLAND'S BABY TEETHING TABLETS	ITEM CODE: BTET-T135	
ZE:	135 TABS	LOT NO : N/A	
EPORTER:	(b) (6).		
DDRESS:	N/A		
	N/A	(b) (6)	
TY:	N/A	STATE:	
OUNTRY:	USA	ZIP CODE: N/A	
HONE #	(b) (6)		
MAIL:	N/A		
OSPITALIZED FOR	AND WAS DESCRIBED AS TREMBLING, FES ROLLING (6) THE 5TH SEIZURE OCCURRED A FEW MINUTES AFTER S WAS ON (6) AND SINCE THEN CHILD HAS NOT HAD ANOTHER CHILD HAD NO FEVER SO THEY CHANGED THE DIAGNOSIS TO S R 1.5 DAYS FOR OBSERVATION. HAS A CT SCAN AND EEG SCHI INJURY, AND NO FAMILY HISTORY OF SEIZURES. FOR ADDITIONAL SPACE PLEASE USE REVERSE	EDUCED AUGUST 1211. NO VACCION TOTAL RECEIVED	S AS LD WAS /, NO
	FOR ADDITIONAL SPACE PLEASE USE REVERSE	UKATAGNA SEPARATE SILET	
	FD FOR Y N PRO	ODUCT BEING RETURNED FOR INSPECTION: Y	\bigcirc
PRODUCT RECEIVE NSPECTION:	(CIRCLE ONE)		CLE ONE)
		DATE REQUESTED PRODUCT BE RETURNED:	
		Υ	(N)
		UPS CALL TAG ISSUED: (CIR	CLE ONE)
		DATE PRODUCT RECEIVED:	
SECTION II:	INVESTIGATION	28 10 21 22 23 24 24 24 24 24	
201101111			
NVESTIGATION:	PLEASE SEE ATTACHED INVESTIGATION REPORT		
			_
			_
DVERSE EVENT F	FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:	07/07/2015	
DVERSE EVENT	FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:	EDYTA FRACKIEWICZ	
SECTION III:	CORRECTIVE ACTION:		
			-
CORRECTIVE ACT	TION(S) COMPLETED BY:	DATE:	
and a second	100000000000000000000000000000000000000	AE # 4624	Doo
SECTION IV:	ADVERSE EVENT REPORTS	AE #1621	DSS
ADVERSE EVENT	SERIOUS: Y / N		JUL 23 2
ADVERSE EVENT	REPORTED ON: 07/07/2015	BY: EDYTA FRACKIEWICZ	
SECTION V:		2na	
Individu	al Case Safety Report	DATE 07-10-15	1111 00
		DATE OF TOTAL	JUL 22
	18 JURA 8181 F JURA 1818 JURA 1918 1818 1818 1818 1818 1818 1818 181	DATE 07-10-15	

cc: QA / QG Packaging Shipping / Receiving

Form # VD1





CaseID: 11301071

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.

JAL-UU30-2015

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, scopolamine and CBOT testing. The results for Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(b)}$ pm.

Conclusion:

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

7/9/2015

Date

JUL 2 2 2015



EVENT DATA FORM



		COMPLAINT #: 2631	
SECTION I:	PATIENT INFORMATION (IF DI	IFFERENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:	1		_
	-		_
CITY:		STATE:	_
COUNTRY:) =	ZIP CODE:	_
PHONE #: E-MAIL:			_
S 100 / 101			
SECTION II:	PACKAGING INFORMATION:		
AFI	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
manufactures, and resigned of real service for the religion of the service for the religion of the service of the religion of the extended produced on the religion of the religion of the religion of the first produced of the religion of the produced of the religion of t	Teething Tablets Barden upp is Controlled State of the process o	Raby Teething Tablets	
		The state of the s	
SECTION III:	CORRECTIVE ACTION:	Will charf. A service of the control	Dec
SECTION III:	CORRECTIVE ACTION:	Will charf. A service of the control	_ DSS
SECTION III:	CORRECTIVE ACTION:	Will charf I. Service and the service and the	_ DSS JUL 23 20
	CORRECTIVE ACTION: CTION(S) COMPLETED BY:		
		DATE:	
CORRECTIVE AC		DATE:	JUL 23 20



The FDA Safety Information and

Adverse Event Reporting Program

umer Report CDER

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

RY reporting of duct problems and product use errors

Triage unit	FDA USE ONLY	-
Triage unit sequence #	609469	

1. Patient Identifie b) (6)	r 2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1	2 to 3 tablet times daily		ur times ily	Taken b	y mouth	
In confidence	(b) (6)	✓ Male	or kg	100				1		
	Land I am an an an an an an an an an an an an an	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		(0	ates of Use (If unknown best estimate) 3/06/2015 - 05			Stoppe	t Abated Afte d or Dose Re res / No	
	Error Problem with Differ	No.		#2				#2 🗔	res \ \ \ No	Doesn't
(Check all that a		ability or Permanen	4 Damana	11 3 1 6 5 7	agnosis or Reason f My son was teetr pain .	- 20 1 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	The second secon	8. Even	t Reappeare	
Life-threaten	(mm/dd/yyyy)	ngenital Anomaly/Bi	Contract of	#2				#1. []	Yes No	Doesn's
3-0	on - initial or prolonged [7] Other ervention to Prevent Permanent			6, Lc	ot# 00 624 9659	1 1 1 1 1 1 1 1 1	30/2016	10, -	Yes ☐ No # or Unique	Doesn'i
3. Date of Event (The second second second second	ite of this Report		#2		#2		-	-3127-1	
08/09/201		/09/2015			SUSPECT MED	ICAL DE	VICE			
				2. Co	ommon Device Name	0)			CTU	
See addit	ional page(s)	for compl	ete text.	3. M	anufacturer Name, C	ity and Sta	te	1	AUG 1 0	2015
				4. M	odel#	Lot#			5. Operator	r of Device Professional
				Ci	atalog #	Expir	ation Date (n	nm/dd/yyyy,	Lay Use	er/Patient
i. Relevant Tests	/Laboratory Data, Including D	ates		Se	erial #	Other	#			
See addit	ional page(s)	for compl	ete text.	6. If	Implanted, Give Date	e (mm/dd/yy	yy) 7. If E	xplanted, (Sive Date (mi	m/dd/yyyy)
					this a Single-use De					atient?
Other Relevant	History, Including Preexistin	g Medical Conditi	ons (e.g.,	9. 11	Yes to Item No. 8, Ent	er Name and	Address of H	Reprocesso	,	
	pregnancy, smoking and alcoho				OTHER (CONCO					
See addit	ional page(s)	for compl	ete text.	Se	e addition	al pag	e(s) f	or con	mplete	text.
PRODUCT	AVAILABILITY				REPORTER (See	e confide	ntiality sec	tion on b	ack)	D
	for Evaluation? (Do not send	product to FDA)		100,00						AUG 1
	Returned to Manufactu	rer on:	m√dd/yyyy)							406 1
Name, Strength	PRODUCT(S) A, Manufacturer (from product) and's Teething Tablets	1		Pho (b) (6)			E-mai (b) (6)			
Manufacturer:	and's Teething Table Manufactured for Hyl	ts and's inc.,			ealth Professional?	3. Occupat	ion	,	1. Also Repo	
2 Name: Strength: Manufacturer				5. If	Yes No you do NOT want you the manufacturer, pla				☐ Manufa ☐ User Fa	



My name is (0)(6)

I have a now 17month old son by the name of (0)(6)

Well I'm here to tell you my story. After my son 1st birthday (b)(6)

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 (b)(6)

(b)(6) my son had a seizure and I called the paramedics and they rushed him to the hospital. They sent us home and on (0)(6)

he had 2 more seizure and he was rushed to the hospital once again. They gave him a CatScan and 1 hour EEG and A MRI. He was also admitted 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 seizure 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 Locked into what I need to do to get help please contact me as soon as possible for further information. Thank you! My Number Is (b)(6)

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

(b) (6) he was tested for COMPREHENSIVE METABOLIC PANEL , URINALYSIS , XR CHEST 1 VW PORTABLE , DRUG SCREEN/TOX , CBC COMPONENT , CLINITEST . As of (b) (6) He Was Admitted As of (b) (6) He Had An CatScan As of (b) (6) He Had An EEG As of (b) (6) 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 KEPPRA

OTC Meds:

Individual case safety Report

11374329-01-00-01

y user-facilities, itors and manufacturers ITORY reporting

11 of 5

Form Approved: OMENO. 0910-9291, Explant 6/30					
Mfr Report # 54973					
UF/Importer Report #					

A. PATIENT IN			Sex 4. Weight	C. SUSPECT P	d strength & mfr/labeler)	1		
(b) (6)	of Event:		Female lb	## HYLAND'S B	ABY TEETHING T			
In confidence	Date of Birth:		☐ Male or kg	#2				
In confidence	of Birth: VENT OR PROD	ICT PROBLEM		2. Dose, Frequency	& Route Used	3. Therapy Dates		jive durat
		E. C. A. W. SHILL YOU	No. of Part and Part of the Pa	#1 UNKNOWN		from/to (or bes	(вышланы)	
1 Adverse Even	ted to Adverse Event	roduct Problem (e.g	., defects/malfunctions)	#2		#2		
(Check all that appl				4. Diagnosis for Use	(Indication)		nt Abated Afte	r Use
Death	(mm/dd/yyyy)	Disability or	Permanent Damage		F TEETHING PAIN	Stop	pped or Dose F	Reduced'
Life-threatenin		Congenital A	nomaly/Birth Defect	#2	N. William	#1	Yes No	☑ Do
· V Hospitalization	1 - initial or prolonged	Other Seriou	s (Important Medical Events	6. Lot #	7. Exp. Date	#2	Yes No	Do
Required Inter	vention to Prevent Per	manent impairment/0	amage (Devices)	#1	#1	8. Ever	nt Reappeared	
3. Date of Event (min		HER WAS A SECOND RESTREET	eport (mm/dd/yyyy)	1 =		Rein	stroduction?	
	28/2015		7/31/2015	9 NDO# or Unique II	#2	#1	Yes No	Doe App
 Describe Event or CHILD EXPERIE 		IKE ACTIVITY	WITH POSSIBLE	9. NDC# or Unique II 54973-3127-		#2	Yes No	Doe
HOSPITALIZATI			Cally Street Table		dical Products and The			
		Recei	ved	2 Common Device I	lame	2b	Procode	_
		2000		1. Brand Name				
		Recei	Aeri	2. Common Device I	lame	2b.	Procode	
			7	3. Manufacturer Nam	e, City and State			
		AUG 11	2015					
				4. Model#	Lot #		5. Operator	of Device
		CDI	2				Health	Professio
		CD.	*	Catalog #	Expiration	Date (mm/dd/yyyy)	Lay Us	er/Patient
				Serial #	Unique Ide	ntifier (UDI)#	Other:	
2.7.7		Y Y	Continue on page 3)	6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Explanted, G	ive Date (mm/	dd/yyyy)
6. Relevant Tests/Lat	poratory Data, Includi	ng Dates		8. Is this a Single-us	e Device that was Repr	ocessed and Reus	ed on a Patien	t?
				Yes N				
				9. If Yes to Item No. I	5. Enter Name and Add	ress of Reprocess	or	
				A company to				
					for Evaluation? (Do not			
				Yes No	for Evaluation? (Do not	anufacturer on:	(mm/dd/yy	
			Continue on page 3)	Yes No	for Evaluation? (Do not	anufacturer on:		
Other Relevant His race, pregnancy, sm	tory, Including Preex oking and alcohol use,			Yes No	for Evaluation? (Do not	anufacturer on:		
Other Relevant His race, pregnancy, sm	tory, including Preex loking and alcohol use.			Yes No.	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:		event)
. Other Relevant His race, pregnancy, sm	tory, including Preex loking and alcohol use,			Yes No.	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:	e treatment of a	event)
. Other Relevant His race, pregnancy, sm	tory, Including Preex oking and alcohol use.			Yes No.	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:	e treatment of a	event)
Other Relevant His race, pregnancy, sm	tory, including Preex loking and alcohol use,			Yes No. 11. Concomitant Med E. INITIAL REPO	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:	e treatment of a	event)
'. Other Relevant His race, pregnancy, sm	tory, including Preex loking and alcohol use,			Yes No. 11. Concomitant Med E. INITIAL REPO	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:	e treatment of a	event)
. Other Relevant His race, pregnancy, sm	tory, including Preex oking and alcohol use.			Yes No. 11. Concomitant Med E. INITIAL REPO	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:	e treatment of a	event)
Other Relevant His race, pregnancy, sm	tory, including Preex oking and alcohol use,	isting Medical Cond hepalic/renal dysfun		Yes No. 11. Concomitant Med E. INITIAL REPO	for Evaluation? (Do not Returned to M lical Products and The	anufacturer on:	e treatment of a	event)

2 of 5

Case) 1	11	13	74	32	9
FUA USI	U	NLY					

11374329-01-00-02

User Facility importer						
3. User Facility or Importer Name/Address						
ĺ						
į						
4. Contact Person 5. Phone Number						
6. Date User Facility o	r	7. Type of Report	8. Date of This Report			
Importer Became Aware of Event (mm	n/dd/yyyy)	☐ Initial	(mm/dd/yyyy)			
-						
O. Approximate	10 Event	Follow-up #	-			
9. Approximate Age of Device	Ι.	Problem Codes (Relet to co	ung manual)			
	Patient Code	-	-			
	Device					
	Code					
11. Report Sent to FDA	4?	12. Location Where Even				
Yes	hanad	Hospital	Outpatient Diagnostic Facility			
∏ No (mm/aa	7777)	☐ Home	☐ Ambulatory			
13. Report Sent to Mar	ufacturer	Nursing Home Outpatient Treatme	Surgical Facility			
Yes	A	Facility	ent.			
No (mm/dd/yyyy) Other:			(Specify)			
l □			(Зреспу)			
	e/Address					
14. Manufacturer Name	e/Address					
	e/Address					
	e/Address					
	e/Address					
14. Manufacturer Name						
14. Manufacturer Name	CTUREI	२इ	La Phane Number			
14. Manufacturer Name G. ALL MANUFA 1. Contact Office (and	CTUREI	२इ	2. Phone Number			
14. Manufacturer Name	CTURE Manufact	२इ	310-768-0700			
14. Manufacturer Name G. ALL MANUFA 1. Contact Office (and Name	CTURE Manufact	२इ	⊣ I			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address	CTURE Manufact	२इ	310-768-0700 3. Report Source			
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G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC.	CTURE! Manufacto	RS uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA	CTURE! Manufacto	RS uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST	CTURE Manufacti CZ CREET A 9006	RS uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST. LOS ANGELES, CA. Email Address STANDARD@HYLAND 4. Date Received by	CTURE Manufacto ICZ TREET A 9006	RS uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST STLOS ANGELES, CAEMAI Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d)	CTURE Manufacto CCZ CREET A 9006 DS.COM d/yyyy)	RS uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d) 07/28/20	CTUREI Manufacto CCZ CREET A 9006 DS.COM d/yyyy)	RS uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST STLOS ANGELES, CAEMAI Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d)	CTUREI Manufacto CCZ CREET A 9006 DS.COM d/yyyy)	TS uring Site for Devices) 1 5. (A)NDA # IND #	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d) 07/28/20	CTUREI Manufacto CCZ CREET A 9006 DS.COM d/yyyy)	1 5. (A)NDA #	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor			
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G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST STLOS ANGELES, CAEMAI Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 07/28/20 6. If IND, Give Protocol 7. Type of Report (Check all that apply) 5-day 30-dae	CTURE Manufacto CCZ CREET A 9006 DS.COM d/yyyy) D15	1 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST STLOS ANGELES, CAE Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d	CTURE Manufacto CCZ CREET A 9006 DS.COM d/yyyy) D15	5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes Pre-1938 Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST STLOS ANGELES, CAEMAI Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d	CTURE Manufacto CCZ CREET A 9006 DS.COM d/yyyy) D15	Suring Site for Devices) 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d)	CTURE Manufacto CCZ TREET A 9006 DS.COM d/yyyy) D15	Suring Site for Devices) 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes Pre-1938 Yes OTC Product Y Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CA Email Address STANDARD@HYLAND 4. Date Received by Manufacturer (mm/d 77/28/20 6. If IND, Give Protocol 7. Type of Report (Check all that apply) 5-day 30-da 7-day Perior 10-day Initial 15-day Follow 9. Manufacturer Report	CTURE Manufacto CCZ TREET A 9006 DS.COM d/yyyy) D15 I #	5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes Pre-1938 Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:			
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEWI Address HYLAND'S, INC. 154 W. 131ST ST LOS ANGELES, CAE Email Address STANDARD@HYLANI 4. Date Received by Manufacturer (mm/d 07/28/20 6. If IND, Give Protocol 7. Type of Report (Check all that apply) 5-day Period 10-day Initial 15-day Follow	CTURE Manufacto CCZ TREET A 9006 DS.COM d/yyyy) D15 I #	Suring Site for Devices) 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(s	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:			

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:

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

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer required to respond to, as information unless it dis PRAStaff@ida.hhs.gov related 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."

cc: QA / QC Packaging

BY:

SECTION V:

REVIEWED BY MANAGEMENT BY:

Production Shipping / Receiving

Form # VD1





Adverse Event -0032-2015

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 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 Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $s_{(4)}^{(b)}$ ppm.

Conclusion:

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

Prepared by

8 3/2015

Date

CaseID: 11374329



SE EVENT DATA FORM



AE #: 162	3	COMPLAINT #: 2633
SECTION I:	PATIENT INFORMATION (IF DIFFER	ENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:		
CITY:		STATE:
COUNTRY:	USA	ZIP CODE:
PHONE #:		
E-MAIL:		
SECTION II:	PACKAGING INFORMATION:	
AFF	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE
Ĺ		(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	Tentra Tables Tentra Tables Tentra Tables Tentra Tables	Carrier Control
(S)		(Marking d.)
F		
		Schring Books Control
Ĺ		The state of the s
S.		
	Harris Harris Co.	The second of th
	Market Annual Control	ASSESSED AND ASSESSED AND ASSESSED ASSE
SECTION III:	CORRECTIVE ACTION:	
CORRECTIVE AC	TION(S) COMPLETED BY:	DATE:
		1
SECTION IV:		n I
REVIEWED BY MA	ANAGEMENT BY: (A N	DATE: 08-06-15
	Gua Bar	DATE: 08-06-15 DATE: 08-05-15
BY:	QA / QC DIRECTOR	DATE: <u>08-1/3-13</u>



The FDA Safety Information and Adverse Event Reporting Program

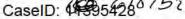
reporting of _____uct problems and product use errors

177	CaseID: 11395428
onn Approved: OM	See OMB statement on reverse;

FDAUSEONLY

Triage unit sequence #

A COLUMN	NFORMATION			2. Dose or Amo	ount	Frequen	cy Route	
	2. Age at Time of Ever	it or 3. Sex	4. Weight	#1		100		
(6)	Date of Birth:	Female	17 lb					
	(b) (6)	✓ Male	or kg	#2				
In confidence					au v base s		Samuel E Euro	nt Abatad Affarilia
ck all that apply		PROBLEM OR ER		3. Dates of Use (In (or best estimate #1 one dose	unknown, g e)	ive duration)	Stopp	nt Abated After Use ed or Dose Reduced? Yes No Doesn't
Adverse Eve		om (e.g., defects/malfuncti Different Manufacturer of	and the second second second	#2	_			Apply
Product Use		and the state of the fact	Same Medicine	4. Diagnosis or R	eason for U	se (Indication	#2	Yes No Doesn't
Check all that ap	outed to Adverse Event		1	#1 Moderate t	eething p	ain		nt Reappeared After
Death:		Disability or Permanent D	Damage	#2				Yes No Doesn't
Life-threatenin	(mm/dd/yyyy) ng	Congenital Anomaly/Birth	n Defect					Apply
Hospitalizatio	n - initial or prolonged	Other Serious (Important	Medical Events)	6, Lot #	7 #	Expiration	Date #2	Yes No Doesn't
Required Inte	rvention to Prevent Perma	anent Impairment/Damage	(Devices)	#1			9. NDC	C # or Unique ID
Date of Event (n	nm/dd/yy/yl	A Date of this Report (m	im/dd/yyyy)	#2	#:			
8/14/2015	X .	08/15/2015		E. SUSPECT	MEDICA	L DEVICE		
Describe Event,	Problem or Product Us	e Error		1. Brand Name				
								COR COMP IV
				2. Common Device	e Name			CTU
							i	Min = = =
ee addit	ional page(s) for comple	te text.	3. Manufacturer N	lame, City a	ind State		AUG 1 7 2015
	200000000000000000000000000000000000000		-					
				4. Model#		Lot#		5. Operator of Device
								Health Professional
				Catalog #		Expiration	Date (mm/dd/yyy	y) Lay User/Patient
								☐ Other
Relevant Tests/	Laboratory Data, Includ	ing Dates		Serial #		Other#		- Conten
320161-0116-15-15-15-1				Serial #		Other w		
							Te ve	
				6. If Implanted, G	ive Date (mi	m/da/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
						that was Re	processed and I	Reused on a Patient?
				Yes No			- 5702	
				9. If Yes to Item No	. 8, Enter Na	ame and Add	ress of Reprocess	or
Other Relevant	History, Including Preex	sting Medical Condition	is (e.g.,					
allergies, race, p	regnancy, smoking and a	lcohol use, liver/kidney pro	noiems, etc.)	E OTHER (C	ONCOM	TANIEL ME	DICAL DROP	UCTS
				F. OTHER (C				
ee addit	ional page(s) for comple	te text.	Trouve names a	apy	lavein	valing it of cy	
				See addit	ional	page (s) for co	mplete text.
					5-	25-9		
				G. REPORTER		nfidential	ity section on	back)
PRODUCT	AVAILABILITY			1. Name and Add (b) (6)	ress			The state of the s
	for Evaluation? (Do not	send product to FDA)						DS
Yes No	Returned to Manu	facturer on:						110 4 7
		(mm/	(dd/yyyy)					UG 17
	PRODUCT(S)	dual Ishall		Phone #			E-mail	
Name teeth	, Manufacturer (from pro	duct (apel)		(b) (6)	10		(b) (6)	
Strength hyle	and's teething ta	blets		Sanda Sanda Sanda				
Manufacturer,	nyland's			2. Health Profess		ccupation		4. Also Reported to:
2 A Calaman				Yes No	,			Manufacturer
2 Name: Strength:				5. If you do NOT w			7	User Facility





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 vomitting)

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: 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

DSS AUG 17 2015



the the salety miormation and

Adverse Event Reporting Program

er Report

☐ Distributor/Importer

0910-0291 Exertes: 12/31/2011 See OMB statement on reverse.

reporting of t problems and product use errors

FDA USE ONLY Triage unit sequence #

A. PATIENT I	VFORMATION			2. Dose or A	to the second second	Frequency	Route	- V
	2. Age at Time of Eve Date of Birth:		4. Weight	#1 2 pill	S	At bedtin	Taken b	y mouth
mail:	7 Months (b) (6)	✓ Female	or	#2				
In confidence	EVENT PROBLE	Male Male	кд	2 Detro of W	e (If unknown, a	itto elimpiant for	m/to 5 Euro	Abated After Use
heck all that apply:		T PROBLEM OR E	RRUR	(or best esti-			Stopper	or Dose Reduced?
Adverse Ever		lem (e.g., defects/malfund	And the second second	#1 08/10/20	115 - 08/15	7.2013	#1 🗸	Apply
Outcomes Attrib	outed to Adverse Even	Different Manufacturer	or same medicine		or Reason for U	se (Indication)	#2 🔲	Apply
(Check all that ap		Disability or Permanen	District	#1 Teethin sleeple	g pain, fuss ssness	iness, and		t Reappeared After roduction?
	(mm/dd/yyyy)	Congenital Anomaly/Bi	7 3 1,12	#2			#1 🗸	res No Doesn'
☐ Life-threatenin ☐ Hospitalization	7	Other Serious (Importa		6, Lot#	7	Expiration Dat	e #2 []	res No Doesn'
		nanent Impairment/Dama		#1 B31914	#			# or Unique ID
Date of Event (m	Transfer of the second	4. Date of this Report (mm/dd/yyyy)	#2	CT MEDICA		54973	-3197-1
08/13/2015	Problem or Product U	08/21/2015		1. Brand Nam	CT MEDICA	L DEVICE		
. Describe Event,	Problem of Product o	Se Elloi						
				2. Common D	evice Name			CT:
								Ciu
See addit	ional page(s) for comple	ete text.	3, Manufactur	er Name, City a	nd State	AUG	2 4 2015
							075	~ 2 2010
				4. Model #		Lot#	*	5. Operator of Device
								Health Professiona
				Catalog #		Expiration Da	te (mm/dd/yyyy)	Lay User/Patient
						-		Other:
Relevant Tests/I	Laboratory Data, Inclu	ding Dates		Serial#		Other #		
See addit	ional page (s) for comple	ete text.	6. If Implanted	d, Give Date (mr	n/dd/yyyy) 7.	If Explanted, G	Sive Date (mm/dd/yyyy)
						that was Repro	cessed and Re	eused on a Patient?
				9. If Yes to Item	J No n No. 8, Enter Na	me and Address	of Reprocessor	-
Other Relevant I	History, Including Pres	existing Medical Condition	ons (e.a.	F A 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2				
allergies, race, pr	regnancy, smoking and	alcohol use, liver/kidney p	roblems, etc.)		(0.0)			loro.
					(CONCOMIT	THE RESERVE AND DESCRIPTION OF THE PERSON NAMED IN		
See addit	ional page(s) for comple	ete text.					
				See add	itional	page(s)	for con	mplete text.
				G. REPOR	TER (See co	nfidentiality	section on b	ack)
. PRODUCT	AVAILABILITY			1. Name and A				
	for Evaluation? (Do no	nt send product to FDA)		-				DSS
☑ Yes ☐ No	Returned to Man	ufacturer on:	n/dd/yyyy)					6 2 4 2
. SUSPECT	THE REAL PROPERTY.		- un	Dhe #		15	and II	124 (
	Manufacturer (from proting Ta			(b) (6)			-mail (6)	
Strength:		200,00		2. Health Prof	focelonal2 2 O	ccupation		Alea Panertad to
Manufacturer: F	iyland's Baby	1- 1-1		2. Health Prof		copation	4	Also Reported to: Manufacturer
Strength:				5. If you do NO	OT want your ide			User Facility
Manufacturer:				to the manu	facturer, place a	n "X" in this box	: 1	Distributor/Importer

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



11415807-01-00-02

We used Hyland's nighttime teething tablets on my 7 month old daughter starting 8/9/2015. 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 (b)(6) my daughter got much worse and was having torso and head spasms. I have a video of her having an episode in her highchair where her head and torso collapsed onto the tray and bobbed there. I drove her to Children's Hospital in $^{(b)}(6)$ 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 they ran an MRI which came back normal and did an EEG that afternoon. The neurologist filmed my video from (b)(6) 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 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 (b)(6) -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.

DSS AUG 24 2015



The FDA Safety Information and Adverse Event Reporting Program

umer Report ty reporting of ,uct problems and product use errors

CaseID: 11419862 pproved: QMB No. 0910-0291, Expires: 12/31/2011

-0.7	See OMB statement on reverse	
	FDA USE ONLY	
iage unit equence #		

A PATIENT	INFORMATION				2.	De	se or Amount		requen	cv R	oute		
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to the manufacturer, place an "X" in this box:

Distributor/Importer



After taking Hylands teething tablets my 8 month old was extremely agitated and had involuntary twitching of her legs and abdomin. 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

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)



FORM FDA 3500 (1/09)

umer Report

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

Y reporting of uct problems and product use errors

	FDA USE ONLY	
riage unit equence #		
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Adverse Event R		li alli		2 Dose or Amount	Fréque	LO 136		
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Life-threatening		Congenital Anomaly		70.00	1= = 1 = 1	#2 [Yes No	Apply
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08/21/2015 5. Describe Event, P	roblem or Produc	09/03/2015 t Use Error		E. SUSPECT MI 1. Brand Name	EDICAL DEVIC			
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See additi	onal page	(s) for comp	lete text.	3. Manufacturer Nam	e, City and State	SEP -	4 2015	
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D. SUSPECT PR	RODUCT(S)		mm/dd/yyyy)	City:		State	ZIP	SEP -4
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Manufacturer: Hy Name:				2. Health Professions	3. Occupation		4. Also Repo	acturer
Strength: Manufacturer:				5. If you do NOT want to the manufacturer,	your identity disclos , place an "X" in this		User F	acility utor/importer

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 vet 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

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

RX Meds: none

OTC Meds: currently-none, previously used Tylenol-prn

DSS SEP - **4** 2015



user-facilities, ors and manufacturers FORY reporting

Form App@egget No: 09100497, Bone 3/30/201 See OMB statement on reverse

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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:

H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event Death Serious Injury Malfunction Correction Additional Information Response to FDA Reque Device Evaluated by Manufacturer Not Returned to Manufacturer 4. Device Manufacture Date (mm/yyyy)
Death Serious Injury Malfunction Malfunction Device Evaluated by Manufacturer? Not Returned to Manufacturer Correction Response to FDA Reque Device Evaluation 4. Device Manufacture Date (mm/yyyy)
Device Evaluated by Manufacturer? Not Returned to Manufacturer 4. Device Manufacture Date (mm/yyyy)
Yes Evaluation Summary Attached No (Attach page to explain why not) or provide code: 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 Reuse Unknown 9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
10. Additional Manufacturer Narrative and / or 11. Corrected Dat
DSS SEP - 8 2015 SEP - 4 201
Department of Health and Human Services OMB Statement: "An agency may n

CaseID: 11473233

Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff

conduct or sponsor, and a person is not required to respond to, a collection of Paperwork Reduction Act (PRA) Staff information unless it displays a currently PRAStaff@fda.hhs.gov valid OMB control number."

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

1.1.2	473233-01-00-03	COMPLAINT #: 2639	
7.15	110200 01 00 00	DATE OF COMPLAINT: 08/17/2015	-181
PRODUCT:	BABY TEETHING TABLETS	ITEM CODE: BTET	
SIZE:	N/A (b) (6)	LOT NO.: N/A	
REPORTER:	100		
ADDRESS:	N/A		
CITY:	N/A	3636-2 197	
COUNTRY:	N/A USA	STATE: N/A	
PHONE #:	N/A	ZIP CODE: N/A	
E-MAIL:	(b) (6)	4 (1-41)	
NATURE OF COM	MPLAINT	194	
JSES. WHEN I W	EST SONNOW HAS SEIZURES WITHOUT WARNING /ENT BACK 2 WEEKS LATER. THEY TOLD US AN INC ARE YOU STILL SELLING THIS PRODUCT? YOU SH	D TO HYLAND'S E-MAIL: MY SONS HAVE BEEN USING THESE BHE HAS BEEN TO SEVERAL DOCTORS AND ASKED US TO NO GREDIANT YOU USE CAN CAUSE SEIZURES EVENTUALLY LE HOULD INFORM THE PUBLIC OF ITS RISK, I KNOW I AM	ALIC EVEDVELING LE
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PRODUCT RECE INSPECTION:	VED FOR Y (CIRCLE ONE)	PRODUCT BEING RETURNED FOR INSPECTION: DATE REQUESTED PRODUCT BE RETURNED:	(CIRCLE ONE)
		UPS CALL TAG ISSUED:	Y (CIRCLE ONE)
		CONTRACTOR OF MANAGEMENT	
		DATE PRODUCT RECEIVED:	
SECTION II:	INVESTIGATION PLEASE SEE ATTACHED INSPECTION R		
NVESTIGATION,	PLEASE SEE ATTACHED INSPECTION R	REPORT.	
NVESTIGATION;	PLEASE SEE ATTACHED INSPECTION R	ALUATION ON: 08/17/2015	
NVESTIGATION;	PLEASE SEE ATTACHED INSPECTION R	ALUATION ON:	
NVESTIGATION, ADVERSE EVENT ADVERSE EVENT SECTION III:	PLEASE SEE ATTACHED INSPECTION R FORWARDED TO PHARMACIST / NURSE FOR EVA	ALUATION ON: 08/17/2015	
NVESTIGATION, ADVERSE EVENT ADVERSE EVENT SECTION III:	PLEASE SEE ATTACHED INSPECTION R FORWARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION:	ALUATION ON: OB/17/2015 EDYTA FRACKIEWICZ	
ADVERSE EVENT SECTION III: CORRECTIVE AC SECTION IV:	PLEASE SEE ATTACHED INSPECTION R FORWARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: TION(S) COMPLETED BY: ADVERSE EVENT REPORTS	ALUATION ON: OB/17/2015 EDYTA FRACKIEWICZ DATE:	SEP
ADVERSE EVENT ADVERSE EVENT SECTION IV: ADVERSE EVENT ADVERSE EVENT ADVERSE EVENT ADVERSE EVENT	PLEASE SEE ATTACHED INSPECTION R FORWARDED TO PHARMACIST / NURSE FOR EVA CORRECTIVE ACTION: TION(S) COMPLETED BY: ADVERSE EVENT REPORTS SERIOUS: Y N	ALUATION ON: ALUATION BY: DATE: AE #: 1629 BY: EDYTA FRACKIEWICZ	SEP

cc: QA / QC Packaging

Production Shipping / Receiving



SEP - 8 2015





Adverse Event

SAE-0038-2015

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 ≤(4) ppm.

Conclusion:

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

8/24/2015

Date



SEP = 4 2015

CaseID: 11473233



EVENT DATA FORM

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	Vaple	Hapleneral's

	AE #: 16	29	COMPLAINT #: 2639
- Te	SECTION I:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)
	NAME:	(b) (6)	
	ADDRESS:	-	
	CITY:		STATE:
	COUNTRY:		ZIP CODE:
	PHONE #:	-	
	E-MAIL:	(b) (6)	
	SECTION II:	PACKAGING INFORMATION:	
	A	AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE
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-	SECTION III:	CORRECTIVE ACTION:	
	-		
	-		
	CORRECTIVE	ACTION(S) COMPLETED BY:	DATE:
DSS	SECTION IV:		Jell + DATE: 08-25-15
		MANAGEMENT BY:	1011
JEF - 6 20		1 12	V
	BY:	QA/QC DIRECTOR	DATE: 08-25-15



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6				FDA Use Only
C. SUSPECT P				
	d strength & mfr/labeler BABY NIGHTTIME		G TABLE	TS
		3-0-0-0-0	100 200	
#2 N/A	n Danie Hand	la Thorn	ov Dator //	funknown, give duration)
. Dose, Frequency		from/t	o (or best es	stimate)
#12 TABS QHS	X 1 WEEK	#1		
#2 N/A		#2		
Diagnosis for Use				Abated After Use od or Dose Reduced?
#1 TEMP RELIE	F NITE TEETHIN	G PAIN	#1 🗸 Y	es No Doesn'
#2 N/A				- Doesn'
Lot#	7. Exp. Date		#2 \Y	— — Арріу
#1B31914	#1			Reappeared After oduction?
#2N/A	#2		#1 🗸 Y	es No Doesn'
NDC# or Unique	D			Doesn's
54973-3197-	1 idical Products and Th	-	#2 \Y	— Дрву
D. SUSPECT N	EDICAL DEVICE		- 1	ontinue on page 3)
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. Common Device	Name		20.1	10000
3. Manufacturer Na	me, City and State			
I. Model#	Lot#			5. Operator of Device
Catalog #	Expiratio	n Date (mn	n/dd/yyyy)	Lay User/Patient
Serial #	Unique la	lentifier (U	DI) #	Other:
6. If implanted, Give	e Date (mm/dd/yyyy)	7. If Exp	planted, Giv	re Date (mm/dd/yyyy)
I. Is this a Single-u	so Device that was Re	processed	and Reuse	d on a Patient?
Yes	No			
				SEP 1 0 201
	e for Evaluation 7 (Do n			
		D. D. L.	- /Fueludo	(mm/dd/yyyy)
1. Concomitant Mi	edical Products and Th	terapy Date	S (EXLIDE	treatment of eventy
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Towns of the Paris	nal? 3. Occupation			Initial Reporter Also Sen Report to FDA
Yes I/N	o INA			/ Yes No Unk

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



2 of 6

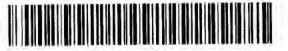
FDA USE ONLY

F. FOR USE BY U	ISER FA	CILITY/IMPO	RTER (D	evices Only)	H. DE	VICE MAN	NUFA	CTURERS	ONLY			
I. Check One				eport Number	1. Type	of Reportabl	le Ever	nt		2. If Follow-u	p, What Type?	
User Facility	Impo		-	l		Death				Corre	ection	
3. User Facility or Impo						Serious Injury	v			Addit	ional Information	
. Cast Facility of Hillpo	va	r.uuruu			1 =	Malfunction	,				onse to FDA Request	, 1
				waijunction								
				l						Liberio	ce Evaluation	
					3. Devic	e Evaluated	by Ma	nufacturer?		4. Device Ma	nufacture Date	╛
					1 _	Not Returned	-			(mm/yyyy)		- 1
			[_			Hackad			- 1
. Contact Person			5. Phone N	umber				on Summary A		5 Labeled fo	z Cingle Han?	4
						No (Attach pa provide code		explain why no	t) or	5. Labeled to	r Single Use?	
B. Date User Facility or	. 7	7. Type of Repor	rt	8. Date of This Report (mm/dd/yyyy)		provide code	.			Yes	☐ No	
Importer Became Aware of Event (mm/	/dd/yyyy)	Initial		(IIIIII GG YYYY)								
	1	_			6. Event	Problem an	nd Eval	luation Codes	(Refer to co	oding manual)		
		Follow-up #			1	Patie	ient [7_ [
3. Approximate Age of Device	10. Event P	roblem Codes (Refer to codi	ng manual)	1	Çod	ie _		」 ¯ <u> </u>			
	Patient					Devi			-	-		
	Code		· L			Code	ie [
	Device		-	_		Meth	nod	-		-	-	
	Code L					5	L					
11. Report Sent to FDA	?	12. Location W	here Event			Resu	ults	_		-	-	
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No (mm/dd/)	YYYY)	Home			1	Conclusio	ons	[-]		-	-	
	ufacture?	Nursing	g Home	Ambulatory Surgical Facility	7 14 0	nodial Acti	n leiti-	tod Chark To	ne le	Usage of Devi		_
13. Report Sent to Man	uracturer/	, –	ent Treatmer	,	/. If Ref	nediai Action	titta	ited, Check Ty	Pa 6.	_		
Yes		Facility				Recall		Notification		Initial Us	se of Device	
No (mm/dd/)	yyyy)	Other:				Repair		Inspection	- 1	Reuse		
		<u> </u>		(Specify)		Replace	П	Patient Monito	ring	Unknow	n	
 Manufacturer Name 	e/Address					Relabeling	n	Modification/	9.	if action repor	ted to FDA under	
					"	•	ليبا	Adjustment		removal repor	, list correction/ ting number:	ļ
						Other:						- 1
												_
					10.	Additional M	/lanufa	cturer Narrativ	re an	nd / or 11.	. Corrected Data	۱
G. ALL MANUFA	CTURER	S										ļ
. Contact Office (and	Manufactu	ring Site for Dev	ices)	2. Phone Number								ļ
Name				310-768-0700	ŀ							ļ
EDYTA FRACKIEWI	CZ			3. Report Source								ļ
Address				(Check all that apply)	1							ļ
WEARD C THE				Foreign								
HYLAND'S, INC.	יםקקסי			Study								
154 W. 131ST ST LOS ANGELES, CA				Literature								
Jos Intonnation Ch		-		Consumer								
Email Address				Health Professional								
TANDARD@HYLAND	S,COM											
I. Date Received by		5.		User Facility								
Manufacturer (mm/de	d/yyyy)	(A)NDA#		Company								
08/21/1	.5	1815.4		Representative Distributor								
. If IND. Give Protocol	#	IND#		(-								
,,		BLA#		Other:								
		PMA/										
. Type of Report		510(k) #										
(Check all that apply)		Combination										
5-day 30-day	-	Product	Yes							^-		
7-day Period	dic	Pre-1938	Yes							55	Y 1 0 2015	- 1
10-day 🗸 Initial		OTC Product	✓ Yes								- A	
15-day Follow	v-up #	1.5	¥ 103								65	16
. Manufacturer Report	t Number	8. Adverse Ev	rent Term(s)								1	'n
54973 AE # 163	80	SEIZURES									\vee \wedge	
54973 AE # 163	, ,										\Q \ \	-
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					Decedes	- t of Up alth a	and U	Condess		OMB Statemen	4- EA	

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@ida.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."

PRAStaffigida.hhs.gov. valid QMB control numb
Please DO NOT RETURN this form to the above PRA Staff email address.



MIPLAIN I RECUR



2.13	300132	01-00-03				OMPLAINT #:	2640	
	778355	Dr. 2005.			DATE OF	COMPLAINT:	08/21/2015	
PRODUCT:		BABY NIGHTTI	ME TEETHING TABLE	TS		ITEM CODE:	BTNT—T135	
SIZE:		135 TABS				LOT NO.:	B31914	
REPORTER:	(b) (6)							
DDRESS:								
ITY-					STAT	E: (b) (6)		
OUNTRY:	USA				ZIP COI	DE		
IONE #:	(0) (6)							
MAIL:	N/A							
ATURE OF CO								
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	EIVED FOR		(CIRCLE ONE)		DATE REQUESTE		E RETURNED:	Y (CIRCLE ONE)
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ISPECTION:	EIVED FOR		(CIRCLE ONE)				TAG ISSUED:	y (N)
	INV		(CIRCLE ONE)			UPS CALL	TAG ISSUED:	y (N)
NSPECTION:	<u>INV</u>	ESTIGATION		/ALUATION ON		UPS CALL	TAG ISSUED:	y (N)
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@aseID: 11500192

F/U POSTED TO (b) (6)

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 teething tablets we had just started giving her, caused the saizures. He called them seizures but said they weren't epileptic, that they were likely triggered by the magnesium and/or beliadonna 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 than 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 these 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

F/U FROM PHONE CALL WITH (b) (6) 08/26/15

(b) (6) called me today insisting to speak with the legal department. She stated that she gave you a report last week about her child having seizures from the nighttime teething 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 morns 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 beliadonna. 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 napping 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

Individual Case Safety Report

11500192-01-00-04

SEP 1 0 2015

055 1788

Individual Case Salety Report

11500192-01-00-05



Je 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 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 with in specification of $\leq_{43}^{(6)}$ ppm.

Retention Samples:

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

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

Other investigations:

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

Date

8/25/2015

SEP 1 0 2015

Prepared by

CaseID: 11500192



DATA FORM



AE #:16	30	COMPLAINT #: 2640
SECTION I:	PATIENT INFORMATION (IF DIFFER	ENT FROM REPORTER ON FORM VD1)
NAME:	(b) (5)	
ADDRESS:		
21.C.E.		
CITY:	\	STATE:
COUNTRY: PHONE #:		ZIP CODE:
E-MAIL:		
SECTION II:	PACKAGING INFORMATION:	
	AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	7. Part 1. (1.)	reething Tablets
		Mylands (Hylands), Mylands
	I languar	College Colleg
		Tablets Tab
	The second secon	The state of the s
SECTION III:	CORRECTIVE ACTION:	
CORRECTIVE /	ACTION(S) COMPLETED BY:	DATE:
SECTION IV:	O_{I}	SED LO PORE -
REVIEWED BY	MANAGEMENT BY:	DATE: DATE: DATE:
BY:	QUI BOUND	DATE: 08-28-15



Adverse Event Reporting Program

umer Report OZA

Form Approved: QMB to .0916-0291, Expires: 12/31/2011 See QMB statement on reverse

	XY reportin	g of
	luct probler	ns and
produc	t use errors	11

Tri

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORM Patient Identifier 2. Age a				Dose or Amount	Frequency	100	
	Time of Event or	3. Sex	4. Weight	#1 2-3	As needer	d Taken b	y mauth
15 Mo	1000	☐ Female		#2			
(b) (6)		✓ Male	orkg				
B. ADVERSE EVENT,	PRODUCT PR	OBLEM OR E	RROR	3. Dates of Use (If unk (or best estimate)	nown, give duration) fro		t Abated After Use d or Dose Reduced?
neck all that apply:	reduct Problem /s	a defectalment in	otions)	#1 09/04/2015 -	09/10/2015	200	res No Doesn't
Adverse Event Froduct Use Error F	roduct Problem (e. Problem with Differe			#2		#2 🗔	Apply (es No Doesn't
Outcomes Attributed to A	dverse Event			4. Diagnosis or Reason	on for Use (Indication)		Apply t Reappeared After
(Check all that apply) Death:	Disa	bility or Permanent	Damage	#1 Teething		Reint	roduction?
(mm/dd/yy	yy)	genital Anomaly/Bit	5 75 75	#2		#1 📋	res No Doesn't
Hospitalization - initial or				6. Lot#	7. Expiration Da	te #2 🗌	res No Doesn't
Required Intervention to		the same of the sa	and the second s	#1 B00215	#1	9. NDC	# or Unique ID
. Date of Event (mm/dd/yyyy		te of this Report (mm/dd/yyyy)	#2	#2		
09/10/2015		14/2015		E. SUSPECT ME	EDICAL DEVICE		
Describe Event, Problem	or Product Use Erro	or.		1. Diana name			
				2. Common Device No	ame		10000
				Section Delive III	2,12		CTU
See additional	page(s) f	or comple	ete text	3. Manufacturer Name	e. City and State		mra a
oc gadicional	Trade (2) T	or compac	ere conti		4.600000		SEP 1 5 201
				4. Model #	Lot#		5. Operator of Device
							Health Professional
				Catalog #	Expiration Da	te (mm/dd/yyyy,	Lay User/Patient
	ALL OF THE WAY			1			Other:
. Relevant Tests/Laborator	/ Data, including Da	ALES.		Serial #	Other#		
						West to the second	
				6. If Implanted, Give I	Date (mm/dd/yyyy) 7	. If Explanted, C	Give Date (mm/dd/yyyy)
				the same of the sa			eused on a Patient?
					Device that was Repr	ocessed and Re	
				Yes No	Device that was Repr Enter Name and Address	3.2	
Other Palevint History	cluding Processial	Madical Condition	ne /e c	Yes No		3.2	
Other Relevant History, In allergies, race, pregnancy,	cluding Preexisting smoking and alcohol	Medical Condition	ons (e.g., roblems, etc.)	Yes No	Enter Name and Address	s of Reprocesso	
Other Relevant History, In allergies, race, pregnancy,	cluding Preexisting smoking and alcohol	Medical Conditions of the Medical Condition use, liver/kidney p.	ons (e.g., roblems, etc.)	Yes No 9. If Yes to Item No. 8, I	Enter Name and Address COMITANT) MED	s of Reprocesso	JCTS
allergies, race, pregnancy,	smoking and alcohol	use, liver/kidney p	roblems, etc.)	Yes No 9. If Yes to Item No. 8, I	Enter Name and Address	s of Reprocesso	JCTS
allergies, race, pregnancy,	smoking and alcohol	use, liver/kidney p	roblems, etc.)	Yes No 9. If Yes to Item No. 8, I	Enter Name and Address COMITANT) MED	s of Reprocesso	JCTS
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On $^{(b)(6)}$ 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)

DSS SEP 15 2016



iser-facilities, ors and manufacturers ORY reporting

Form ApproCase	Lae dMBQaleQQQUeverse.
Mfr Report # 54973	
UF/Importer Report #	10

rage 1 of 5

FUKM	FUA	3500A	(2/13)

Patient Identifier	2. Age at Time	3. Sex 4. Weigh
b) (6)	of Event: CHIL	D Female
	or	or or
In confidence	of Birth:	Male
B. ADVERSE E	VENT OR PROD	UCT PROBLEM
✓ Adverse Eve	ent and/or P	Product Problem (e.g., defects/malfunctions)
Outcomes Attrib	uted to Adverse Event	
Death:	F-77	Disability or Permanent Damage
	(mm/dd/yyyy)	Congenital Anomaly/Birth Defect
Life-threaten	on - initial or prolonged	Other Serious (Important Medical Ev
		rmanent Impairment/Damage (Devices)
Date of Event (n		4. Date of This Report (mm/dd/yyyy)
00,	/00/0000	09/03/15
Describe Event	or Problem (b) (6)	CHILD HAD SEIZURES WHEN
THEY TOOK TH		
		1
	aive	be
	Receive SEP 152	
		OAE
	CEP 152	CIU
	OLI -	
	CDF	2
		(Continue on page
6. Relevant Tests/	Laboratory Data, Inclu	ding Dates
UNKNOWN		
		(Continue on page
	History Including Pro	existing Medical Conditions (e.g., allergies.
7 Other Relevant	amaking and alcohol u	se, hepatic/renal dysfunction, etc.)
race, pregnancy	, smoking and accorde a	
7. Other Relevant race, pregnancy UNKNOWN	, smoking and alcohor o	
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race, pregnancy	, smoking and according	
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race, pregnancy	, smoking and according	
race, pregnancy	, smoking and according	
race, pregnancy	, smoking and according	
race, pregnancy	, smoking and according	(Continue on page

	001107/0			1	FDA Use	Only
. SUSPECT PR Name (Give labeled						
#1 HYLAND'S BA			EETHIN	G TABLE	TS .	
#2 N/A						
Dose, Frequency 8	Route Used	1	3. Thera	py Dates (If	unknown, give dura	tion)
#1 UNKNOWN			#1	o (or best es	imale)	
#2 N/A			#2			- 4
Diagnosis for Use			7.71		bated After Use d or Dose Reduced	?
#1 TEMP RELIEF	F NITE TH	EETHING	PAIN	#1 \(\text{Y}\)	E DNO DD	esn't
#2 N/A	7 Ex	o. Date	_	#2 🗌 Ye		esn't
#1N/A	#1				Reappeared After	
					duction?	oesn't
#2N/A NDC# or Unique II	#2		-	#1 \ Ye		ply
54973-3197-1				#2 \ Y		pesn't
D. SUSPECT M	EDICAL D	EVICE		(C	ontinue on page	3)
Brand Name Common Device N	Nome			2h P	rocode	
2. Common Device i	vame					
3. Manufacturer Nan 4. Model#	ne, City and	Lot #			5. Operator of Dev	ice
4. Model#		2011			Health Profess	
Catalog #		Expiration	Date (mn	r/dd/yyyy)	Lay User/Patie	ent
Serial #		Unique Ide	entifier (U	DI) #	Other:	
6. If Implanted, Give	Date (mm/de	d/yyyy)	7. If Exp	olanted, Giv	e Date (mm/dd/yyy))
8. Is this a Single-us		at was Rep	rocessed	and Reuse	d on a Patient?	
9. If Yes to Item No.		ne and Add	ress of R	eprocesso	3	
					Ds	'c
10. Device Available			t send to	FDA)	SEP 16	()
	lo R	make some or of the B	Annufact.	ror on:	OLP P	
U U			/lanufactur		(mm/dd/yyyy)	20
11. Concomitant Me				es (Exclude	(mm/dd/yyyy) treatment of event)	20
11. Concomitant Me	edical Produc			es (Exclude	(mm/dd/yyyy)	20
U U	edical Produc			es (Exclude	(mm/dd/yyyy) treatment of event)	20
11. Concomitant Me E. INITIAL REF 1. Name and Addre	edical Produc	cts and The		es (Exclude	(mm/dd/yyyy) treatment of event)	20
11. Concomitant Me E. INITIAL REF 1. Name and Addre (b) (6)	PORTER	cts and The	erapy Dat	es (Exclude	(mm/dd/yyyy) treatment of event)	3)

11		

1. Check One			2 UF/Impo	rter Repo	rt Number	
User Facility	☐ Imp	oorter				
3. User Facility or Im	porter Nam	e/Address				
4. Contact Person			5. Pho	one Numb	er	
Date User Facility Importer Became Aware of Event (m)		7. Type of F			Date of Th mm/dd/yy	
9. Approximate Age of Device	10. Event	Problem Co	des (Refer to	coding m	anual)	
Age of Device	Patient Code		-]-[
	Device Code		1-		7-	
11. Report Sent to FI		12. Locati	ion Where E	vent Occi	ırred	
13. Report Sent to Ma	ld/yyyy) anufacturer	7 0	ospital ome ursing Home utpatient Tre acility		Ambula	stic Facility
□ No (minut	w, 3, 3, 3, 3		ther:	15	Specify)	
G. ALL MANUF	Company of the last			To 1	Dh M	
Contact Office (an Name	d Manufacti	uring Site for	Devices)		Phone Nu 0-768-0	
EDYTA FRACKIEW	NICZ				Report So	
Address HYLAND'S, INC. 154 W. 131ST & LOS ANGELES, (STREET	1			(Check all Foreign Study Literature Consume	that apply)
Email Address	Mar Later					ofessional
STANDARD@HYLAN 4. Date Received by Manufacturer (mm. 08/31) 6. If IND, Give Protoc	/dd/yyyy) /15	5. (A)NDA # IND # BLA #	¥ 		User Fac Company Represer Distribute Other:	ntative
☐ 10-day 📝 Initia	day odic	510(k) # Combina Product Pre-1938 OTC Pro	ation Y	es —		
9. Manufacturer Repo		8. Advers	se Event Ter ES	m(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 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

CaseID:	1151	6350
EDALISE ON	V	

of 5

DEVICE MANUFACTURERS ONLY Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
Device Evaluated by Manufacturer?	Device Manufacture Date (mm/yyyy)
Not Returned to Manufacturer	
Yes Evaluation Summary Attached	E Labeled for Circle Hard
No (Attach page to explain why not) or provide code:	5. Labeled for Single Use?
	Yes No
Event Problem and Evaluation Codes (Refer to	coding manual)
Patient _	-
Code	
Code	-
Method -	
Results	
Conclusions	-
f Remedial Action Initiated, Check Type	. Usage of Device
Recall Notification	Initial Use of Device
Repair Inspection	Reuse
Replace Patient Monitoring	Unknown
Relabeling Modification/	
Trefabeling Modification	If action reported to FDA under
Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Adjustment Other:	21 USC 360i(f), list correction/ removal reporting number:
Adjustment Other:	21 USC 360i(f), list correction/ removal reporting number:

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

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.

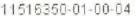
	44546350 04 00 02	COMPLAINT#: 2647
TAKEN BY:	11516350-01-00-03 EDYTA FRACKIEWICZ	DATE OF COMPLAINT: 08/31/2015
PRODUCT:	HYLAND'S BABY NIGHTTIME TEETHING TABLETS	ITEM CODE: BTNTT135
SIZE:	135 TABS	LOT NO.: N/A
REPORTER:	(b) (6)	
ADDRESS:	N/A	
	N/A	
CITY:	N/A	STATE: N/A
COUNTRY	USA	ZIP CODE: N/A
HONE #:	N/A	
-MAIL:	N/A	
NATURE OF CO		HAD SEIZURES WHEN THEY TOOK THE TEETHING TABS.
PRODUCT RECE NSPECTION:	EIVED FOR Y (CIRCLE ONE)	PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE)
		DATE REQUESTED PRODUCT BE RETURNED:
		UPS CALL TAG ISSUED: Y (CIRCLE ONE)
		DATE PRODUCT RECEIVED:
NVESTIGATION	PLEASE SEE ATTACHED INSPECTION REPORT.	
	IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON	
ECTION III:	CORRECTIVE ACTION:	
ORRECTIVE AC	CTION(S) COMPLETED BY:	DATE:
ECTION IV:	ADVERSE EVENT REPORTS	AE #:1637
VERSE EVEN	T SERIOUS:	
		BV. EDVTA EDACUISAGO?
DVERSE EVEN	T SERIOUS: Y N T REPORTED ON: 08/31/2015	BY: _EDYTA FRACKIEWICZ
DVERSE EVEN		1
DVERSE EVENT		A DATE: 09-09-15
ECTION V:	T REPORTED ON: 08/31/2015	1

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1







CaseID: 11516350

SAE-0046-2015

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 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 (4) ppm.

Conclusion:

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

Prepared by

Date

9/3/2015

DSS SEP 16 2011



E EVENT DATA FORM

Case	ID: 11516350	
W.A	TO STATE OF THE PARTY OF THE PA	

E#: 1637		COMPLAINT #: _2647
CTION I:	PATIENT INFORMATION (IF DIFF	ERENT FROM REPORTER ON FORM VD1)
ME:	UNKNOWN	
RESS:		
-		
/ :		STATE:
NTRY:	USA	ZIP CODE:
NE #: _		
AIL:		
TION II:	PACKAGING INFORMATION:	
AFFIX	PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
	. About Face	In all room to the region of the second of t
		Group Funne Eine Group and Annie Anderson Annie
	Page2	Mylands Hylands Mylands
		Exercise the contract of the c
		Charles a more stronger and production of the control of the contr
- 1	Paget3	The state of the s
TION III.	CORRECTIVE ACTION	
TION III:	CORRECTIVE ACTION:	
RECTIVE ACTION	ON(S) COMPLETED BY:	DATE:
ION IV:		De
EWED BY MAN	AGEMENT BY:	DATE: 09-09-15SEP 16
	GHIA Bor	M DATE: 09-08-15
	QA / QC DIRECTOR	DATE: UTUOTO

DISTRIBUTION: FDA

ADVERSE EVENT FILE

FORM SAE01

SFP 1 5 2015

I WINIT I DA SOUDA (EI 13)

user-facilities, ors and manufacturers FORY reporting

Form App@ase	No: 0910 059 See OMB st	6352/30/2016 atement on reverse
Mfr Report # 54973	- 1	
UF/Importer Report #	001	

, age 1 of 5

FDA Use Only

A. PATIENT IN	AND ADDRESS OF THE PARTY OF THE	23 .30	2,237.2	C. SUSPECT PR		F. AT	1	COAT	
Patient Identifier (b) (6)	2. Age at Time of Event: CHILD	3. Sex	4. Weight	1. Name (Give labeled			ומגיי בי	Em.c	
	orCHILD	Fem		#1 HYLAND'S BA	BI NIGHTIME	TEETHIN	G IABL	E15	
In confidence	Date of Birth:	✓ Male	or kgs	#2 N/A					
	VENT OR PRODUCT	PROBLEM	- Ngo	2. Dose, Frequency &	Route Used	3. Thera from/t	py Dates o (or best e	(If unknown, g estimate)	ive duration
I. ✓ Adverse Ever	NAME OF TAXABLE PARTY.	ict Problem (e.g., defects/r	malfunctions)	#1 UNKNOWN		#1		200010004	
	uted to Adverse Event	ict Problem (e.g., delects/	nanunctions)	#2 N/A		#2			
(Check all that app				4. Diagnosis for Use (Indication)			Abated After	
Death:	(mm/dd/yyyy)	Disability or Permanent	Damage	#1 TEMP RELIEF	NITE TEETHIN	G PAIN		ed or Dose R	Decer
Life-threatening	ng [Congenital Anomaly/Bit		#2 N/A			#1 [] `	Yes No	Apply
Hospitalizatio	n - initial or prolonged	Other Serious (Importar	nt Medical Events)	6. Lot #	7. Exp. Date		#2 🔲 🗎	Yes No	Doesn Apply
Required Inte	ervention to Prevent Perman	ent Impairment/Damage (D	evices)	#1N/A	#1		8. Event	Reappeared	41.8
Date of Event (mi		Date of This Report (mr		#0X1 / 7	_			roduction?	Doesn
	00/0000	09/02/1		#2N/A	#2		#1 \	Yes No	Apply
Describe Event or EPORTER POST	r Problem (b) (6)	NOTHER GAVE THE I	ABLETS TO	9. NDC# or Unique ID 54973-3197-1			#2 🔲	Yes No	Doesn Apply
	D UP IN HIS EAR, S						"	Continue on	nage 3)
			4.1	D. SUSPECT ME	DICAL DEVICE		10	Johnnue on	page 3)
			1	1. Brand Name	DICAL DEVICE				
				2.2	77.2		105.		
			- 1	2. Common Device Na	me		20. F	Procode	
			- 1	3. Manufacturer Name	, City and State				
i .		RECO	-						
		REC SEP 15		4. Model#	Lot #			5. Operator	of Device
		SED 4 -						Health	Professiona
		SEP 15	2015	Catalog #	Expiration	Date (mm)	dd/yyyy)	Lay Us	er/Patient
		-		Serial #	Unique Id	entifier (UD	1)#	Other:	
		CDR	N. Committee						
		(Continue	on page 3)	6. If Implanted, Give D	ate (mm/dd/yyyy)	7. If Exp	anted, Giv	ve Date (mm/c	ld/yyyy)
Relevant Tests/La	boratory Data, Including D			8. Is this a Single-use	Device that was Ren	rocessed a	nd Reuse	d on a Patien	t?
INKNOWN				Yes No				a on a racion	
			1	9. If Yes to Item No. 8,	Enter Name and Ad	dress of Re	processor	r	
			1	1 2 2 2 2 3					
			- 1	10. Device Available for	r Evaluation? (Do no	ot sand to El	24)		
			- 1	Yes No	Returned to !				
						via iu iuuture	OII	(mm/dd/yy	(yy)
	Salara Araba	(Continue	on page 3)	11. Concomitant Medic	al Products and The	erapy Dates	(Exclude	treatment of e	event)
Other Relevant His race, pregnancy, sr.	story, Including Preexistin moking and alcohol use, hep	g Medical Conditions (e.g. atic/renal dysfunction, etc.)	., allergies,						
NKNOWN			- 1				(C	continue on	page 3)
				E. INITIAL REPO	RTER	F 15	100	P-000	
			1	1. Name and Address (b) (6)					Da
			1		- /	711	00	7	000
						(I '	17	SE	P 16
						u	10	-	40
				Phone #	Em	ail Address			
		(Continue	on page 3)						
ibmission of a r	eport does not const	tute an admission th	at medical	2. Health Professional	3. Occupation		4.1	nitial Reporte	r Also Sent
irsonnei, user fa	acility, importer, distri	butor, manufacturer	or product	Yes No	NA		i	Report to FDA	

Yes No V Unk.



1. Check One User Facility	[] Imp	2. UF/Importe	er Report Number
3. User Facility or Imp			
4. Contact Person		5. Phon	e Number
6. Date User Facility of Importer Became Aware of Event (mr		7. Type of Report Initial Follow-up #	8. Date of This Report (mm/dd/yyyy)
9. Approximate	10. Event	Problem Codes (Refer to d	oding manual)
Age of Device	Patient Code	-	1-1
4	Device Code	-	7-
11. Report Sent to FD		12. Location Where Eve	ent Occurred
Yes(mm/do	nufacturer	Home Nursing Home Outpatient Treat Facility	Outpatient Diagnostic Facility Ambulatory Surgical Facility
No (mm/do	d/yyyy)	Other:	(Specify)
G. ALL MANUFA	ACTURE	RS	
1. Contact Office (and	d Manufact	uring Site for Devices)	2. Phone Number
Name EDYTA FRACKIEW	TCT		310-768-0700
Address	102		3. Report Source (Check all that apply)
HYLAND'S, INC. 154 W. 131ST S LOS ANGELES, C	TREET	1	Foreign Study Literature Consumer
Email Address	P. P. S. S.		Health Professional
STANDARDOHYLAN	DS.COM	I s	User Facility
4. Date Received by Manufacturer (mm/		5. (A)NDA #	Company Representative
08/27/		IND#	Distributor
6. If IND, Give Protoc	ol#	BLA#	Other:
10-day Initia	lay odic	510(k) # Combination Product Ye Pre-1938 Ye OTC Product Y Ye	s
9. Manufacturer Repo		8. Adverse Event Term HIGH FEVER, VOI	

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:

		-
-	- 6	-
1	OT.	-

_	
DEVICE MANUFACTURERS ONLY	
pe of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
rice Evaluated by Manufacturer?	Device Manufacture Date (mm/yyyy)
Not Returned to Manufacturer	1
Yes Evaluation Summary Attached	5 1 1 1 1 1 6 6 1 1 11 2
No (Attach page to explain why not) or provide code:	5. Labeled for Single Use?
	Yes No
ent Problem and Evaluation Codes (Refer to	coding manual)
Patient	
Code	
Device Code	-
ton a l	
Method	
Results -	-
Conclusions	
	0. Neare of Decider
emedial Action Initiated, Check Type	Usage of Device Initial Use of Device
Recall Notification	Reuse
Repair Inspection	Unknown
Replace Patient Monitoring Relabeling Modification/	9. If action reported to FDA under
Relabeling Modification/ Adjustment	21 USC 360i(f), list correction/ removal reporting number;
Other:	
Additional Manufacturer Narrative	and / or 11. Corrected Data
	Da
	DS
	SED 1 0
	SEP 16
	SEP 1 5 2015

CaseID: 11516352

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

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.

		COMPLAINT #:	2646	
TAKEN BY:	1515352-01-00-03 EDYTA FRACKIEWICZ	DATE OF COMPLAINT:	13.00 7.00 13	
PRODUCT:	HYLAND'S BABY NIGHTTIME TEETHING TABLETS	ITEM CODE	BTNTT135	
SIZE:	135 TABS	LOT NO.:	N/A	
REPORTER	(b) (6)			
ADDRESS	N/A			
	N/A			
CITY:	N/A	STATE: N/A		
COUNTRY:	USA	ZIP CODE: N/A		
PHONE #:	N/A			
E-MAIL:	N/A			
PRODUCT RECINSPECTION:	(CIRCLE ONE)	ODUCT BEING RETURNED FOR	INSPECTION:	Y (CIRCLE ONE)
		UPC CALL	TAG ISSUED:	Y (CIRCLE ONE)
		UPS CALL	TAG IGGOLD.	(OMOLE ONE)
SECTION II:	INVESTIGATION	DATE PRODUC		(ONOLE ONE)
INVESTIGATION			T RECEIVED: _	(CINCLE GNL)
	PLEASE SEE ATTACHED INSPECTION REPORT.	DATE PRODUC	T RECEIVED: _	(CINCLE CINE)
ADVERSE EVEN ADVERSE EVEN SECTION III:	PLEASE SEE ATTACHED INSPECTION REPORT. IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:	DATE PRODUC	T RECEIVED: _	(CINCLE CINE)
ADVERSE EVEN ADVERSE EVEN SECTION III:	PLEASE SEE ATTACHED INSPECTION REPORT. IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: CORRECTIVE ACTION:	DATE PRODUC	T RECEIVED: _	(CINCLE CINE)
ADVERSE EVEN ADVERSE EVEN SECTION III:	PLEASE SEE ATTACHED INSPECTION REPORT. IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: CORRECTIVE ACTION: CTION(S) COMPLETED BY: ADVERSE EVENT REPORTS	DATE PRODUC	5 RACKIEWICZ	(CINCLE CINE)
ADVERSE EVEN SECTION III: CORRECTIVE AN	PLEASE SEE ATTACHED INSPECTION REPORT. IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: CORRECTIVE ACTION: CTION(S) COMPLETED BY: ADVERSE EVENT REPORTS	DATE PRODUC	5 RACKIEWICZ 1636	
ADVERSE EVEN ADVERSE EVEN SECTION III: CORRECTIVE AI SECTION IV:	PLEASE SEE ATTACHED INSPECTION REPORT. IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: CTION(S) COMPLETED BY: ADVERSE EVENT REPORTS IT SERIOUS: Y N	DATE PRODUC 08/27/201 EDYTA F DATE: AE #:	5 RACKIEWICZ	SED.
ADVERSE EVEN SECTION IV: ADVERSE EVEN ADVERSE EVEN ADVERSE EVEN ADVERSE EVEN ADVERSE EVEN ADVERSE EVEN	PLEASE SEE ATTACHED INSPECTION REPORT. IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: CORRECTIVE ACTION: CTION(S) COMPLETED BY: ADVERSE EVENT REPORTS IT SERIOUS: Y N	DATE PRODUC 08/27/201 EDYTA F DATE: AE #:	5 RACKIEWICZ 1636	SED.

cc: QA / QC Packaging

Production Shipping / Receiving

SEP 1 5 2015





CaseID: 11516352

SAE-0045-2015

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 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 (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

3/2015

DSS SEP 16 2015



SE EVENT DATA FORM

Case	ID: 11	516352
4	1	

AE #:16	536	COMPLAINT #: 2646
SECTION I:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
DDRESS:		
	-	
ITY:	-	STATE:
OUNTRY:	USA	ZIP CODE:
HONE #:		
ECTION II:	PACKAGING INFORMATION:	
A	Pages Pa	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) Leching Tobles Leching Tob
ECTION III:	CORRECTIVE ACTION:	
DRRECTIVE A	ACTION(S) COMPLETED BY:	DATE:
CTION IV:		
VIEWED BY	MANAGEMENT BY:	DATE: 09-09-15
:	Sylic Bru	U DATE: 09-08-15
	OA / OC DIRECTOR	0,000

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01



y user-facilities, utors and manufacturers ATORY reporting

	Form Approv	asell.	. 0910-029 See OMB :	Expires: 6	/30/2
rt	# 54973				

Mfr Report # 54973		
UF/Importer Report #	00	TC
	()	EDA Hea Only

FORM FDA 3500A (2/13)	Page	1 of 5				1
A. PATIENT INFORMATION		C. SUSPECT	PRODUCT(S)	355		FDA Use C
Patient Identifier Age at Time of Event:	3. Sex 4. Weight	1. Name (Give labe	led strength & mfr/labeler)			
(D) (b) of Event:	7 Months Female Ibs	#1 HYLAND'S	BABY NIGHTTIME T	EETHING	TABLETS	
Date	Male or	#2 N/A				
In confidence of Birth:	kgs	2. Dose, Frequenc	y & Route Used	3. Therap	y Dates (If unkno	wn. give duratio
B. ADVERSE EVENT OR PR		#1 UNKNOWN			(or best estimate)	
1. Adverse Event and/or	Product Problem (e.g., defects/malfunctions)	-		-		
 Outcomes Attributed to Adverse Ex (Check all that apply) 	vent	#2 N/A 4. Diagnosis for Us	ne (Indiantian)	#2		
Death:	Disability or Permanent Damage		EF NITE TEETHING		Event Abated Stopped or Do	After Use ose Reduced?
(mm/dd/yyyy) Life-threatening	Congenital Anomaly/Birth Defect		DE MILE IEEINING	EVIII	#1 Yes	No Does
✓ Hospitalization - initial or prolong	ged Other Serious (Important Medical Events)	#2 N/A	7.5.5.		#2 Yes	No Does
Required Intervention to Prevent	Permanent Impairment/Damage (Devices)	6. Lot # #1N/A	7. Exp. Date	-		— Арріу
3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	#1197 A	#1		Event Reappe Reintroduction	n?
00/00/0000	09/02/15	#2N/A	#2		#1 Yes	No Does
5. Describe Event or Problem(b) (6) REPORTER POSTED ON	PRODUCT CAUSED THE CHILD TO	9. NDC# or Unique			#2 Yes	No Does
	HOSPITALIZED AND HAVE A NUMBER	54973-3197-	- 1 edical Products and Ther			Apply Apply
	CD 1 C 2015	D. SUSPECT N 1. Brand Name	MEDICAL DEVICE		-	
S	EP 1 5 2015	Brand Name Common Device	Name		2b. Procode	
		2.11			3557135346	
	CDR	3. Manufacturer Na	me, City and State			
		4. Model#	Lot#			ator of Device
		Catalog #	Expiration D	Date (mm/do	d/yyyy)	ealth Professiona y User/Patient
		Serial #	Unique Iden	tifier (UDI)	# Ott	her:
	(Continue on page 3)	6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Explan	nted, Give Date (r	nm/dd/yyyy)
i. Relevant Tests/Laboratory Data, Incl JNKNOWN	luding Dates	8. Is this a Single-us	se Device that was Repro	cessed and	Reused on a Pa	atient?
1			No		V V V	7.17
		9. If Yes to item No.	8, Enter Name and Addre	ess of Repr	ocessor	
		10. Device Available	for Evaluation? (Do not s	send to FDA)	D.S
		Yes N			(mm/d	4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Other Delevery III	(Continue on page 3)	11. Concomitant Me	dical Products and Thera	py Dates (Exclude treatment	of event)
	eexisting Medical Conditions (e.g., allergies, use, hepatic/renal dysfunction, etc.)					
NKNOWN		La Caracia			(Continue	on page 3)
		E. INITIAL REP		Sec.	-1.239	- unc
		 Name and Addres (b) (6) 	s			
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		1.24		u	1	< 1175
	(01)	Phone #	Email /	Address		
hmission of a most does	(Continue on page 3) constitute an admission that medical					
rsonnel, user facility, importer, used or contributed to the ever	distributor manufacturer or product	2. Health Profession Yes No	7.00		Report to	
or contributed to tile evel	III.	1 140	13.30.3		☐ Vee ☐	I NIa / I I I I I



Check One User Facility	Importer	2. UF/Import	er Report Number
3. User Facility or Im	porter Name/Addres	S	
Contact Person		5. Phon	e Number
5. Date User Facility Importer Became Aware of Event (m	m/dd/yyyy) 🔲 Init	of Report	8. Date of This Report (mm/dd/yyyy)
Approximate Age of Device	10. Event Problem Patient Code Device		coding manual)
3. Report Sent to Ma	d/yyyy)	cation Where Eve Hospital Home Nursing Home Outpatient Treatr	Outpatient Diagnostic Facility Ambulatory Surgical Facility
G. ALL MANUFA	PARTIE NO.		
Varne DYTA FRACKIEW Address YLAND'S, INC. 54 W. 131ST S OS ANGELES, C	TREET	for Devices)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature
TANDARD@HYLAN Date Received by Manufacturer (mm/c 08/29/ If IND, Give Protoco Type of Report (Check all that apply) 5-day	5. (A)NE 15 IN BL PMA 510(Comb Produ dic Pre-11	D# A# V k)# ination Yes	Consumer Health Professional User Facility Company Representative Distributor Other:
Manufacturer Repor	w-up #	1 100	

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:

Case	D:	11	151	6354
FDA US	E ONL	Y	-	

DEVICE MANUFACTURERS ONLY	
ype of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury Malfunction	Additional Information
Manufiction	Response to FDA Reque Device Evaluation
Device Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary Attached	
No (Attach page to explain why not) or provide code:	5. Labeled for Single Use?
provide code.	Yes No
vent Problem and Evaluation Codes (Refer to	coding manual)
Patient Code	-
Device	
Code	
Method -	
Results -	1-
Conclusions	
Relabeling Modification/ Adjustment Other:	9. If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number:
Additional Manufacturer Narrative	and / or 11. Corrected Date

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

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

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TAKEN BY:	11516354-01	-00-03 A FRACKIEWICZ	DATE OF COMPL	AINT#	2645 08/29/2015	
PRODUCT:	-	ND'S BABY NIGHTTIME TEETHING TAE		CODE	BTNTT135	
SIZE:	135 TA			OT NO.:		
REPORTER:	(b) (6)			50 175 179	1417	
ADDRESS:	N/A					
	N/A					
CITY:	N/A		STATE: N	V/A		
COUNTRY:	USA		ZIP CODE:	N/A		
PHONE #:	N/A					
E-MAIL:	N/A					
PRODUCT RECI NSPECTION:	EIVED FOR	Y (CIRCLE ONE)	PRODUCT BEING RETURNED DATE REQUESTED PRODUCT			Y (CIRCLE ONE)
SECTION II:	INVESTIGAT	ON			'AG ISSUED:	(CIRCLE ONE)
	INVESTIGAT	ION EE ATTACHED INSPECTION REPORT.	DATE P			
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cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 11516354

SAE-0044-2015

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 Clostridia botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\stackrel{\text{(b)}}{\leq}$ ppm.

Conclusion:

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

Prepared by

Date

-

DSS SEP 16 2011



11516	354-01-00-05	EVENT DATA FORM
AE #:16:	35	COMPLAINT #: 2645
SECTION I:	PATIENT INFORMATION (IF DIF	FFERENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:		
CITY:	22	STATE:
COUNTRY: PHONE #:	USA	ZIP CODE:
E-MAIL:	-	
SECTION II:	PACKAGING INFORMATION:	
AF	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY
	The state of the s	PANELS)
	Laby Face	Li restina Teething Tablets (Section Tablets)
		Drieg Familie Anisot september Anisot septembe
	Page2	(Mylands) (Mylands) (Calify) (Calify)
		From the control of t
	Pngs3	The contraction of the first part of the Contraction of the Contractio
		The first of the second of the
SECTION III:	CORRECTIVE ACTION:	
CORRECTIVE AC	CTION(S) COMPLETED BY:	DATE:
SECTION IV:		DSS SEP 1 6 2015
REVIEWED BY M	IANAGEMENT BY:	DATE: 09-09-15 SEP 1 6 2015
	Quia Prais	0.000
BY:	OA/OC DIRECTOR	DATE: 09-08-15

DISTRIBUTION: FDA ADVERSE EVENT FILE

SEP 1 5 2015

CaseID: 11516354



user-facilities, ors and manufacturers ORY reporting

	Form Api AS PAID . 11-5463676/30/20 See OMB statement on revers	
r	t#	

Mfr Report #		
MII Report # 54973		
UF/Importer Report #	- 1	1
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	A lan	A Uma Only

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A. PATIENT INF	ORMATION			
Patient Identifier	2. Age at Time		3. Sex	4. Weigh
(b) (6)	of Event: INF	ANT	Female	220
	or			or
In confidence	of Birth:		✓ Male	
B. ADVERSE EV	ENT OR PRO	DUCT PROBLE	M	
1 Adverse Event	and/or	Product Problem (6	a. defects/malfu	inctions)
2. Outcomes Attribut		Charles of the same of	ngi) uorosioriiaie	inotionity .
(Check all that appl)				
Death:	(mm/dd/yyyy)	Disability of	r Permanent Dar	nage
Life-threatenin		Congenita	Anomaly/Birth D	efect
Hospitalization	- initial or prolonge	d Other Seri	ous (Important M	edical Eve
Required Interv	vention to Prevent P	ermanent Impairmen	/Damage (Device	es)
3 Date of Event (mm	/dd/yyyy)	4. Date of This	Report (mm/dd/	(vvvv)
Market State of the State of State of	0/2015		08/31/15	
5. Describe Event or CHILD HAD SEI2		THE TIME US	WAS HETNE	pur
		SOLVED WHEN T		
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		and the second		
	Rec	eived		
		# F 000F		
	SEF	1 5 2015		
		CDR		
			(Continue on	page 3)
6. Relevant Tests/Lab	oratory Data, Inclu	iding Dates		, ,
UNKNOWN				
	<u> / / /</u>		(Continue on	
7. Other Relevant Hist	ory, Including Pre	existing Medical Co	Action 111111111111111111111111111111111111	
7. Other Relevant Hist race, pregnancy, sm UN KNOWN	ory, Including Pre	existing Medical Co se, hepatic/renal dysf	Action 111111111111111111111111111111111111	
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Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

	ed strength & mfr/	labeler)		
#1 HILAND'S E		IME TEETHIN	G TABLE	ETS
#2 N/A				
2. Dose, Frequency	& Route Used	3. Thera	apy Dates (If unknown, give duration
#1 UNKNOWN		from/	to (or best e	estimate)
#2 N/A		#2	_	
4. Diagnosis for Use	(Indication)	#2	5. Event	Abated After Use
#1 TEMP RELIE		THING PAIN	Stopp	ed or Dose Reduced?
#2 N/A			#1 🗸 Y	res No Apply
6. Lot#	7. Exp. D	ate	#2 🔲 Y	es No Does
#1N/A	#1			Reappeared After
#2N/A	#2			oduction?
9. NDC# or Unique II				Apply
54973-3197-	1		#2 🔲 Y	es No Doesi
D. SUSPECT M Brand Name C. Common Device N			2b. P	rocode
3. Manufacturer Nan	Again.			****
. Model#	Lot	#		5. Operator of Device
Catalog #	Exp	iration Date (mm	/dd/yyyy)	Health Professiona Lay User/Patient
	Unio	que Identifier (UC)I) #	Other:
Serial #				
	Date (mm/dd/yyy	(y) 7. If Exp	lanted, Giv	e Date (mm/dd/yyyy)
6. If Implanted, Give		,,,	V	
6. If Implanted, Give 8. Is this a Single-us 9. Yes No.	e Device that wa	as Reprocessed a	and Reuse	d on a Patient?
6. If Implanted, Give 8. Is this a Single-us 1. Yes No. 1. 9. If Yes to Item No. 1. 10. Device Available	e Device that wa o 8, Enter Name ar for Evaluation?	as Reprocessed and Address of Re	eprocessor	d on a Patient?
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1. Check One			2. UF/Importe	r Report Number
User Facility	Imi	porter		
. User Facility or Ir	mporter Nam	e/Address		
Contact Person			5. Phone	Number
Date User Facility Importer Became Aware of Event (r	200	7. Type of Initial		8. Date of This Report (mm/dd/yyyy)
Approximate	I 10 Event	Follow Co	odes (Refer to co	- I
Age of Device		Problem Co	des (Reier to co	ding manual)
	Patient Code		-	-
	Device [7 =	
	Code			
Report Sent to F	DA?	12. Locat	ion Where Ever	
Yes		. Пн	lospital	Outpatient Diagnostic Facilit
No (mm/	dd/yyyy)	Пн	lame	Ambulatory
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☐ Yes			lutpatient Treatm acility	ent
No (mm/c	dd/yyyy)	11		
□ No			ther:	(Specify)
	me/Address			
G. ALL MANUF		RS		
THE RESIDENCE	ACTURE	77	r Devices)	2. Phone Number
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This section applies only to requirements of the Paperwork Reduction Act of 1995.

54973 AE # 1634

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

CaseID	115	16357

2 of 5

I. DEVICE MANUFACTURERS ONLY	
Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
Device Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary Attached	
No (Attach page to explain why not) or	5. Labeled for Single Use?
provide code:	Yes No
Event Problem and Evaluation Codes (Refer to co	ding manual)
Patient	
Code	
Device Code	-
5540	
Method -	
Results -	-
Conclusions -	
If Remedial Action Initiated, Check Type 8.1	Usage of Device
Recall Notification	☐ Initial Use of Device
	Reuse
	Unknown
	f action reported to FDA under
Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:	emoval reporting number.
Additional Manufacturer Narrative and	/or 11. Corrected Data
Additional Manufacturer Narrative and	/or 11. Corrected Data
Additional Manufacturer Narrative and DSS	

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer

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

Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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WIFEAUNT RECORD

CaseID: 11516357

	357-01-	-00-03		COMPLAINT	#: 2644	
TAKEN BY:		DYTA FRACKIEWICZ	DAT	E OF COMPLAIN	NT: 08/29/2015	
PRODUCT:	HY	YLAND'S BABY NIGHTTIME TEETHIN	NG TABLETS	ITEM COD	DE: BTNTT135	
SIZE:	_135	35 TABS		LOT NO	O.: N/A	
REPORTER:	(b) (6)					
DDRESS:	N/A					
	N/A					
CITY:	N/A			STATE: N/A		
COUNTRY:	USA		ZIP	CODE: N/A	1 2 1-0	
PHONE #:	N/A					
E-MAIL:	N/A					
ACTUALLY VERY GLO SAME TIME HE WAS	THE FOLLO AD I CAME A USING THIS ERFECTLY F	CROSS THIS. A FEW MONTHS BAC SAME PRODUCT AND ONCE WE ST FINE EVER SINCE WE STOPPED US	TOPPED GIVING TO HIM, EV SING HYLANDS TABLETS. BU	OR WHAT I THOU ERYTHING STO IT I NEVER THO	JGHT WAS SEIZUR PPED AND THERE UGHT THAT THEY	ES. AROUND THAT WAS NO NEED FOR
		FOR ADDITIONAL SPACE PLEASE	USE REVERSE OR ATTACH	I A SEPARATE S	SHEET	
PRODUCT RECEIVED NSPECTION:	FOR	Y (CIRCLE ONE)			OR INSPECTION:	Y N (CIRCLE ONE)
			DATE REQUE	STED PRODUCT	F BE RETURNED:	
				UPS CA	ALL TAG ISSUED:	Y (CIRCLE ONE)
				DATE PROD	OUCT RECEIVED:	
ECTION II:	INVESTIG	GATION				
NVESTIGATION:	TECH	SE SEE ATTACHED INSPECTION RE	ET OIN).			
DVERSE EVENT FO	RWARDED T	TO PHARMACIST / NURSE FOR EVA	LUATION ON:	08/29/	2015	
DVERSE EVENT FO	RWARDED T	TO PHARMACIST / NURSE FOR EVA	LUATION BY:	EDYTA	A FRACKIEWICZ	
ECTION III:	CORR	RECTIVE ACTION:				
ORRECTIVE ACTION	N(S) COMPLE	ETED BY:		DAT	E:	
ECTION IV:	ADVERSE	E EVENT REPORTS		AE	#: _1634	
DVERSE EVENT SER	RIOUS:	(Y)/ N				
OVERSE EVENT RE	PORTED ON:	08/29/2015	BY:	EDYTA FRA	CKIEWICZ	
ECTION V:	CEMENT DI	E	Burth		09-07	1-15 SEP
EVIEWED BY MANA	GEMENT BY:	Que Bou	VVVV	DATE:	000 00	11
		The state of the s				
		QA / QC DIRECTOR				SEP 157

Packaging

Shipping / Receiving

Form # VD1





CaseID: 11516357

SAE-0043-2015

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 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, 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 ≤(4) ppm.

Conclusion:

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

Prepared by

Date

12/2015

DSS SEP 16 2015



EVENT DATA FORM

AE #:16	34	COMPLAINT #: 2644
SECTION I:	PATIENT INFORMATION (IF DIFF	FERENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:		
CITY:		STATE:
COUNTRY:		ZIP CODE:
PHONE #:		
E-MAIL:	1	
SECTION II:	PACKAGING INFORMATION:	
A	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY
		PANELS)
	Physics Phy	Sing fines Exist reproducts Sing fines Exist reproducts Sing fines Exist reproducts Sing fines
SECTION III:	CORRECTIVE ACTION:	, Sur, J. C
CORRECTIVE A	ACTION(S) COMPLETED BY:	DATE:
SECTION IV:	6	2 6 2015
REVIEWED BY	MANAGEMENT BY:	DATE: 09-02-15
BY:	QUE Baun QA/QC DIRECTOR	DATE: 09-02-15

y user-facilities, utors and manufacturers ATORY reporting

Form App	See OMB statement on reverse
Mfr Report # 5497	3
UF/Importer Report	#

Page 1 d

Patient Identifier	2. Age at Time		3. Sex	4. Weight
(b) (6)	of Event: INF	ANT	y wan	
	or		Female	or Ib
In confidence	Date of Birth:		✓ Male	kg
B. ADVERSE EV	VENT OR PRO	DUCT PROBLEM	Л	100
1. Adverse Event	t and/or	Product Problem (e.	a. defects/malt	unctions)
2. Outcomes Attribut		The state of the s	97 12 11 11 11 11	C. T. C. C. C. C. C. C. C. C. C. C. C. C. C.
(Check all that appl)	y)		0.00.0.2	
Death:	(mm/dd/yyyy)	Disability or	Permanent Da	mage
Life-threatenin	g		Anomaly/Birth I	
	- initial or prolonged	L.	us (Important N	
		ermanent Impairment		
3. Date of Event (mn		4. Date of This		Vyyyy)
5. Describe Event or	00/2015 Problem		08/31/15	_
CUSTOMER GAVE HE HAD TWO HEA				
R	Receive	ed		
		-		
	SEP 1 5 20	15		
,	OCI 1 9 20	10		
	CDR			
			(Continue of	n page 3)
	poratory Data, Inclu	dia- Data-		
6. Relevant Tests/Lat	or and J - and the	iding Dates		
6. Relevant Tests/Lat UNKNOWN	,	loing Dates		
		loing Dates		
	,	Joing Dates		
	,	Joing Dates		
	,	Joing Dates		
		Joing Dates		
		Joing Dates	(Continue o	n page 3)
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UNKNOWN 7. Other Relevant His race, pregnancy, sm	story, including Pre	existing Medical Cor	ditions (e.g., a	

5	DODUCT/O			FDA Use Onl
SUSPECT P. Name (Give labele)	RODUCT(S) d strength & mfr/labeler)		
#1 HYLAND'S B	ABY NIGHTTIME	TEETHIN	G TABLE	STS
#2 N/A				
2. Dose, Frequency	& Route Used			If unknown, give duration)
#1 UNKNOWN DO	SE X 2	#1	o (or best e	isumat e)
#2 N/A		#2		
4. Diagnosis for Use	(Indication)			Abated After Use
#1 TEMP RELIE	F NITE TEETHIN	G PAIN	Stopp	ed or Dose Reduced?
#2 N/A				Apply
6. Lot #	7. Exp. Date		#2 Y	es No Apply
#1N/A	#1			Reappeared After oduction?
#2N/A	#2		#1 🗌 Y	'es ☐ No ☑ Doesn
9. NDC# or Unique II			#2 Y	on I INo I Doesn
54973-3197-	dical Products and Th	orany Det		— — Арріу
	EDICAL DEVICE	800	(C	Continue on page 3)
1. Brand Name				
2. Common Device N	lame		2b. P	Procode
3. Manufacturer Nan	ne, City and State			
4. Model#	Lot#			5. Operator of Device
Catalog #	Expiration	n Date (mm	/dd/yyyy)	Health Professiona Lay User/Patient
Serial#	Unique Id	entifier (UD	01)#	Other:
6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Exp	lanted, Giv	ve Date (mm/dd/yyyy)
R le this a Singla-us	e Device that was Rep	vocesed:	and Pausa	d on a Patient?
Yes N		nocesseu a	and Neuse	u on a Patient?
9. If Yes to Item No.	8, Enter Name and Ad	dress of Re	eprocessor	
	for Evaluation? (Do no	ot send to F	DA)	
Yes No	Returned to I	Manufacture	er on:	(mm/dd/yyyy)
11. Concomitant Med	dical Products and The	erapy Date	s (Exclude	1 31727
			(0	continue on page 3)
E. INITIAL REP	ORTER			F-G- 9)
Name and Addres (6)	s			
(4)	SEP 16	S	71.9	SA
Phone #	Em	2015 all Address	SEP 1	5 2015
2. Health Profession	al? 3. Occupation			nitial Reporter Also Sen
☐ Yes ☑ No	NA			Report to FDA

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



1. Check One			UF/Importer	Report Number
User Facility	Imp	orter		
3. User Facility or In	nporter Name	Address		
4. Contact Person			5. Phone I	Number
6. Date User Facility Importer Became Aware of Event (n	100	7. Type of Rep		8. Date of This Report (mm/dd/yyyy)
Approximate Age of Device	10. Event	Problem Code		-] ling manual)
	Code Device Code		-	
1 Danset Sant to E		12 Location	Where Event	Occurred
11. Report Sent to F Yes	dd/yyyy)	Hosp	oital	Outpatient Diagnostic Facility Ambulatory
13. Report Sent to M			ing Home atient Treatme ity	Surgical Facility
No (mm/c	dd/yyyy)	Othe	r;	
140		100		(Specify)
-	me/Address			
G. ALL MANUF	ACTURER		evices)	2, Phone Number
14. Manufacturer Na G. ALL MANUF 1. Contact Office (ar Name	ACTURES		evices)	310-768-0700
G. ALL MANUF 1. Contact Office (ar Name EDYTA FRACKIE Address	ACTURER nd Manufactu WICZ		evices)	310-768-0700 3. Report Source
G. ALL MANUF 1. Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, ING	ACTURER nd Manufactu WICZ . STREET	ring Site for De	evices)	310-768-0700 3. Report Source (Check all that apply, Foreign Study Literature
G. ALL MANUF Contact Office (ar Name CDYTA FRACKIE Address HYLAND'S, ING 154 W. 131ST OS ANGELES,	ACTURER nd Manufactu WICZ . STREET	ring Site for De	evices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer
G. ALL MANUF Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address	ACTURES and Manufactu WIC2 STREET CA 9006:	ring Site for De	evices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional
G. ALL MANUF Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, ING 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA Date Received by Manufacturer (mm	ACTURES and Manufactu WIC2 STREET CA 9006:	ring Site for De		310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company
G. ALL MANUF Contact Office (ar Name CDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST OS ANGELES, Email Address STANDARD@HYLA Date Received by Manufacturer (mm	ACTURER and Manufactur WICZ STREET CA 9006: NDS.COM	Ting Site for Do		310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional
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G. ALL MANUF Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA Date Received by Manufacturer (mm 08/27	ACTUREF and Manufactu WICZ STREET CA 9006: NDS COM Add/yyyy) /15 col#	5. (A)NDA#_ IND#_ BLA#_ PMA/ 510(k)#_		3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor
G. ALL MANUF Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA Date Received by Manufacturer (mm 08/27 G. If IND, Give Protoc (Check all that app) 5-day 30-	ACTUREF and Manufactu WICZ STREET CA 9006: NDS COM Add/yyyy) /15 col#	5. (A)NDA#_ BLA#_ PMA/ 510(k)#_ Combinatio	n Yes	3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor
G. ALL MANUF 1. Contact Office (an Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA 3. Date Received by Manufacturer (mm 08/27 3. If IND, Give Protocom (Creck all that appl 5-day 30-	ACTURES and Manufactur WICZ STREET CA 9006: NDS. COM andd/yyyy) /15 col #	5. (A)NDA#_ IND#_ BLA#_ PMA/ 510(k)#_ Combinatio Product Pre-1938	n Yes	3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor
G. ALL MANUF 1. Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA 4. Date Received by Manufacturer (mm 08/27 7. Type of Report (Check all that app) 5-day 30- 7-day Per 10-day Initi	ACTURES and Manufactur WICZ STREET CA 9006: NDS. COM andd/yyyy) /15 col #	5. (A)NDA#_ BLA#_ PMA/ 510(k)#_ Combinatio	T Yes	3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor
G. ALL MANUF 1. Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA 4. Date Received by Manufacturer (mm 08/27 6. If IND, Give Protoc 7. Type of Report (Check all that appl 5-day 30- 7-day Per 10-day Initi	ACTUREF and Manufactu WICZ STREET CA 9006: NDS COM Add/yyyy) /15 col #	5. (A)NDA#_ BLA#_ PMA/ 510(k)#_ Combinatio Product Pre-1938 OTC Produ	∩ Yes Yes ct Yes	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:

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

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

Case	D:	11	51	63	69
FDA USE	ONL	Y	1	Red C	100

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

Results Conclusions 7. If Remedial Action Initiated, Check Type 8. Usage of Device Initial Use of Device Recall Notification Reuse Repair Inspection Unknown Replace Patient Monitoring If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number: Modification/ Adjustment Relabeling Other:

> DSS SEP 16 201

11. Corrected Data

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

10. Additional Manufacturer Narrative

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."

PRASIaff@fda.hhs.gov
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5 2015

CaseID: 11516369

11:	516369-								
TAKEN BY:		EDYTA FRACK	IEWICZ		DATE OF CO	MPLAINT:	08/27/2015		
PRODUCT:		HYLAND'S BAB	BY NIGHTTIME TEETHING	G TABLETS	IT	EM CODE:	BTNTT135		_
SIZE:	263.75	135 TABS				LOT NO.:	N/A		
REPORTER:	(b) (6)								
ADDRESS:	N/A								_
	N/A				97				-
CITY:	N/A			-	STATE:	N/A			
COUNTRY:	USA				ZIP CODE:	N/A			_
PHONE #:	N/A								
E-MAIL:	N/A								
#1: I HAD GIVEN THEM TO HIM. I LITTLE ONE WIL ON YOUR SIDE!	MY SON TH THOUGHT SO L BE ALRIGH	E NIGHT TIME TA OMETHING WAS HT, THIS SCARES ONLY TOOK THE EING THIS IT SCA	MESSAGES ON (D) (6) ABLETS ON 2 DIFFEREN UP BUT HE DIDNT DO I ME SO MUCH. POST # TABLETS TWICE BUT HA ARES THE HELL OUT OF	T AGAINAND I DIDN 2: I WILL BE FOLLOW AD THE SAME HEAD ME TO THINK I HAV	HE HAD 2 HEA I'T USE THE TA I'NG Y'ALL'S S' DROPS YOUR E HIM SOMETH	D DROPS II BLETS AFT TORY I CA DAUGHTEF IING THAT	N THE DAYS AF TER THAT. I REA NT HELP FINAN R HAS I DIDN'T DID THAT TO HI	TER I HAD GIVE ALLY HOPE YOU CIALLY BUT I KNOW WHAT	EN JR AM
PRODUCT RECEINSPECTION:	EIVED FOR		Y (CIRCLE ONE)	PRODUC	F BEING RETU	RNED FOR	INSPECTION:	Y (CIRCLE O	NE
				DATE F	REQUESTED PR	RODUCT BE	RETURNED:		
						HPS CALL	TAC ICCUED.	Y (CIRCLE O	N
						UI O CALL	TAG ISSUED:	(CINOLL O	,/
					DAT			(CINCLE O	,-/
SECTION II:	INV	ESTIGATION			DAT		T RECEIVED:	(OINOLL O	
			ACHED INSPECTION RE	PORT.	DAT			(ONOLL O	
INVESTIGATION	<u>_</u> F	PLEASE SEE ATTA	ACHED INSPECTION RE	Zarosano.	DAT		T RECEIVED:	(ONOLL O	
ADVERSE EVEN	T FORWARD	PLEASE SEE ATTA	CIST / NURSE FOR EVAL	.UATION ON:	DAT	TE PRODUC	T RECEIVED:	(ONOLL O	
INVESTIGATION	T FORWARD	PLEASE SEE ATT	CIST / NURSE FOR EVAL	.UATION ON:	DAT	TE PRODUC	T RECEIVED:		
ADVERSE EVEN ADVERSE EVEN SECTION III:	T FORWARD T FORWARD	PLEASE SEE ATTA	CIST / NURSE FOR EVAL	.UATION ON:	DAT	TE PRODUC	T RECEIVED:		
ADVERSE EVEN ADVERSE EVEN SECTION III:	T FORWARD T FORWARD	PLEASE SEE ATTA	CIST / NURSE FOR EVAL CIST / NURSE FOR EVAL TION:	.UATION ON:	DAT	08/27/201 EDYTA FI	T RECEIVED:		
ADVERSE EVEN ADVERSE EVEN SECTION III:	T FORWARD T FORWARD CTION(S) COL	DED TO PHARMACE ORRECTIVE ACT	CIST / NURSE FOR EVAL CIST / NURSE FOR EVAL TION:	.UATION ON:	DAT	08/27/201 EDYTA FI	5 RACKIEWICZ		
ADVERSE EVEN ADVERSE EVEN ADVERSE EVEN CORRECTIVE ACCEPTION IV:	T FORWARD T FORWARD CTION(S) COL	DED TO PHARMACE ORRECTIVE ACT	CIST / NURSE FOR EVAL CIST / NURSE FOR EVAL TION:	.UATION ON:		08/27/201 EDYTA FI	5 RACKIEWICZ		
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cc: QA/QC Packaging

Production Shipping / Receiving

Form # VD1

SEP 1 5 2015





CaseID: 11516369

SAE-0042-2015

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 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 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 $\stackrel{(b)}{=}_{(4)}$ ppm.

Conclusion:

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

Prepared by

Date

DSS SEP 1 6 2015



EVENT DATA FORM

-	Case	eID:	115	16369
		MANN	1	

AE #: 16	33	COMPLAINT #:2643	_
SECTION I:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:	-		_
CITY:		STATE:	-
COUNTRY:	USA	ZIP CODE:	-
PHONE #:			_
E-MAIL:			-
SECTION II:	PACKAGING INFORMATION:		
А	AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY	
		PANELS)	
	TOTAL COLUMN TOTAL TOTAL COLUMN	in the and all results in a social and the second s	
	Latel Face	Feething Toblets William Street Control of the Con	
	(Marie Barrier	Hylands Hylands (Hylands)	
	Page2	The second secon	
		Consider a statement long size (the first extension of the first ext	
	Page3	The second secon	
SECTION III:	CORRECTIVE ACTION:		
			-
CORRECTIVE A	ACTION(S) COMPLETED BY:	DATE:	
SECTION IV:		/	DSS SEP 16 2015
	\mathcal{D}_{a} .	111A	SEP 1 6 2015
REVIEWED BY	MANAGEMENT BY:	- VVV	
BY:	QA/QC DIRECTOR	DATE: 09-02-15	_



user-facilities, tors and manufacturers TORY reporting

Form Apploase	See C	JMB statement	on revers
Mfr Report # 54973	06	TC	
UF/Importer Report #	10		

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1 age	٠,	Oi	

FORM FDA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

FORM FDA 350	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	, ago ,		DUOT(O)		FDA Use Only
A. PATIENT IN 1. Patient Identifier	Contraction and the second	3. Sex 4. Weight	C. SUSPECT PRO 1. Name (Give labeled st		r)	
(b) (6)	of Event: INFANT		#1 HYLAND'S BAB		N	
	or	Female lbs	***************************************	37757-3111		
In confidence	Date of Birth:	✓ Male kgs	#2 2. Dose, Frequency & R	ente Hearl	2 Thomas Day	to Munkagua siya dunting
B. ADVERSE E	VENT OR PRODUCT PRO	OBLEM		oute Usea		tes (If unknown, give duration) est estimate)
1 Adverse Eve	nt and/or Product Pro	blem (e.g., defects/malfunctions)	#1 UNKNOWN		#1	
	uted to Adverse Event		#2		#2	
(Check all that app Death:		sability or Permanent Damage	4. Diagnosis for Use (Inc.	dication)		vent Abated After Use opped or Dose Reduced?
	(mm/dd/yyyy)		#1 FEMP RELIEF	reething pai	N	✓ Yes No Doesn't
Life-threateni		ngenital Anomaly/Birth Defect her Serious (Important Medical Events)	#2			Apply Doesn't
	ervention to Prevent Permanent Imp		6. Lot #	7. Exp. Date	#2	Yes No Apply
3. Date of Event (m		of This Report (mm/dd/yyyy)	#1	#1	8. Ev	vent Reappeared After eintroduction?
the state of the s	00/2012	08/31/2015	#2	#2		Yes No Doesn't
5. Describe Event o			9. NDC# or Unique ID			Apply Apply Doesn't
	LESS THAN THE RECOMMENT ING AND SPASMING. RES		54973-3127-3		#2 [Yes No Apply
	Received		D. SUSPECT MED			(Continue on page 3)
			2. Common Device Nam	e	2	2b. Procode
	SEP 1 5 2015		3. Manufacturer Name, (City and State		
	CDR		4. Model#	Lot#		5. Operator of Device
			Catalog #	Expiration	n Date (mm/dd/yy)	Health Professional Lay User/Patient
		0	Serial #	Unique Id	lentifier (UDI)#	Other:
		(Continue on page 3)	6. If Implanted, Give Dat	e (mm/dd/yyyy)	7. If Explanted	, Give Date (mm/dd/yyyy)
	aboratory Data, Including Dates		8. Is this a Single-use De	evice that was Rep	processed and Re	used on a Patient?
UNKNOWN			Yes No			
			9. If Yes to Item No. 8, E 10. Device Available for Yes No	Evaluation? (Do no		
			11. Concomitant Medica	Products and Th	orany Dates /Eyol	(mm/dd/yyyy)
7 Other Relevant Hi	story, Including Preexisting Med	(Continue on page 3)	The Goldenmant medica	r roducts and rin	erapy bates (Exc	ude il earnerit or event)
race, pregnancy, si	moking and alcohol use, hepatic/rei	nal dysfunction, etc.)				(Continue on page 3)
			E. INITIAL REPOR	TER	7777	
			1. Name and Address (b) (6)		DSS SEP 16	771SA
		(Continue on page 3)	Phone #	Em	ail Address	
ersonnel, user fa	report does not constitute a acility, importer, distributor uted to the event.		2. Health Professional? Yes No	3. Occupation NA		4. Initial Reporter Also Sent Report to FDA Yes No V Unk.
						J 2015

7 Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

Importer

3. User Facility or Importer Name/Address

1. Check One

User Facility

4. Contact Person

Approximate

Age of Device

11. Report Sent to FDA?

Yes

No

Name

Address

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

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

154 W. 131ST STREET

STANDARD@HYLANDS.COM

08/27/2015

30-day

✓ Initial

✓ 15-day Follow-up #

54973 AE # 1632

9. Manufacturer Report Number

Periodic

Date Received by Manufacturer (mm/dd/yyyy)

6. If IND, Give Protocol#

(Check all that apply)

7. Type of Report

5-day

7-day

10-day

LOS ANGELES, CA 90061

HYLAND'S, INC.

Email Address

1. Contact Office (and Manufacturing Site for Devices)

2. UF/Importer Report Number

5. Phone Number

Date of This Report (mm/dd/yyyy)

Outpatient
Diagnostic Facility

Surgical Facility

Ambulatory

(Specify)

2. Phone Number

Foreign

Literature

√ Consumer

User Facility

Company

Distributor

Other:

Study

310-768-0700

Report Source (Check all that apply)

Health Professional

Representative

CaseID:	11516392
FDA USE ON	Y

	ACTURERS ONL	2. If Follow-up, What Type?
Death		Correction
Serious Injury		Additional Information
Malfunction		Response to FDA Reques
		Device Evaluation
B. Device Evaluated by Ma	anufacturer?	4. Device Manufacture Date
Not Returned to Ma		(mm/yyyy)
	on Summary Attached	i l
No (Attach page to	explain why not) or	5. Labeled for Single Use?
provide code:		Yes No
6. Event Problem and Eva	luation Codes (Refer	to coding manual)
Patient	1-1	
Code L		
Code		-
Method	-	
Results	-]-[]-
Conclusions		
. If Remedial Action Initia		8. Usage of Device
Recall	Notification	Reuse
Repair	Inspection	Unknown
Replace	Patient Monitoring	9. If action reported to FDA under
Relabeling	Modification/ Adjustment	21 USC 360i(f), list correction/
	riajustrient	removal reporting number:
Othor		
Other:		
Other:		
Other:	cturer Narrative	and / or 11. Corrected Data
	cturer Narratíve	and / or 11. Corrected Data
	cturer Narrative	and / or 11. Corrected Data
	cturer Narrative	and / or 11. Corrected Data
	cturer Narrative	and / or 11. Corrected Data
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	cturer Narrative	and / or 11. Corrected Data
	cturer Narrative	and / or 11. Corrected Data
	cturer Narrative	
	cturer Narrative	and/or 11. Corrected Data

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

(A)NDA#

IND#

BLA# PMA/

510(k)#

Combination Product

OTC Product

8. Adverse Event Term(s)

SEIZING, SPASMING

Pre-1938

Yes

Yes

√ Yes

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

Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

information unless it displays a currently valid OMB control number Please DO NOT RETURN this form to the above PRA Staff email address.

44				COMPLAINT #:	2642	
TAKEN BY:	516392-01-0 EDYT	TA FRACKIEWICZ	DATE	F COMPLAINT:	73773422	
PRODUCT:	HYLA	ND'S BABY TEETHING TABLETS		ITEM CODE:	BTET	
SIZE:	N/A			LOT NO.:	N/A	
REPORTER:	(b) (6)					
ADDRESS:	N/A					
	N/A					
CITY:	N/A		STA	TE: N/A		
COUNTRY:	USA		ZIP CO	DDE: N/A		
PHONE #:	N/A					
E-MAIL:	N/A					
THE FULL SUGG	7 3 WHEN HE WAS A BESTED DOSE AND I IT ONLY USED FROZ E BOY. AND HAS NE	CUSTOMER POSTED THE FOLLOW BABY AND ONLY A FEW MONTHS MY BABY STARTED SEIZING OR S EN PACIFIERS TO SOOTH HIS TEE VER DONE THAT BEFORE OR AFT OR ADDITIONAL SPACE PLEASE U	OLD AND TEETHING I TRIED PASMING. I STOPPED IMMED ETHING. I AM CONVINCED TH FER I STOPPED THOSE.	HYLANDS TEE DIATELY. THEN T HOSE TABLETS V	WERE THE CAUS	I DIDN'T EVEN USE TS STOPPED.
PRODUCT RECEINSPECTION:	EIVED FOR	Y (CIRCLE ONE)	PRODUCT BEING F	RETURNED FOR	INSPECTION:	Y (CIRCLE ONE)
			DATE REQUESTS	ED PRODUCT BE	E RETURNED:	
				UPS CALL	TAG ISSUED:	Y (CIRCLE ONE)
				DATE PRODUC	T RECEIVED:	
SECTION II:	INVESTIGA	TION			1	
INVESTIGATION:	PLEASE	SEE ATTACHED INSPECTION REP	PORT.			
ADVERSE EVENT	T FORWARDED TO F	PHARMACIST / NURSE FOR EVALU	JATION ON:	08/27/201	5	
ADVERSE EVENT	T FORWARDED TO F	PHARMACIST / NURSE FOR EVALU	JATION BY:	EDYTA F	RACKIEWICZ	
SECTION III:	CORREC	TIVE ACTION:				
CORRECTIVE AC	CTION(S) COMPLETE	D BY:		DATE:		
SECTION IV:	ADVERSE EN	VENT REPORTS		AE #:	1632	
ADVEDSE EVEN	CEDIOUS	(C)				
ADVERSE EVENT	REPORTED ON:	08/27/2015	DV.	EDVIA EDACIA	EWIO7	
SECTION V:	THE ON TED ON.	08/27/2015	BY: _	EDYTA FRACKI	EVVICE	
	ANAGEMENT BY	Pl	Walt	DATE:	09-02	DSS SEP 16 20
BY:	Q	Oue Dawi		DATE: (09-02-15	021 10 20

cc: QA / QC Packaging

Production Shipping / Receiving

SEP 1 5 2015





CaseID: 11516392

SAE-0041-2015

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 $\leq_{(4)}^{(b)}$ ppm.

Conclusion:

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

Prepared by

912/2015

Date

DSS SEP 16 201

SEP 1 5 2015



SE EVENT DATA FORM

137107377	Case	eID:	11516	5392
CALL Advantagement	tion!	una	2	

AE #: 163	32	COMPLAINT #: 2642	_
SECTION I:	PATIENT INFORMATION (IF DIFF	FERENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		_
ADDRESS:	,———	*	-
CITY:		STATE:	-
COUNTRY:	USA	ZIP CODE:	-
PHONE #: E-MAIL:			-
SECTION II:	PACKAGING INFORMATION:		
AF	FFIX PACKAGING LABEL HERE Service of the control o	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
SECTION III:	CORRECTIVE ACTION:		
CORRECTIVE A	CTION(S) COMPLETED BY:	DATE:	DSS
SECTION IV:			SEP 16 20
REVIEWED BY M	MANAGEMENT BY:	JOHA DATE: 09563-15	715
BY:	QA/QC DIRECTOR	DATE: 09-02-15	-



PLEASE TYPE OR USE BLACK INK

y user-facilities, utors and manufacturers ATORY reporting

Form A GASON	No. 1910 See O	52 64 04: 6/30/2015 MB statement on reverse
Mfr Report# 54913	-	10
UF/Importer Report #	10	

rage 1 of 5

F	DA	Us	e	Only	
	שמ	US		Only	

FORM FDA 3500A (2/13)	rage 1	of 5		40		FDA Use Only
A. PATIENT INFORMATION		C. SUSPECT PE	RODUCT(S)	6 1	70000	T DA OSC OIII
Patient Identifier 2. Age at Time	3. Sex 4. Weight	THE RESERVE OF THE PARTY OF THE	d strength & mfr/labeler)			
(b) (6) of Event:	Months Female lbs	#1 HYLAND'S B.	ABY NIGHTTIME T	CEETHING	TABLETS	
Date	or	#2 N/A				
In confidence of Birth:	Male kgs	2. Dose, Frequency 8	& Route Used		Dates (If unknown,	give duration)
B. ADVERSE EVENT OR PRODU	CT PROBLEM	#1 UNKNOWN		from/to	(or best estimate)	
1. Adverse Event and/or Pro	oduct Problem (e.g., defects/malfunctions)	-				
Outcomes Attributed to Adverse Event (Check all that apply)		#2 N/A		#2		
Death:	Disability or Permanent Damage	4. Diagnosis for Use		0.00	Event Abated After Stopped or Dose I	
(mm/dd/yyyy) Life-threatening	Congenital Anomaly/Birth Defect	-	F NITE TEETHING	PAIN	#1 Yes No	Doesn's
Hospitalization - initial or prolonged	Other Serious (Important Medical Events)	#2 N/A			#2 Yes No	Doesn'
Required Intervention to Prevent Perm		6. Lot #	7. Exp. Date			☐ Apply
3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	#1N/A	#1		Reintroduction?	
04/01/2015	08/28/15	#2N/A	#2		#1 Yes No	Doesn's
5. Describe Event or Problem	No burner also was me on	9. NDC# or Unique ID			#2	Doesn't
CHILD STOPPED BREATHING, HAI RESUSCITATED. NO SEQUELAE.	O NO PULSE, AND HAD TO BE	54973-3197-1	lical Products and The		#2 Yes No	L Apply
Red	eived	D. SUSPECT ME	EDICAL DEVICE		(Continue or	page 3)
		2. Common Device N	lama.		2b. Procode	
SED	1 5 2015	Z. Common Device N	ame		20. Procode	
OLI	1 9 2013	3. Manufacturer Nam	e, City and State			
	CDR	4. Model #	Lot#		5. Operator	of Device
					122	Professional
	- 31	Catalog #	Expiration	Date (mm/de	d/yyyy)	er/Patient
	- 3	Serial#	Unique Ide	ntifier (UDI)	# Other:	
	(Continue on page 3)	6. If Implanted, Give I	Date (mm/dd/yyyy)	7. If Explan	nted, Give Date (mm/	dd/yyyy)
Relevant Tests/Laboratory Data, Includin		8 Is this a Single-use	Device that was Repre	ocessed and	d Roused on a Paties	+2
		Yes No		oocooca an	a neaded on a racie	
		9. If Yes to Item No. 8	, Enter Name and Addr	ress of Repr	ocessor	
*						
		10. Device Available f	or Evaluation? (Do not	send to FDA)	
		Yes No	Returned to Ma	anufacturer o		
	and the second second	11 Concemitent Med	ical Bandusta and The	non Determine	(mm/dd/yy	
Other Polyant History Including Security	(Continue on page 3)	11. Concomitant Med	ical Products and Ther	apy Dates (Exclude freatment of	even()
Other Relevant History, Including Preexist race, pregnancy, smoking and alcohol use.	hepatic/renal dysfunction, etc.)					
NKNOMN					(Continue on	page 3)
		INITIAL REPO Name and Address	CONTRACTOR OF THE PARTY OF THE		4 1 1 1 1 1	7
		(b) (6)	D	SS	U.S.F.P. 1	1
	1		SEP 1	6 2019	5	5 2015
	To Control	Phone #		Address	,	
	(Continue on page 3)					
ubmission of a report does not con		2. Health Professiona	l? 3. Occupation		4. Initial Report	er Also Sent
ersonnel, user facility, importer, dis aused or contributed to the event.	stributor, manufacturer or product	Yes No	NA		Yes 1	

 	 -

1. Check One 2. UF/Importer Report Number User Facility Importer 3. User Facility or Importer Name/Address 5. Phone Number 4. Contact Person Date User Facility or Importer Became 7. Type of Report Date of This Report (mm/dd/yyyy) Aware of Event (mm/dd/yyyy) Initial Follow-up # Approximate
 Age of Device 10. Event Problem Codes (Refer to coding manual) Patient Code Device Code 11. Report Sent to FDA? 12. Location Where Event Occurred Outpatient
Diagnostic Facility Hospital (mm/dd/yyyy) Home No Ambulatory Nursing Home Surgical Facility 13. Report Sent to Manufacturer? Outpatient Treatment Facility Yes (mm/dd/yyyy) No Other: (Specify) 14. Manufacturer Name/Address **G. ALL MANUFACTURERS** 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number Name 310-768-0700 EDYTA FRACKIEWICZ 3. Report Source (Check all that apply) Address Foreign HYLAND'S, INC. Study 154 W. 131ST STREET LOS ANGELES, CA 90061 Literature √ Consumer Email Address Health Professional STANDARD BHYLANDS. COM User Facility 4 Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 08/25/15 Distributor IND# 6. If IND, Give Protocol # Other: BLA# PMA/ Type of Report 510(k)# (Check all that apply) Combination Product 30-day 5-day Yes Periodic 7-day Pre-1938 Yes √ Initial 10-day OTC Product √ Yes √ 15-day Follow-up # 9. Manufacturer Report Number 8. Adverse Event Term(s) LACK OF VITAL SIGNS 54973 AE # 1631

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:

Casell	D: 1	1151	640	04
EDA LISE	ONLY	5.75	77.30	-

Correction Correction Additional Information Response to FDA Request Device Evaluation ice Manufacture Date Vyyyy) eled for Single Use? Yes No
Correction Additional Information Response to FDA Request Device Evaluation ice Manufacture Date Vyyyy) eled for Single Use? Yes No
Correction Additional Information Response to FDA Request Device Evaluation ice Manufacture Date Vyyyy) eled for Single Use? Yes No
Correction Additional Information Response to FDA Request Device Evaluation ice Manufacture Date Vyyyy) eled for Single Use? Yes No
Additional Information Response to FDA Request Device Evaluation ice Manufacture Date Vyyyy) eled for Single Use? Yes No
Response to FDA Request Device Evaluation ice Manufacture Date Vyyyy) eled for Single Use? Yes No
Device Evaluation ice Manufacture Date v/yyyy) eled for Single Use? Yes No
ice Manufacture Date //yyyy) eled for Single Use?
eled for Single Use? Yes No
eled for Single Use?
Yes No
Yes No
- - - - - - - - - - - - -
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reported to FDA under 360i(f), list correction/ I reporting number:
11. Corrected Data

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

SEP 1 5 2015

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

CaseID: 11516404

11516404-01-00-03	COMPLAINT #:	2011	
TAKEN BY: EDYTA FRACKIEWICZ	DATE OF COMPLAINT:	08/25/2015	
PRODUCT: HYLAND'S BABY NIGHTTIME TEETHING TABLETS	ITEM CODE:	BTNTT135	
SIZE: 135 TABS	LOT NO.;	NOT PROVIDED	
REPORTER: (b) (6)			
ADDRESS: N/A			
N/A			
CITY: N/A	STATE: N/A		
COUNTRY: USA	ZIP CODE: N/A		
PHONE #: N/A			
E-MAIL: N/A			
NATURE OF COMPLAINT:			
INSPECTION: (CIRCLE ONE)	UCT BEING RETURNED FOR II	NSPECTION: Y (CIR	CLE ONE)
	UPS CALL T	Υ	CLE ONE)
	DATE PRODUCT	RECEIVED:	
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON:	08/25/2015		
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY:		ACKIEWICZ	
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION:			
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY:	EDYTA FR	ACKIEWICZ	
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS	EDYTA FR.	ACKIEWICZ	
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS ADVERSE EVENT SERIOUS: Y N	DATE:	ACKIEWICZ	nse
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION: CORRECTIVE ACTION(S) COMPLETED BY: SECTION IV: ADVERSE EVENT REPORTS ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED ON: 08/25/2015	DATE:	ACKIEWICZ	DSS
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION: CORRECTIVE ACTION: CORRECTIVE ACTION: ADVERSE EVENT REPORTS ADVERSE EVENT REPORTED ON: O8/25/2015 SECTION V:	DATE:	ACKIEWICZ	
ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: SECTION III: CORRECTIVE ACTION: CORRECTIVE ACTION: ADVERSE EVENT REPORTS ADVERSE EVENT SERIOUS: Y N	DATE:	ACKIEWICZ	DSS SEP 16 2

Packaging

Shipping / Receiving

Form # VD1





CaseID: 11516404

SAE-0040-2015

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 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 botulinum have been "negative" and the total Atropine and Scopolamine levels and was found to meet the specification of $\leq_{(4)}^{(6)}$ bpm.

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

912 12015

Date

DSS SEP 1 6 2015

SEP 15 21

Page 1 of 1



SE EVENT DATA FORM

Ca	selD:	11	516404	1
W.				

AE #: 1631		COMPLAINT #:2641	-
SECTION I: PATIENT	T INFORMATION (IF DIFFERE	ENT FROM REPORTER ON FORM VD1)	
NAME: (b) (6)			<u> </u>
ADDRESS:			-
CITY:		STATE:	_
COUNTRY:		ZIP CODE:	
PHONE #:			_
E-MAIL:			_
SECTION II: PACKAC	GING INFORMATION:		
	FINAS	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS) The parent of the	
SECTION III: CORRE	CTIVE ACTION:		-)
CORRECTIVE ACTION(S) COM	PLETED BY:	DATE:	- DSS SEP 16 20
SECTION IV:		1-0-4	
REVIEWED BY MANAGEMENT	BY:	DATE: 09-02-15	SEP 15
BY:	LE BALLI A / QC DIRECTOR	DATE: 09-02-15	

	11516539-01-00-		iser-facilities, ors and manufacturers ORY reporting	Form All Mfr Report # 549 UF/Importer Repo	n#
A. PATIENT INF	ORMATION 2. Age at Time of Event: 6 Months or Date of Birth:	3. Sex 4. Weigh	C. SUSPECT PROD	ength & mfr/labeler)	FDA Use Only
B. ADVERSE EV	ENT OR PRODUCT PRO	BLEM lem (e.g., defects/malfunctions)	2. Dose, Frequency & Ro #1 1 DOSE IN 2009 #2 N/A	9	Therapy Dates (If unknown, give duration) from/to (or best estimate) #1 #2
(Check all that appl)	/) Disa	bility or Permanent Damage genital Anomaly/Birth Defect	4. Diagnosis for Use (Indi #1 TEMP RELIEF TI	cation)	5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Apply
	vention to Prevent Permanent Impa	er Serious (Important Medical Eve irment/Damage (Devices) f This Report (mm/dd/yyyy)		7. Exp. Date #1	#2 Yes No Doesn't Apply 8. Event Reappeared After Reintroduction?
00/0	0/2009	09/04/15	#2 9. NDC# or Unique ID	#2	#1 Yes No Doesn't
(b) (6) THAT TEETHING TABLE SORT OF OUT OF STARTED TURNIN WERE ROLLING 1	Problem LD ON THE NEWS STATION CHILD TOOK ONE DOSE TTS AND WAS OFF, NOT NOT INTERPOLATION FOR IT AND THEN HE STARM G COLORS, STOPPED BRICK IN THE BACK OF HIS HEAUTH BIG BLACK EYES.	OF THE HYLAND'S REALLY ACTING HIMSEL PED VOMITING. HE EATHING AND HIS EYES AD. HIS PUPILS WERE	54973-7504-1 10. Concomitant Medical	Products and Therap	#2 Yes No Doesn't Apply by Dates (Exclude treatment of event)

RECEIVED

AMBULANCE TO A HOSPITAL, EXAMINED, AND SYMPTOMS

SEP 1 5 2015

CDR

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates UNKNOWN

RESOLVED.

PLEASE TYPE OR USE BLACK INK

(Continue on page 3)

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

(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.

2. Dose, Frequency 8	Route Used	3. Ther	apy Dates (If unknown, give durati
#1 1 DOSE IN 2	11 DOSE IN 2009 #1		/to (or best e	estimate)
#2 N / A	#2 N/A #2			
Diagnosis for Use (Indication)		5 Event	Abated After Use	
#1 TEMP RELIEF		IN		ed or Dose Reduced?
#2 N/A			#1 🔲 ነ	res No ✓ Doe App
6. Lot #	7. Exp. Date		#2 🔲 y	/es ☐ No ☐ Doe App
#1N/A	#1		8. Event	Reappeared After
#2	#2			oduction?
9. NDC# or Unique ID			#1 L Y	es [No V App
54973-7504-1			#2 🔲 Y	res No App
D. SUSPECT ME	DICAL DEVICE		(C	Continue on page 3
2. Common Device N	ame		2b. P	rocode
3. Manufacturer Name	e, City and State			
. Model#	Lot#			5. Operator of Device
Catalog #	Expiration	Expiration Date (mm/d		Health Professio
Serial #	Unique I	dentifier (U	DI) #	Other:
6. If Implanted, Give D	ate (mm/dd/yyyy)	7. If Exp	planted, Giv	re Date (mm/dd/yyyy)
3. Is this a Single-use	Device that was Re	processed	and Reuse	d on a Patient?
Yes No				
). If Yes to Item No. 8,			opi otosso.	
0. Device Available fo	or Evaluation? (Do r			//IV
Yes No	Returned to	Manufactur	er on:	(mm/dd/yyyy)
Yes No	Returned to	Manufactur	er on:es (Exclude	111111111111111111111111111111111111111
Yes No 1. Concomitant Medi	Returned to	Manufactur	er on:es (Exclude	treatment of event) DS ontinue proage 3)
O Device Available for Yes No Concomitant Medi E. INITIAL REPO Name and Address b) (6)	Returned to	Manufactur	er on:es (Exclude	treatment of event) OS ontinue propage 3)
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Yes No 1. Concomitant Medi E. INITIAL REPO Name and Address	Returned to	Manufactur	er on:(C	treatment of event) OS ontinue propage 3)

		e/Address		
Contact Person			5. Phone	Number
6. Date User Facility of Importer Became Aware of Event (mi		7. Type of Repo		8. Date of This Report (mm/dd/yyyy)
9 Approximate	10. Event	Problem Codes		- ding manual)
Age of Device	Patient			1-
	Code [Device [-	
	Code	Tion		
11. Report Sent to FD	A?	12. Location V	0041.9	Outpatient
Yes(mm/de	d/yyyy)	Home	al	Diagnostic Facility
No 13. Report Sent to Ma	anufacturar	☐ Nurein	g Home	Ambulatory Surgical Facility
	mulacturer	Outpat	ent Treatm	
Yes(mm/de	d/yyyy)	Facility		
		Порис		(Specify)
G. ALL MANUFA				
1. Contact Office (and			ices)	2. Phone Number
G. ALL MANUFA 1. Contact Office (and Name EDYTA FRACKIEM	d Manufact		ices)	310-768-0700
1. Contact Office (and Name	d Manufact		ices)	
1. Contact Office (and Name EDYTA FRACKIEW	d Manufact		ices)	310-768-0700 3. Report Source (Check all that apply) Foreign
Name EDYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S	d Manufacto	uring Site for Dev	ices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study
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This section applie	s only to requireme	ents of the Pane	rwork Reductio	n Act of	1995

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

	CaseID: 1151653
-	FDA USE ONLY

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Reportable Event ath rious Injury Ilfunction Evaluated by Manufacturer? It Returned to Manufacturer Is Evaluation Summary Attached to (Attach page to explain why not) or ovide code: Patient Code Patient Code (Refer Code Patient Code Patient Code Patient Code Patient Patient Code Patient Monitoring Patient Monitorin	If Follow-up, What Type? Correction Additional Information Response to FDA Request Device Evaluation
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Action Initiated, Check Type call Notification pair Inspection place Patient Monitoring Modification/ Adjustment	(111112/3/3/)
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Patient Code Refer Patient Code Device Code Method Results - Conclusions - Conclusions Inspection pair Inspection place Patient Monitoring Modification/ Adjustment	5. Labeled for Single Use?
Patient Code Device Code Method Results Conclusions Conclusions Inspection Patient Monitoring Modification/ Adjustment her:	Yes No
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Device Code Method	-
Code Method Results Conclusions Conclusions Habeling Modification Adjustment Method Results Modification Adjustment Modification Adjustment	
Results - Conclusions - Conclu	+
Conclusions	
Conclusions	
dial Action Initiated, Check Type call Notification pair Inspection place Patient Monitoring Habeling Modification/ Adjustment her:	
pair Inspection place Patient Monitoring habeling Modification/ Adjustment	
pair Inspection place Patient Monitoring labeling Modification/ Adjustment her:	8. Usage of Device
pair Inspection place Patient Monitoring labeling Modification/ Adjustment her:	Initial Use of Device
place Patient Monitoring labeling Modification/ Adjustment her:	Reuse
Habeling Modification/ Adjustment Adjustment	Unknown
Adjustment her:	If action reported to FDA under
	21 USC 360i(f), list correction/ removal reporting number:
ditional Manufacturer Narrative	Tanatan aparang nama
ditional Manufacturer Narrative	

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

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.

	516539-0		COMPLAI		
EN BY:		EDYTA FRACKIEWICZ	DATE OF COMPL	4.4	
DUCT:		HYLAND'S TEETHING TABLETS	ITEM C	NO.: N/A	
E.	(b) (6)	N/A	LOI	NO N/A	
PORTER:	N/A				
/KE33.	N/A				
Y:	(b) (6)		STATE: (b) (i	5)	
JNTRY:	USA		ZIP CODE: N	A	
ONE #:	N/A				
AIL:	N/A				
THER STATE OUT OF IT. A TING TO TAL LD WAS RUS IN THE TEET	ED THAT AFTE AND THEN HE K TO HIM AND SHED BY AMBI THING TABLET	ER GIVING CHILD A DOSE OF TEETHING STARTED VOMITING. HE STARTED TUI) HIS EYES WERE ROLLING IN THE BAC ULANCE TO A HOSPITAL "THEY CHEC S AND TOLD ME TO DO SOME RESEAR	S TABLETS: "HE JUST WAS KIND OF 'OF RNING COLORS AND I SAID, HE IS NOT F CK OF HIS HEAD. HIS PUPILS WERE LIKE KED HIM OUT AND HE EVENTUALLY WA RCH ON IT AND WHAT HE SAID WAS BEL RACTIVE BECAUSE IT WOULD DILATE TI	REALLY BREATHING A MARBLES, JUST BIG S OK. THE ER DOCTO LADONNA IN LATIN W	NG HIMSELF, SORT ND WE WERE BLACK EYES." PR WAS FAMILIAR
ANDILO	FEE TOOK SO		USE REVERSE OR ATTACH A SEPARAT		
DUCT RECI PECTION:	EIVED FOR	(CIRCLE ONE)	PRODUCT BEING RETURNED		Y (CIRCLE ONE)
TION II:	INVE	STIGATION		CALL TAG ISSUED:	(CIRCLE ONE)
ESTIGATION	: PL	EASE SEE ATTACHED INVESTIGATION	I REPORT.		
	IT FORWARDE	ED TO PHARMACIST / NURSE FOR EVA	LUATION ON: 09/	03/2015	
ERSE EVEN	IT FORWARDE	ED TO PHARMACIST / NURSE FOR EVAI ED TO PHARMACIST / NURSE FOR EVAI ORRECTIVE ACTION:		03/2015 YTA FRACKIEWICZ	
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ERSE EVEN TION III: RECTIVE A	T FORWARDE	ED TO PHARMAGIST / NURSE FOR EVALORED FOR EV	LUATION BY: ED	PATE: AE #:1641	
ERSE EVEN TION III: RECTIVE A	CTION(S) COM	ORRECTIVE ACTION: MPLETED BY: RESE EVENT REPORTS	LUATION BY: ED	YTA FRACKIEWICZ	SFD 7

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

SEP 1 5 2015





CaseID: 11516539

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 products a review is not possible.

Other investigations:

With no lot number for the units involved a review the customer complaints and Deviation systems is not possible, additionally TEET was withdrawn from the market in 2010. Hyland's Baby Teething (BTET) is the new formulation that was released to the market after the TEET was withdrawn.

A review of the customer complaint system was performed and it did reveal that in the last twelve months that there have been 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.

Prepared by

9/10/2015

Date

SEP 1 5 2015 SEP 16



EVENT DATA FORM

AE #: 1641	COMPLAINT #:2651
NAME: (b) (6)	PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)
DDRESS:	(b) (6)
COUNTRY: US	STATE: (b) (6) ZIP CODE:
HONE #:	
-MAIL:	
ECTION II:	ACKAGING INFORMATION:
AFFIX PA	CKAGING LABEL HERE AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
time of in Section or instancing. It appropries parent late review these viewers depoy in yoursen, or I britishine permisht, information and send created in the con- city of the cost and created in the cost office, if you can prosperate or versing it into greated the souther of a Section of latent cost perthyrational facilities using medications and of the results of anticlares. In passe of an octoriosis hardware and prosperation section activities and of the section of an activities and other sections of the control of the section of an activities the control of an octoriosis hardware and a position section activities and other and other and ordered a formation activities activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of an activities of the section of the activities of the section of the activities of the section of the activities of the section of the activities of the section of the activities of the section of the activities of the activiti	Francisco Calabrato Wildowskin D. Will, Confess Covin 33 (1982), Behatisman 38 WIRDOWSKIN Confess Covin 33 (1982), Behatisman 38 WIRDOWSKIN Confess Covin 33 (1982), Behatisman 18 Description Tablets Ta
ECTION III:	CORRECTIVE ACTION:
DRRECTIVE ACTION(S) COMPLETED BY: DATE: SEP 16
CTION IV:	2 /
VIEWED BY MANAG	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
' :	QA/QC DIRECTOR DATE: 09-11-15

y user-facilities, itors and manufacturers iTORY reporting

.,,	Case	See OMB statement on reverse.
Mfr Report #	54973	10
UF/Importer I	Report #	

Mfr Report # 54973	10
UF/Importer Report #	OCT (
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rage 1 of 5

	ORMATION		200	17 66	C. SUSPECT P	RODUCT(S)	S131-0	il its	
Patient Identifier	2. Age at Time		3. Sex 4.	Sex 4. Weight 1. Name (Give labeled street)			r)		
(b) (6)	of Event: 5	Months	Female _	lbs	#1 HYLAND'S B	ABY TEETHING T	TABLETS		
In confidence	Date of Birth:		☐ Male	or	#2 N/A				
	VENT OR PRODU	ICT PROBLE	M	kgs	2. Dose, Frequency	& Route Used	3. Therapy Dates		give duration
1. Adverse Even			e.g., defects/malfunct	tions)	#1 1 DOSE X 2	DAYS	from/to (or best #1	estimate)	
	ted to Adverse Event	roduct Problem (6	e.g., derects/manunci	tions)	#2 N/A		#2		
(Check all that appl					4. Diagnosis for Use	(Indication)		nt Abated Afte	er Use
Death:	(mm/dd/yyyy)	Disability	or Permanent Damag	ge	#1 TEMP RELIE	F TEETHING PAI	N	ped or Dose	Reduced? Doesn
✓ Life-threatenin		Congenita	l Anomaly/Birth Defe	ect	#2 N/A		#1 ☑	Yes No	Apply
✓ Hospitalization	- initial or prolonged	Other Seri	ous (Important Medic	cal Events)	6. Lot #	7. Exp. Date	#2	Yes No	Doesn Apply
Required Inter	vention to Prevent Perr	manent Impairmen	t/Damage (Devices)		#1A43515	#1	8. Even	t Reappeared	
3. Date of Event (mn	*****	4. Date of This	Report (mm/dd/yyy	yy)			Rein	troduction?	
	1: 08/28/2015		09/04/15		#2N/A	#2	#1 🗸	Yes No	Doesn' Apply
Describe Event or REPORTER SENT	Problem BY E-MAIL A M	ESSAGE THAT	AFTER GIVING	G HER	9. NDC# or Unique II 54973-3127-		#2 🗍	Yes ☐ No	Doesn' Apply
TABLETS AND SECHILD WAS TAKE DOCTORS COULD	HE CHILD ANOTH HE HAD 3 SEIZI EN TO THE HOSP NOT DETERMINE DW UP BY PHONE NOT RETURNED.	NG EPISODES ITAL. CHILD CAUSE OF T	WITHIN 15 M HAD TESTS BU HE EPISODES.	INS. UT	D. SUSPECT MI	EDICAL DEVICE	(Continue or	n page 3)
					2. Common Device N	lame	[2b]	Procode	
	Rec	eived				1.04			
	OFD	4			3. Manufacturer Nam	e, City and State			
	SEP	1 5 2015			4. Model#	Lot #		5. Operator	of Device
		DR			Catalog #	Expiration	Date (mm/dd/yyyy)		Professional ser/Patient
		NUK			Serial #	Unique Id	entifier (UDI) #	Other:	
			(Continue on pa	age 3)	6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Explanted, Gi	ive Date (mm/	dd/yyyy)
6. Relevant Tests/Lab		ng Dates	(Continue on pa	age 3)	8. Is this a Single-use	e Device that was Rep			
6. Relevant Tests/Lab UNKNOWN		ng Dates	(Continue on pa	age 3)		e Device that was Rep	processed and Reuse	ed on a Patier	
		ng Dates	(Continue on pa	age 3)	8. Is this a Single-use Yes No. 9. If Yes to Item No. 8	e Device that was Rep b, Enter Name and Add for Evaluation? (Do no	processed and Reuse dress of Reprocesso of send to FDA)	ed on a Patier	
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Check One User Facility	[Import	er	
3. User Facility or Impo			
4. Contact Person		5. Pho	one Number
Date User Facility or Importer Became Aware of Event (mm.	20.00	Type of Report Initial Follow-up #	8. Date of This Report (mm/dd/yyyy)
	L. Propert Pro	- 1 - 2 - 3 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	- I
9. Approximate Age of Device	10. Event Pro	oblem Codes (Refer to	o coding manual)
Age of During	Patient Code Device		-
	Code	-	-
11 Depart Sont to EDA	_	12 Leasting Where E	····· Annual
11. Report Sent to FDA	.?	12. Location Where E	
☐ Yes		☐ Hospital	Outpatient Carifford
(mm/dd/	yyyy)	Home	Diagnostic Facility
No	7		Ambulatory
13. Report Sent to Man	ufacturer?	Nursing Home	9
-		Outpatient Tre	alment
Yes	WWW)	Facility	
No (IIIIIIIII	77777	Other:	(Specify)
			(opes)
14. Manufacturer Name	e/Address		
14. Manufacturer Name			
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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:

CaseID: 1151654
FDA USE ONLY

Death Serious Injury Malfunction	FURERS ONL		llow-up, What Type? Correction Additional Information Response to FDA Re Device Evaluation	
Not Returned to Manufa Yes Evaluation S No (Attach page to exp	acturer Summary Attached	(mm	ce Manufacture Date (yyyy) eled for Single Use? Yes No	
6. Event Problem and Evaluation Patient Code Device Code		to coding man	nual)	
Method	-	-	-	
Results	1-		1	
Conclusions	1-			
Other:				
10. Additional Manufactur		and / or	11. Corrected	

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

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SEP 1 6 2015

	1515540				COM	MPLAINT #:	2650	
PRODUCT:		F. J. S. S. S. S.	RACKIEWICZ			OMPLAINT:	09/02/2015	
SIZE:		135 TABS	S BABY TEETHING TABLET	5	IT	EM CODE:	BTETT138	5
REPORTER:	(b) (6)	135 1485	,			LOT NO.:	A43515	-
ADDRESS:	N/A							
	N/A							
CITY:	N/A			STA	TE	(b) (6)		
COUNTRY:	USA			ZIP CC		N/A		
PHONE #:	(b) (6)							
E-MAIL:								
RODUCT RECE	D NOT FIND A	REASONF	OR THE SEIZURES, TAKEN	VER, NO ILLNESS. SEIZURES HA N TO THE ER AND RELEASED. NO E USE REVERSE OR ATTACH A S	SEPA	EEXISTING ARATE SHE	CONDITIONS. ET	Y (N)
ar = strotte			(ONOLE ONE)	DATE REQUESTE	ח פר	ODUCTO	DETUDNES	(CIRCLE ONE)
				DATE REGUESTE	.0 (1)	ODOC1 BE	KETUKNED:	
						UPS CALL 1	AG ISSUED:	Y (N)
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SECTION II:	INVE	STIGATION	i .		DATE	E PRODUCT	RECEIVED:	
		600000						
NVESTIGATION:	PL	EASE SEE	ATTACHED INVESTIGATIO	NREPORT	_			
				1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		1-1:		
			RMACIST / NURSE FOR EVA		-	09/02/2015		
DVERSE EVENT	FORWARDE	D TO PHAR	RMACIST / NURSE FOR EVA				ACKIEWICZ	
OVERSE EVENT	FORWARDE		RMACIST / NURSE FOR EVA		1 1			
OVERSE EVENT	FORWARDE	D TO PHAR	RMACIST / NURSE FOR EVA		1			
DVERSE EVENT	FORWARDE CC	D TO PHAR	RMACIST / NURSE FOR EVA		14			
OVERSE EVENT	FORWARDE CC	D TO PHAR	RMACIST / NURSE FOR EVA		3=			
OVERSE EVENT ECTION III: DRRECTIVE AC	FORWARDE CC	D TO PHAR	RMACIST / NURSE FOR EVA		12	EDYTA FR	ACKIEWICZ	
DVERSE EVENT ECTION III: DRRECTIVE AC	TION(S) COM	DRRECTIVE PLETED BY:	RMACIST / NURSE FOR EVA			EDYTA FR	ACKIEWICZ	no.
DVERSE EVENT DRRECTIVE AC ECTION IV:	TION(S) COM ADVER	PLETED BY:	RMACIST / NURSE FOR EVA	ALUATION BY:		DATE:	ACKIEWICZ	DS
DVERSE EVENT ORRECTIVE AC ECTION IV: DVERSE EVENT	TION(S) COM ADVER	PLETED BY:	RMACIST / NURSE FOR EVA	ALUATION BY:	EDYT	EDYTA FR	ACKIEWICZ	DS. SEP 16
DVERSE EVENT CORRECTIVE ACTION IV: DVERSE EVENT DVERSE EVENT DVERSE EVENT	TION(S) COM ADVER SERIOUS: REPORTED (PLETED BY:	RMACIST / NURSE FOR EVA	ALUATION BY:	EDYT	DATE:	1640	
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SAE-0049-2015

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 (b) (4) 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 $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

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

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

Other investigations:

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

9/16/2015

DSS SEP 1 6 2015

CC-0728-2015 AE-0416-2015

Page 1 of 1

CaseID: 11516540



SE EVENT DATA FORM

AE #:1	640	COMPLAINT #:2650
SECTION I:	PATIENT INFORMATION (IF DIFFERE	NT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:		
CITY:		STATE: (b) (6)
COUNTRY:	USA	ZIP CODE:
PHONE #:	(b) (6)	
E-MAIL:		
SECTION II:	PACKAGING INFORMATION:	
	AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
The state of the s	PRESENCE O THE PROPERTY OF TH	Teething Tablets Well-Street Well-Street Baby Toething Tablets Toething Tablets Toething Tablets Toething Tablets
SECTION III:	CORRECTIVE ACTION:	
CORRECTIVE	ACTION(S) COMPLETED BY:	DATE:
CORRECTIVE SECTION IV:	ACTION(S) COMPLETED BY:	1/
SECTION IV:	By In	DSS
SECTION IV:	Y MANAGEMENT BY:	DATE:

user-facilities, tors and manufacturers TORY reporting

Form Applease	911-59 6663 6/30/2015 See OMB statement on reverse.
Ifr Report # 54973	10
F/Importer Report #	

Mfr Report #		
UF/Importer Report #	00	
	(),	FDA Use Only

~ I 1111	UL	UUUUM	141101

1. Patient Identifier	2. Age at Time		3. Sex	4. Weight
(b) (6)	of Event:	Months		
	or		Female	or or
In confidence	Date of Birth:		✓ Male	- Or
	ENT OR PRODU	JCT PROBLEM		30.10
1 Adverse Even	OCCUPATION AND ADDRESS OF	roduct Problem (e.		unctione)
2. Outcomes Attribut		Sand Linnielli (e.)	g., sereotarnian	
(Check all that appl)		420.73		
Death:	(mm/dd/yyyy)	Disability or	Permanent Da	mage
Life-threatenin	g	Congenital	Anomaly/Birth [Defect
✓ Hospitalization	- initial or prolonged	Other Serio	us (Important N	fedical Eve
Required Inter	vention to Prevent Perr	manent Impairment/	Damage (Device	es)
3. Date of Event (mm		4. Date of This F		<i>(</i> /yyyy)
07/14/201 5. Describe Event or	5 - PRESENT		09/04/15	
CONTINUING. E HEAD AND ARMS DOCTORS ARE PE	CURL UP TO HI	S CHEST AND		
	Receiv	ed		
		7		
	SEP 1 5 2	015		
	CDR			
			(Continue or	page 31
6. Relevant Tests/Lab	oratory Data, Includir			,90 0)
			Continue on	nogo 21
7 Other Relevant Hist	ory, Including Preexis	sting Medical Cond	ditions (e.g., al	, ,
race, pregnancy, sme NONE	oking and alcohol use	hepatic/renal dysfur	nction, etc.)	
		(Continue on	page 3)

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

f 5	>		U	1	FDA Use O
C. SUSPECT F		(laheler)	STELL		
#1 HYLAND'S					
#2 N/A					
2. Dose, Frequency	& Route Used	3 The	rapy Dates (/	funknown	nive duratio
#1 2 TABS SL		from	to (or best es		ive duratio
-	BIU A 3 NE.	EKS #1			
#2 N/A	- 0 - 0 - 0 - 1	#2	To an analysis		
 Diagnosis for Us #1 TEMP RELIE 		DATM		Abated Afte ed or Dose I	
0.00	ar indining	EATH	- #1 □ Y	es 🗸 No	Ooes Apply
#2 N / A 6. Lot #	7 Eve D	Nata.	#2 TY	es No	Does
#1A68015	7. Exp. D	rate		Reappeared	After Apply
	#1			duction?	
#2N/A	#2		#1 Y	es No	Does Apply
 NDC# or Unique 54973-3127- 			#2 TY	es No	Does Apply
10. Concomitant Me		nd Therapy Dat	es (Exclude h	reatment of	
D. SUSPECT N	MEDICAL DEV	/ICE	(Co	ontinue or	page 3)
1. Brand Name					
2. Common Device	Name		2b. Pr	ocode	
3. Manufacturer Na	me City and Stat	· P			
4. Model#	Lot	#	1	5. Operator	of Device
Catalog #	Evo	iration Date (mr	m/dd/mand	Health	Profession
		matron pare (m	noda yyyyy	Lay Us	er/Patient
Serial #	Unio	que Identifier (U	DI) #	Other:	
If Implanted, Give	Date (mm/dd/yyy	(y) 7. If Ex	planted, Give	Date (mm/	dd/yyyy)
3. Is this a Single-us	se Device that wa	as Reprocessed	and Reused	on a Patier	it?
	No			And and aires	
If Yes to Item No.					
	8, Enter Name ar	nd Address of R	deprocessor		
	8, Enter Name ar	nd Address of R	Reprocessor		
	8, Enter Name ar	nd Address of R	Reprocessor		
	o for Evaluation?	(Do not send to l	FDA)		
0. Device Available	o for Evaluation?		FDA)	(mm/dd/yy	yy)
Yes N	o for Evaluation?	(Do not send to led to Manufactur	FDA) rer on:		/
Yes N	o for Evaluation?	(Do not send to led to Manufactur	FDA) rer on:		/
Yes N	o for Evaluation?	(Do not send to led to Manufactur	FDA) er on: es (Exclude ti	reatment of	event)
Yes N	o for Evaluation? O Returned Codical Products an	(Do not send to led to Manufactur	FDA) er on: es (Exclude ti		event)
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10. Device Available Yes N 11. Concomitant Me E. INITIAL REP 1. Name and Addres (b) (6) Phone # (b) (6)	ofor Evaluation? Returned ical Products and ORTER	(Do not send to hed to Manufacturind Therapy Date	rer on:(Co	entinue on	page 3) S 2015



User Facility	□ lmi	z. ur/importe	r Keport Number
User Facility or Imp			
4. Contact Person		5. Phone	Number
Date User Facility of Importer Became Aware of Event (mr.		7. Type of Report Initial Follow-up#	8. Date of This Report (mm/dd/yyyy)
9. Approximate	10. Event	Problem Codes (Refer to co	oding manual)
Age of Device	Patient Code	-	1-
	Device [Code	-	-
11. Report Sent to FD	A?	12. Location Where Ever	nt Occurred
Yes		☐ Hospital	Outpatient
No (mm/do	Vyyyy)	Home	Diagnostic Facility
13. Report Sent to Ma	nufacturer	? Nursing Hame	Ambulatory Surgical Facility
☐ Yes		Outpatient Treatm	ent
No (mm/da	Vyyyy)	Other:	
			(Specify)
G. ALL MANUFA	CTURE	RS	
	Manufactu	uring Site for Devices)	2. Phone Number
Name EDYTA FRACKIEW	100		310-768-0700
Address	104		Report Source (Check all that apply)
			Foreign
HYLAND'S, INC. 154 W. 131ST ST	PREET		Study
LOS ANGELES, CA		1.	Literature
Facility Address			Consumer
Email Address TANDARD@HYLANI	S COM		Health Professional
Date Received by	Carto	5.	User Facility
Manufacturer (mm/d		(A)NDA #	Company Representative
09/01/1			representative
If IND, Give Protoco		IND#	Distributor
	I #	BLA#	Distributor Other:
. Type of Report	1#	BLA#	
(Check all that apply)		BLA#	
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5-day 30-da 7-day Period 10-day Initial	y dic v-up # t Number	BLA# PMA/ 510(k)# Combination Product Yes Pre-1938 Yes	Other:

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-		7
•	OT	-

H. DEVICE MANUFACTURERS ONLY	CENTRAL CONTRACTOR
. Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
Device Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary Attached	
No (Attach page to explain why not) or	5. Labeled for Single Use?
provide code:	Yes No
Event Problem and Evaluation Codes (Refer to	coding manual)
Patient -	1-
Code	
Device Code	-
Method -	
Results -	1-
Conclusions	
	3. Usage of Device
Recall Notification	Initial Use of Device
Repair Inspection	Reuse
	Unknown
	If action reported to FDA under
Relabeling Modification/ Adjustment	21 USC 360i(f), list correction/
Other:	removal reporting number:
-	
Additional Manufacturer Narrative	and / or 11. Corrected Data
	DSS
	SEP 1 6 2015
	SEP 1 5 2015

CaseID: 11516601

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
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TAKEN BY:			COMP	LAHAT #:	2648		
	EDYTA	FRACKIEWICZ	DATE OF COM	PLAINT:	09/01/2015		
PRODUCT:	HYLAN	ID'S BABY TEETHING TABLETS	ITEM	CODE:	BTET-T135		
SIZE:	135 TAI	BS		OT NO.:	A68015		
REPORTER:	(b) (6)						
ADDRESS:	N/A						
	N/A			L1 /01			
CITY:	N/A		STATE:	b) (6)			
COUNTRY	USA		ZIP CODE:	N/A			
PHONE #:	(b) (6)						
E-MAIL:							
CO TELL EVERYO CAN FEEL FREE T CUSTOMER SENT S ALSO A NUMBE SPOKE TO THE C O) (6) AND	INE TO NEVER USE Y TO CONTACT ME ANI T THE FOLLOWING MER ON THE SIDE OF CUSTOMER'S HUSBA THEY ARE RUNNING LIKE CHILD IS NODD JINED.	YOUR PRODUCTS. MY SON HAS ID I WILL BE CONTACTING A LAW MESSAGE AND INCLUDED HER PHATE BOTTLE A68015. AND ON 9/3/2015: SYMPTOMS DE G TESTS. STOPPED USING THE IDING HIS HEAD AND ARMS CURL	JCTS AND I CAN ASSURE YOU I HA' BEEN IN AND OUT OF THE HOSPIT. YER TO TAKE LEGAL ACTION AGAIL HONE NUMBER: THE NUMBER ON T ESCRIBED AS SEIZURE LIKE ACTIVI BABY TEETHING TABLETS ON JULY UP TO HIS CHEST AND HE SHAKES	AL FOR TH NST YOUR THE BOTTL TY. HAS BI 14TH. GI THEM. I O	IS REOCCURF COMPANY. O E SAYS NDC 5 EEN TO THE D VING 2 TABS B FFERED A REI	RING ISSUE 0N 9/2/15 54973-3127- 0OCTOR AT BID X 3 WEI	E. YOU -1.THERE (b) (6) EKS.
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DVERSE EVENT E	PLEASE SE FORWARDED TO PH FORWARDED TO PH CORRECTE	EE ATTACHED INVESTIGATION R HARMACIST / NURSE FOR EVALU- HARMACIST / NURSE FOR EVALU- TIVE ACTION:	DATE EPORT ATION ON:	PRODUCT 19/01/2015 EDYTA FRA DATE:	RECEIVED: _	(CIRCLI	SEL
DVERSE EVENT OF ECTION III:	PLEASE SE FORWARDED TO PH CORRECTI TON(S) COMPLETED ADVERSE EVE	EE ATTACHED INVESTIGATION R HARMACIST / NURSE FOR EVALU- HARMACIST / NURSE FOR EVALU- TIVE ACTION:	DATE EPORT ATION ON:	PRODUCT 19/01/2015 EDYTA FRA DATE:	CKIEWICZ	(CIRCLI	SEI
DVERSE EVENT EDUCATION III:	PLEASE SE FORWARDED TO PH CORRECTI TION(S) COMPLETED ADVERSE EVE	HARMACIST / NURSE FOR EVALU. HARMACIST / NURSE FOR EVALU. IVE ACTION: BY: ENT REPORTS	DATE SEPORT ATION ON: ATION BY:	PRODUCT 19/01/2015 EDYTA FRA DATE:	CKIEWICZ	(CIRCLI	SEL
ADVERSE EVENT OF SECTION IV: SECTION IV: SOURCES EVENT OF SECTION IV: SOURCES EVENT OF SECTION IV: SOURCES EVENT OF SECTION IV:	PLEASE SE FORWARDED TO PH CORRECTI TION(S) COMPLETED ADVERSE EVE	HARMACIST / NURSE FOR EVALUATIVE ACTION: BY: ENT REPORTS	DATE SEPORT ATION ON: ATION BY:	DATE:	CKIEWICZ	(CIRCLI	SEL
ADVERSE EVENT F	PLEASE SE FORWARDED TO PH CORRECTE TION(S) COMPLETED ADVERSE EVE SERIOUS: REPORTED ON:	HARMACIST / NURSE FOR EVALUATIVE ACTION: BY: ENT REPORTS	DATE SEPORT ATION ON: ATION BY:	DATE:	CKIEWICZ		SEI

cc: QA / QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 11516601

SAE-0047-2015

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 (b) (4) 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 with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

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

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

Other investigations:

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

Prepared by

Date

116/2015

SEP 16 2015



SE EVENT DATA FORM

AE #:163	38	COMPLAINT #: 2648
SECTION I:	PATIENT INFORMATION (IF DIFFE	RENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:		
CITY:		STATE:
COUNTRY:		ZIP CODE:
PHONE #:		
E-MAIL:	-	
SECTION II:	PACKAGING INFORMATION:	
AF	FIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
Section of the contraction of th	Teething Tablets	Telething Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets
SECTION III:	CORRECTIVE ACTION:	
CORRECTIVE AC	CTION(S) COMPLETED BY:	DATE: SEP 1 6 2015
SECTION IV:		
REVIEWED BY M	ANAGEMENT BY:	DATE: 09-11-15
BY:	Goula Bours	DATE: 09-11-15

A. PATIENT INFORMATION

(1.	For a poved O	CaseID: 11536908		
eporting of problems and		See OMB statement on reverse.		
rors	le.	16628		
2. Dose or Amount	Frequency Four times	Route		
#2 3. Dates of Use (If unkno (or best estimate) #1 09/16/2015 - 09	daily wn, give duration) from/to	5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't		
12	7/10/2013	Apply Apply		
L Diagnosis or Reason	for the (Indication)	#2 Yes No Doesn't		
#1 Teething pain	tor use (maicanori)	8. Event Reappeared After Reintroduction? #1 Yes No Doesn't Apply		
5. Lot#	7. Expiration Date	#2 Yes No Doesn't Apply		
#1	#1	9, NDC # or Unique ID		
#2	#2			

CTU

SEP 2 1 2015

DSS

SEP 2 1 2015

Manufacturer

User Facility

Distributor/Importer

1. Patient Identifie (b) (6)	2. Age at Time of Eve Date of Birth:		4. Weight 35 _{lb}	#1		Four tim	nes	
	10 Months (b)(6)	☐ Female		#2				
In confidence	11742	✓ Male	kg	4-11				
B. ADVERSE Check all that apply	EVENT, PRODUC	T PROBLEM OR E	RROR	(or best est	se (If unknown, give imate) 015 - 09/18/2		Stopped	Abated After Use for Dose Reduced?
1. Adverse Eve	ent Product Problem with	lem (e.g., defects/malfund		40	2000-1-1001007	7.0		Apply
	buted to Adverse Event		or came modified		or Reason for Use	(Indication)	#2 \Y	Apply
(Check all that a	pply)			#1 Teethir	ng pain			Reappeared After roduction?
Death:	(mm/dd/yyyy)	Disability or Permanen	Damage	#2			#1 🗆 Y	es No Doesn'
Life-threaten		Congenital Anomaly/Bi				Contraction to the	#2 Y	
transaction of the second second second	on - initial or prolonged ervention to Prevent Perm	Street Control of the		6. Lot# #1	#1	xpiration Da	-	# or Unique ID
3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)	#2	#2			
09/17/201	5	09/19/2015		E. SUSPE	CT MEDICAL	DEVICE		
				2. Common D	evice Name			SEP 2
See addit	ional page(s	s) for comple	ete text.	3. Manufactu	rer Name, City and	State		
				4. Model #	- 11	_ot#		5. Operator of Device
				s, modern		700		Health Professiona
				Catalog #	E	Expiration Da	ate (mm/dd/yyyy)	Lay User/Patient
6. Relevant Tests	Laboratory Data, Includ	ding Dates		Serial #	C	Other#		
See addit				6. If Implante	d, Give Date (mm/c	dd/yyyy) 7	7. If Explanted, G	ive Date (mm/dd/yyyy)
				8. Is this a Si	The second section is a second second second	nat was Repr	rocessed and Re	used on a Patient?
				9. If Yes to Ite	m No. 8, Enter Name	e and Addres	s of Reprocessor	
7. Other Relevant allergies, race, p	History, Including Preed pregnancy, smoking and a	xisting Medical Condition alcohol use, liver/kidney p	ons (e.g., roblems, etc.)		(CONCOMITA	المراوفي البارات	THE RESERVE OF THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED	
See addit	ional page(s	s) for comple	ete text.	Product nam	es and therapy da	ies (excidue	readment of ever	Q.
C BRODUCT	AVALABILITY			1. Name and	TER (See conf Address	fidentiality	section on b	ack)
	AVAILABILITY for Evaluation? (Do not	t send product to FDA)		(b) (6)				DS
	Returned to Manu		n/dd/yyyy)					3EP 2 1
#1 Name: Hylar	PRODUCT(S) n, Manufacturer (from pro nd's teething tab		-,	Phone # (b) (6)		100	E-mail (6)	
Strength: Manufacturer:	Hyland			2. Health Pro	fessional? 3. Occ	upation	14	Also Reported to:

FORM FDA 3500 (1/09)

#2 Name:

Strength:

Manufacturer:

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

5. If you do NOT want your identity disclosed

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

Yes No



My 10 month year 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)

DSS SEP 21 2015

Report

porting of roblems and

Dose or Amount

	SA USE ONLY
Triage unit sequence #	- 10 Acres -

Route

Frequency

CaseID: 11544456

A. PATIENT INFORMATION	2. Dose or Amount	Frequency	Route	
. Patient Identifier 2. Age at Time of Event or 3. Sex 4. Weight	#1	Twine dai	1ÿ Taken b	y mouth
Date of Birth: 13 Months Female 20 lb	#2			
(b) (6) V Male or kg	74			
In confidence B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	3. Dates of Use (If unknow	n, give duration) from	n/to 5. Even	t Abated After Use
heck all that apply:	(or best estimate) #1		3/95	d or Dose Reduced? Yes No Doesn't
Adverse Event Product Problem (e.g., defects/malfunctions)	-		* (V)	Apply
Product Use Error Problem with Different Manufacturer of Same Medicine	4. Diagnosis or Reason fo	or Use (Indication)	#2 🔲	Yes No Doesn't Apply
2. Outcomes Attributed to Adverse Event (Check all that apply)	#1 My son was teeth	And the state of the second of the state of		t Reappeared After troduction?
Death:	#2			Yes No Doesn't
✓ Life-threatening			40 171	Apply Yes No Doesn't
✓ Hospitalization - initial or prolonged ✓ Other Serious (Important Medical Events)	6. Lot #	7. Expiration Dat		Apply
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#2	#2	9. NDC	# or Unique ID
3, Date of Event (mm/dd/yyyy) 09/19/2015 4. Date of this Report (mm/dd/yyyy) 09/22/2015	E. SUSPECT MEDI	100	4	
09/19/2015 09/22/2015 5. Describe Event, Problem or Product Use Error	1. Brand Name	ONLOCKE		- 16V
2 DOUBLE LIVING FIRSTON ST. FIRSTON ST. FIRSTON				CTU
	2. Common Device Name	i i		SLAV V V AND
				SEP 2 3 2015
See additional page(s) for complete text.	3 Manufacturer Name, C	ity and State		
see additional page(3) for complete text.	5 managadari Name, s	ny ana onata		
	4. Model #	Lot#		5. Operator of Device
		4		Health Professional
	Catalog #	Expiration Dat	te (mm/dd/yyyy)	Lay User/Patient
				Other:
6. Relevant Tests/Laboratory Data, Including Dates	Serial #	Other#		1
	1,000			
	6. If Implanted, Give Date	(mm/dd/yyyy) 7.	If Explanted, C	Give Date (mm/dd/yyyy)
	8. Is this a Single-use De	vies that was Popus	ancead and D	nuced on a Patient?
	Yes No	vice that was kepic	cessed and Ke	rused on a Padent?
	9. If Yes to Item No. 8, Ente	r Name and Address	of Reprocesso	7
7. Other Relevant History, Including Preexisting Medical Conditions (e.g.,				
allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)				
	F. OTHER (CONCO Product names and there	THE RESERVE OF THE PERSON NAMED IN		
See additional page(s) for complete text.	r rouget frames and mera	ib) agree (excinde li	cament or ever	ny
The second of the second secon	1 700 000034340	al page(s)	for cor	mplete text.
	See additiona	The second of th		
	G. REPORTER (See		section on b	ack)
C. PRODUCT AVAILABILITY			section on b	eack)
Product Available for Evaluation? (Do not send product to FDA)	G. REPORTER (See		section on b	
Product Available for Evaluation? (Do not send product to FDA)	G. REPORTER (See		section on b)SS
Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S)	G. REPORTER (See 1. Name and Address (b) (6)	confidentiality		es
Product Available for Evaluation? (Do not send product to FDA) Yes	G. REPORTER (See	confidentiality	section on b)SS
Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) It plame: Hyland's teething tablets	G. REPORTER (See 1. Name and Address (b) (6)	confidentiality	-mail	es
Product Available for Evaluation? (Do not send product to FDA) Yes	G. REPORTER (See 1. Name and Address (b) (6) Phone # (b) (6) 2. Health Professional?	confidentiality	-mail (6))SS JET 23 (
Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label) In plane: Hyland's teething tablets Strength: Hyland's teething tablets	G. REPORTER (See 1. Name and Address (b) (6) Phone # (b) (6)	confidentiality	-mail (6))SS JET 23 20



On (b)(6) at 3:30 am my thirteen month old son had a seizure due from a high fever. Around lam 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.

DSS SEP 23 2015



user-facilities, fors and manufacturers FORY reporting

	Casell beel hourstight of rever
Mfr Report # 54	(3
UF/Importer Repor	t#

A. PATIENT IN		20 mil 15		X1600
Patient Identifier (b) (6)	2. Age at Time of Event:	Months	3. Sex	4. Weight
	or	Months	Female	or
In confidence	Date of Birth:		✓ Male	
B. ADVERSE E	VENT OR PRODU	CT PROBLE	M	417.0
1. Adverse Ever	t and/or Pro	oduct Problem	(e.g., defects/malf	unctions)
2. Outcomes Attribu (Check all that app	ted to Adverse Event			
Death:		Disability	or Permanent Da	mage
Life-threatenin	(mm/dd/yyyy)	Congenit	al Anomaly/Birth D	Defect
Hospitalization	- initial or prolonged	Other Sei	rious (Important M	ledical Ever
Required Inter	vention to Prevent Perm	anent Impairme	nt/Damage (Devic	es)
3. Date of Event (mr		4. Date of Thi	s Report (mm/da	(уууу)
9/1 5. Describe Event or	1/2015		09/15/15	
THE EMERGENCY SEIZURE BY TH	AMBULANCE WAS ROOM AND RELEA E DOCTOR. CUST ASIONS WITH NO	SED. EPIS		SED AS
		R	eceiv	ed
ė.		00	CT 0 5 201	5
			CDR	
			10	
Relevant Tests/Lat	oratory Data Including	n Dates	(Continue on	page 3)
6. Relevant Tests/Lat	oratory Data, Including	g Dates	(Continue on	page :
			(Continue on	
- Other Relevant His race, pregnancy, sm NONE	tory, Including Preexis oking and alcohol use, h	ting Medical Co epatic/renal dys	nditions (e.g., all function, etc.)	ergies,
D:	SS			
OCT 0	6 2015			
			(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.

of 5			-	FDA Use On
C. SUSPECT F	PRODUCT(S) ed strength & mfr/labele	er)		PARTY OF THE
	BABY TEETHING		V	
#2 N/A				
2. Dose, Frequency	& Route Used		rapy Dates	(If unknown, give duration
#1		#1	ino for best	estimate)
#2 N/A		#2		
4. Diagnosis for Us	e (Indication)			Abated After Use
#1 TEMP RELIE	SF TEETHING PA	IN	_ #1 🗸	yes No Does
#2 N/A				Apply
6. Lot #	7. Exp. Date		#2	Yes No Apply
#1B00215	#1			Reappeared After oduction?
#2N/A	#2		#1 🔲	Yes ☐ No ☑ Doesn
9 NDC# or Unique			T	= Does
54973-3127-	·1 edical Products and Th			res No Apply
			(0	Continue on page 3)
D. SUSPECT N	EDICAL DEVICE		The same of	onunue on page 3)
1. Brand Name		25.48.7		
2. Common Device	Name		2b. F	Procode
2 Manufacture No.	0.1			
3. Manufacturer Nar	ne, City and State			
4. Model#	Lot#			5. Operator of Device
Catalog #	Cynivatia	Data /m	es fatalli a u a à	Health Professiona
Catalog #	Expiratio	n Date (mr	n/dd/yyyy)	Lay User/Patient
Serial #	Unique lo	dentifier (U	DI) #	Other:
6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Exp	planted, Giv	re Date (mm/dd/yyyy)
3. Is this a Single-us	se Device that was Rep	processed	and Reuse	d on a Patient?
	8, Enter Name and Ad	Idress of R	eprocessor	
0. Device Available	for Evaluation? (Do no	ot send to F	EDA)	
Yes N	Returned to I	Manufactur	er on:	
1. Concomitant Med	dical Products and Th	erany Date	e (Exclude	(mm/dd/yyyy) treatment of event)
				and an orong
			10	50.W 1 0 0 5 0 5 0 5 0 5 0 5 0 5 0 5 0 5 0 5
E. INITIAL REP	ORTER	100 100	(C	ontinue on page 3)
. Name and Addres	Service State of the Service S			- WSU JANU
b) (6)				
Phone #	Em	ail Address	0	
b) (6)				
-7,5-7				
Health Profession	al? 3. Occupation		4. Ir	nitial Reporter Also Sent Report to FDA



3. User Facility or Im	porter Nam	e/Address	
4. Contact Person		5 Phone	Number
6. Date User Facility Importer Became Aware of Event (m		7. Type of Report Initial Follow-up #	8. Date of This Report (mm/dd/yyyy)
Approximate Age of Device	Patient Code Device Code	Problem Codes (Refer to co	ding manual)
3. Report Sent to Ma Yes (mm/de) No (mm/de) 4. Manufacturer Name	d/yyyy)	Nursing Home Outpatient Treatm Facility Other:	Surgical Facility ent (Specify)
CONTRACTOR OF STREET	Company of the same		2. Phone Number
Contact Office (and Name DYTA FRACKIEW Address YLAND'S, INC. 54 W. 131ST S OS ANGELES, C	Manufactu ICZ TREET A 9006	uring Site for Devices)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional
Name DYTA FRACKIEW Address HYLAND'S, INC. 154 W. 131ST S OS ANGELES, C Email Address STANDARD HYLAN Date Received by Manufacturer (mm/c 09/14/ If IND, Give Protoco	ICZ TREET A 9006 DS.COM dd/yyyy) 15 ol#	uring Site for Devices)	310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer

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 long degenments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DEVICE MANUFACTURERS ONLY	
Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Requ
	Device Evaluation
Device Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary Attached	
No (Attach page to explain why not) or	5. Labeled for Single Use?
provide code:	Yes No
Event Problem and Evaluation Codes (Refer to	anding manual
Patient Patient	coding mandar)
Code	-
Device Code	-
Method -	1-
Results	
Conclusions -	
Repair Inspection Replace Patient Monitoring Relabeling Modification/ Adjustment	Reuse Unknown If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
Additional Manufacturer Narrative a	and / or 11. ☐ Corrected Da

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."

OCT - 5 2015

cc: QA/QC Packaging

BY

REVIEWED BY MANAGEMENT BY

Production Shipping / Receiving DSS DCT 0 6 2015 OCT - 5 2015

Form # VD1





CaseID: 11603023

Iverse Event

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 (b) (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 with in specification of (4) ppm.

Retention Samples:

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

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

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # 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

Date

CC-0748-2015 AE-0427-2015

DSS

OCT - 5 2015



EVENT DATA FORM

AE #:16	42	COMPLAINT #:2652
SECTION I:	PATIENT INFORMATION (IF DIFF	FERENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:	-	
0.774	-	(b) (6)
CITY:	HOA	STATE:
COUNTRY: PHONE #:	USA (b) (6)	ZIP CODE:
E-MAIL:		
SECTION II:	PACKAGING INFORMATION:	
	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
confidence of the confidence o	Teething Tables	Teething Tables Baby Baby Teething Tables Fabrica
SECTION III:	CORRECTIVE ACTION:	■ 職 類 順 三二
CORRECTIVE AC	CTION(S) COMPLETED BY:	DATE:
ECTION IV:		
EVIEWED BY M	IANAGEMENT BY:	STATE 09 32 1-
	Aug Bu	DATE: 09-23-15
Y:	QA / QC DIRECTOR	DATE: 09-23-15

DISTRIBUTION: FDA

ADVERSE EVENT FILE

DSS OCT 06 2015

FORM SAE01



user-facilities, ors and manufacturers FORY reporting

	S e O B statement on revers
Mfr Report # 55/7	120
UF/Importer Report #	
11312 4 92.1	

raye 1 of 5

	DA	114	 2	
- 5	200	US	On	y

A. PATIENT INF					C. SUSPECT PR					Div 2-1
Patient Identifier (b) (6)	2. Age at Time of Event:	Manage	3. Sex 4.	Weight	1. Name (Give labeled		Your m			
-	or	Months	Female _	lbs	#1 HYLAND'S BA	BI TEETHING C	35 L			
in confidence	Date of Birth:		✓ Male	or kgs	#2					
	VENT OR PROD	UCT PROBLE	Л		2. Dose, Frequency &	Route Used		y Dates ((or best e	itf unknown, gi estimate)	ve duration)
Adverse Even	t and/or P	Product Problem (e.	g., defects/malfun	ctions)	#1 FREQUENTLY	X 2 WEEKS	#1			
	ted to Adverse Event				#2		#2			
ik all that appl Death:	y)	☐ Disability o	r Permanent Dama	age.	4. Diagnosis for Use (A		Abated After ed or Dose R	
55	(mm/dd/yyyy)				#1 TEMP RELIEF	SX PAIN, RED	NESS		es V No	Doesn't
Life-threatenin	r - Initial or prolonged		Anomaly/Birth Defi ous (Important Med		#2			=		Apply Doesn't
	vention to Prevent Per				6. Lot #	7. Exp. Date		#2 Y	es No	Apply
ate of Event (mn			Report (mm/dd/yy		#1126288	#1			Reappeared oduction?	After
	00/2015	The second second	09/24/2015	937	#2	#2		aments.	es \ \ No	Doesn't
scribe Event or	The state of the s	Managarah eta 9		4.	9. NDC# or Unique ID					Apply Doesn't
	ITTED TO THE H ROXIMATELY 1.5	THE RESIDENCE OF A SHARE OF THE PARTY OF THE		TAL	54973-7521-2			#2 Y	es No	Apply
ABY TEETHING AS HAD THE SI	ED THAT THEY H GEL FREQUENTI EZIURES. SEIZ RIGHT AFFECTI	LY DURING THE ZURE DIAGNOSE	TIME THE E	PATIENT	D. SUSPECT ME	DICAL DEVICE		(C	ontinue on	page 3)
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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:

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

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.

				LAINT #:	2655		
AKEN BY:	EDYTA FRACKIE	WICZ	DATE OF COM	PLAINT:	09/23/2015		
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	b) (6)						
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ITY	N/A		STATE: (b) (6)			
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cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

Individual Case Safety Report

11614860-01-00-04



CaseID: 11614860

SAE-0054-2015

Product in Inventory:

No units of Hyland's Baby Teething Gel (TGEL), lot #126288, are currently in the Standard Homeopathic Co. (SHC) warehouse. The entire lot, (ID) (4) units, has been distributed.

Review of Records:

The TGEL 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 ≤(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 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.

9/29/2015

Date

OCT - 8 2015

OCT - 7 2015



EVENT DATA FORM



E#: 16	TOTAL AND S	COMPLAINT #: 2655 RENT FROM REPORTER ON FORM VD1)	
AME: DDRESS:	UNKNOWN		
		(b) (6)	
ITY: OUNTRY:	USA	ZIP CODE:	
HONE #:			
-MAIL:	-		
ECTION II:	PACKAGING INFORMATION:		
А	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
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EVIEWED BY	MANAGEMENT BY:	DATE: 10-01-13	

by user-facilities, outors and manufacturers ATORY reporting

	CaseID: 116149	40
Form A	Approved: M. No. 1910, 1291, Exp ee C 1B statem	pires: 6/30/2015 tent on reverse
Mfr Report #		
UF/Importer Repo	ort #	

FORM FDA 3500A (2/13)

Page 1 of 5

Solution Date Of Birth: Solution Disability or Permanent Damage Months Disability or Permanent Damage Disability or Permanent Damage Disability or Permanent Damage Disability or Permanent Medical Events Disability or Per	1 Patient Identifier 2. Age at Time 3 Sex 4. Weight		PRODUCT(S)	ne)	
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B ADVERSE EVENT OF PRODUCT PROBLEM Adverse Event Product Product Product Profice Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Product Prod	Male 1	kgs			
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2. Continue on page 3) Continue on page 3)	Adverse Event and/or Product Problem (e.g., defects/malfunctions)	#1 UNKNOWN			
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Life-eventancing		4. Diagnosis for Us	se (Indication)		
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(Continue on page 3) Relevant Tests/Laboratory Data, Including Dates NKNOWN (Continue on page 3)	Sant Marin S. E.	Catalog #	Expiration	Date (mm/dd/yyyy)	Lay User/Patient
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Relevant Tests/Laboratory Data, Including Dates NKNOWN Yes		0.00		14	
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Yes No No. 8. Enter Name and Address of Reprocessor DS	The state of the s	8. Is this a Single-us	e Device that was Rep	rocessed and Reuse	ed on a Patient?
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CaseID:	11614940
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Check One User Facility	[] Imp	orter	2. 01	F/importer	Keport Nu	imber		1. Ту
3. User Facility or Imp	orter Name	e/Address						
4. Contact Person				5. Phone I	Number			3. Đe
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Date User Facility o Importer Became Aware of Event (mm.)		7. Type of Initial		t		of This Repo	ort	6. Ev
Approximate	10. Event	Problem Co	v-up#_ odes /R	Refer to cod	ina manua	0	_	
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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:

5		FDA USE ONL	
J			
H. DEVICE MANUFA			140-14
. Type of Reportable Eve	nt		up, What Type?
Death		1 =	rection
Serious Injury Malfunction			itional Information
Maildriction			ponse to FDA Request ice Evaluation
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Device Evaluated by Ma		4. Device Ma (mm/yyyy)	nufacture Date
Not Returned to Ma			
	on Summary Attached	5 Labelad 6	
No (Attach page to provide code:	explain why not) or	5. Labeled 10	or Single Use?
		Yes	☐ No
Event Problem and Eval	uation Codes (Refer to	coding manual)	
Patient			
Code			
Device Code	-	-	
Method			
Results		-	-
Conclusions			-L
f Remedial Action Initiat	ed, Check Type	8. Usage of Device	Į.
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Repair	Inspection	Reuse	
_	Patient Monitoring	Unknown	
	Modification/ Adjustment	 If action report 21 USC 360i(f), 	list correction/
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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov
Please DO NOT RETURN this form to the above PRA Staff email address.

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

Case 10: 14/69/2 940 THOMEOPATHIC A MADE IN THE USA SINCE 1903 SECTION I: COMPLAINT COMPLAINT #: 2656 TAKEN BY: **EDYTA FRACKIEWICZ** DATE OF COMPLAINT: 09/23/2015 PRODUCT HYLAND'S BABY TEETHING TABLETS ITEM CODE: BTET SIZE: NOT PROVIDED LOT NO.: NOT PROVIDED (b) (b) REPORTER: ADDRESS: N/A N/A CITY: N/A STATE: N/A COUNTRY: USA ZIP CODE: N/A PHONE # N/A (b) (6) E-MAIL: NATURE OF COMPLAINT: 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 15 MONTHS OLD ON (b) (6) HE HAD 3 PROLONGED SEIZURES. I HAD GIVEN HIM SOME OF THE TEETHING TABLETS ON (b) (6) AND A FEW DAYS AND A FEW DAYS PRECEEDING. WE WERE IN PICU FOR 2 NIGHTS, 3 DAYS. THERE HASN'T BEEN ANY CAUSE FOR THE SEIZURES FOUND NOR HAS HE HAD ANY RECURRENT 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 N PRODUCT BEING RETURNED FOR INSPECTION: INSPECTION: (CIRCLE ONE) (CIRCLE ONE DATE REQUESTED PRODUCT BE RETURNED: N UPS CALL TAG ISSUED: (CIRCLE ONE DATE PRODUCT RECEIVED: SECTION II: 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 SECTION III: CORRECTIVE ACTION: Individual Case DSS 11614940-01-00-03 OCT - 8 2015 SECTION IV: ADVERSE EVENT REPORTS AE#: 1646 ADVERSE EVENT SERIOUS: ADVERSE EVENT REPORTED ON: 09/23/2015 **EDYTA FRACKIEWICZ** SECTION V: REVIEWED BY MANAGEMENT BY BY

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 11614940

SAE-0055-2015

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-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 $\leq_{(4)}^{(5)}$ 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.

Prepared by

Mille

Date

Reviewed by

10/1/2015

10/01/15

Date

DSS

OCT - 8 2015

OCT - 7 2015





SERIOUS ADVERSE EVENT DATA FORM

SECTION I:	PATIENT INFORMATION (IF DIFFER	RENT FROM REPORTER ON FORM VD1)	
	(b) (6)	SELL LIGHT ON LONG VOIL	
NAME:	70.4		-
ADDRESS:			-
CITY:		STATE:	
COUNTRY:	USA	ZIP CODE:	_
PHONE #:	(b) (6)		
E-MAIL:	-		_
SECTION II:	PACKAGING INFORMATION:		
A	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE	
	The state of the s	(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
	Facturing lablets	(Malarati)	
3		G177	
Į		Toothing Tablets	
	manni	Carlo and Carlo	
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SECTION III:	CORRECTIVE ACTION:		
vidual Ca:	se Safety Report		
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11614			
	CTION(S) COMPLETED BY:	DATE	OCT
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	CTION(S) COMPLETED BY:	DATE:	_ OC1 _

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

amer Report

Y reporting of ...uct problems and product use errors

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

CaseID: 11628084

FDA USE ONLY Triage unit sequence # 1019/81

Adverse Event Reporting Program

1715 STEAL THE						_	Cel7		
	INFORMATION			· · · · · · · · · · · · · · · · · · ·	2. Dose or Am	ount	Frequency	Route	
	er 2. Age at Time of Date of Birth:	f Event or	3. Sex	4. Weight	#1		1	Taken b	y mouth
) (6)	6 Months		✓ Female	18 _{lb}					
	(b) (6)		Male	or to	#2				
In confidence				kg					
B. ADVERS	E EVENT, PROD	DUCT PR	OBLEM OR E	RROR	3. Dates of Use ((or best estima		give duration) from		Abated After Use for Dose Reduced?
heck all that appl	-			C-2	#1 09/24/2015		/2015	1000	es No Doesi
✓ Adverse Ev			g., defects/malfun		#2				Apply
Product Use	e Error Problem	with Differe	ent Manufacturer	of Same Medicine			las dadisation	#2 N	es No Does
Check all that	ributed to Adverse E	Event			4. Diagnosis or F #1 My 6 mont			8. Event	Reappeared After
Death:		☑ Disa	bility or Permanen	t Damage	7 5 50 7 550				roduction?
	(mm/dd/yyyy)				#2			#1 \ \ Y	es No Doesr
✓ Life-threater	ning	Cong	genital Anomaly/Bi	rth Defect		15		#2 TY	es No Does
✓ Hospitalizati	ion - initial or prolonge	ed Othe	r Serious (Importa	nt Medical Events)	6. Lot # #1		LExpiration Date	#2	Apply
Required Int	tervention to Prevent	Permanent	Impairment/Dama	ge (Devices)	-	-		9. NDC	# or Unique ID
Date of Event	(mm/dd/yyyy)	4. Dat	e of this Report (mm/dd/yyyy)	#2		2		
09/27/201	5	10/	09/2015		E. SUSPECT	MEDICA	L DEVICE		
Describe Even	it, Problem or Produ	uct Use Erro	or		1. Brand Name				
									page 1
					2. Common Devi	ce Name			CIU .
								5.5	
								00	1 3 2015
see addi	tional pag	e(s) f	or comple	ete text.	3. Manufacturer	Name, City a	and State		
					4. Model #		Lot#		5. Operator of Device
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see addi	tional pag	e(s) f	or comple	ete text.	900 900	1.00			
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					9. If Yes to Item N	o. 8, Enter Na	ame and Address o	f Reprocessor	
	t History, Including								
allergies, race,	pregnancy, smoking	and alcohol	use, liver/kidney p	roblems, etc.)					
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والمامم مما	rional was	0101 E	or ocme1.	ata taut	Product names a	nd therapy	dates (exclude trea	atment of even	t)
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	PRODUCT(S)				Phone #		E-m	all	9 (
	h, Manufacturer (fro				(b) (6)		(b) (6		
Strength: Hyl	hing tablets a	ind gel	Hylanas						
Manufacturer	ands				2. Health Profess	ional? 3. O	ccupation	4	Also Reported to:
					☐ Yes ☐ N				Manufacturer
Name:				1					
Name: Strength:					5. If you do NOT v		ntity disclosed		User Facility



11628084-01-00-02

My 6 month was given both hylands teething tablets and the gel. A few days later she started to displays clusters of a 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 diagnosed with infantile spasms on the morning of (b)(6)

(b)(6) she had an MRI which came back normal. It is (b)(6) hospital waiting for blood and urine test results

She was given and eeg and Later that day (b)(6) and we are still in the

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



user-facilities, ors and manufacturers ORY reporting

/		statement on revi
13		
rt#		
	ort#	ort #

FURIVI FUA SOUUA (ZI ISI

		4	- 5	5
t	uyu	-1	OI	2

A. PATIENT INF	ORMATION			C. SUSPECT PRO	DUCT(S)		FDA Use O
Patient Identifier	2. Age at Time	3. Sex	4. Weight	1. Name (Give labeled str)	
(b) (6)	of Event: CHILD	Female	lbs	#1 HYLAND'S BAB	Y TEETHING T	ABLETS	
In a second	Date	✓ Male	or	#2			
In confidence	of Birth: VENT OR PRODUCT PRO		kgs	2. Dose, Frequency & R	oute Used	3. Therapy Dates	(If unknown, give duratio
			_	#1 UNKNOWN		from/to (or best	estimate)
Adverse Even	t and/or Product Prol ted to Adverse Event	blem (e.g., defects/malf	functions)	#2		#2	
(Check all that appl				4. Diagnosis for Use (Inc	dication)		Abated After Use
Death:	(mm/dd/yyyy) Dis	ability or Permanent Da	mage	#1 TEMP RELIEF T		Stopp	ed or Dose Reduced?
Life-threatenin	g Cor	ngenital Anomaly/Birth D	Defect	#2		#1 📋	Yes ☐ No ☑ Does Appl
		ner Serious (Important M		6. Lot #	7. Exp. Date	#2 🔲	Yes No Does
	vention to Prevent Permanent Imp			#1	#1		Reappeared After
3. Date of Event (mn	7/2015	of This Report (mm/dd 10/01/2015		#2	#2		roduction?
Describe Event or			-	9. NDC# or Unique ID			Apply
	ED IN AN E-MAIL THAT E HE HAS BEEN TAKING		1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	54973-3127-3		#2 🔲	Yes No Does
	Recei OCT 15	2015		Brand Name Common Device Nam	е	2b. I	Procode
	CDD			3. Manufacturer Name, 0	City and State	'	
	SOU			4. Model #	Lot#		5. Operator of Device
				0-1-1#			Health Profession
				Catalog #	expiration	Date (mm/dd/yyyy)	Lay User/Patient
				Serial #	Unique Ide	entifier (UDI) #	Other:
		(Continue or	n page 3)	6. If Implanted, Give Date	e (mm/dd/yyyy)	7. If Explanted, Gi	ve Date (mm/dd/yyyy)
Relevant Tests/Lat JNKNOWN	poratory Data, Including Dates			8. Is this a Single-use De	evice that was Rep	rocessed and Reuse	ed on a Patient?
311111121111				9. If Yes to Item No. 8, E	nter Name and Add	dress of Reprocesso	r
				10. Device Available for	Evaluation? (Do no	ot send to FDA)	
				Yes No	Returned to M	Manufacturer on:	(mm/dd/yyyy)
		(Continue or	n page 3)	11. Concomitant Medica	Products and The	erapy Dates (Exclude	
7. Other Relevant His	itory, Including Preexisting Med noking and alcohol use, hepatic/rei		, 0				
INKNOMN		, , , , , , , , , , , , , , , , , , , ,				(0	Continue on page 3)
				E. INITIAL REPOR	TER		
			1	1. Name and Address (b) (6)			DSS
							000
							OCT 16 2015
				Phone #	I Fm:	ail Address	
		(Continue or	n page 3)	The state of the s	(b) (d		
ubmission of a re	eport does not constitute a	an admission that	medical		3. Occupation		Initial Reporter Also Se Report to FDA
aused or contrib	uted to the event.	.,a.ia.ia.ia.iai oi	product	Yes V No	NA		Yes No V Un

							CaseID: 1163954
f 1 Check One)-Ü2 er Report Number	DEVICE MANUE	FACTURERS ONL'	2. If Follow-up, What Type?
User Facility 3. User Facility or Im		orter e/Address			Death Serious Injury Malfunction		Correction Additional Information Response to FDA Rec
Contact Person Date User Facility Importer Became	or	7. Type of Rep		8. Date of This Report			4. Device Manufacture Date (mm/yyyy) 5. Labeled for Single Use? Yes No
Aware of Event (n		Initial Follow-up Problem Codes			6. Event Problem and Event Problem Code	valuation Codes (Refer t	
Age of Device	Patient Code Device Code]- -		Device Code Method		1
13. Report Sent to M	DA? dd/yyyy) anufacturer?	Hosp Home	ital e ing Home atient Treat ity	ent Occurred Outpatient Diagnostic Facility Ambulatory Surgical Facility ment (Specify)	Results Conclusions 7. If Remedial Action Ini Recall Repair Replace Relabeling Other:	tiated, Check Type Notification Inspection Patient Monitoring Modification/ Adjustment	8. Usage of Device Initial Use of Device Reuse Unknown 9. If action reported to FDA unde 21 USC 360i(f), list correction/ removal reporting number:
G. ALL MANUF 1. Contact Office (ar Name EDYTA FRACKIE Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address STANDARD@HYLA 4. Date Received by Manufacturer (mn	MICZ STREET EA 9006 NDS.COM	1 5. (A)NDA#_	evices)	2. Phone Number 310-768-0700 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor	10. Additional Manu	facturer Narrative	and / or 11. Corrected
Date Received by Manufacturer (mn	n/dd/yyyy) 2015			Company Representative			

5-day 7-day

7. Type of Report (Check all that apply)

30-day Periodic ✓ Initial 10-day

Follow-up # √ 15-day 9. Manufacturer Report Number 54973 AE # 1648

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

BLA# PMA/ 510(k) #

Combination Product

OTC Product

SEIZURES

8. Adverse Event Term(s)

Pre-1938

Yes

Yes

√ Yes

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

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 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.

DSS

OCT 16 2015

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

IN I KECOKD

CaseID: 11639546

	11639546-01-00-03	COM	PLAINT #:	2658
	11000040-01-00-03	DATE OF CO	MPLAINT:	09/27/2015
PRODUCT:	HYLAND'S BABY TEETHING TABLETS	ITE	M CODE:	BTET
SIZE:	NOT PROVIDED		LOT NO.:	NOT PROVIDED
REPORTER:	(b) (6)			
ADDRESS	N/A			
	N/A			
CITY:	N/A	STATE:	N/A	
COUNTRY:	USA	ZIP CODE:	N/A	
PHONE #:	N/A			
E-MAIL:	(b) (6)			
NATURE OF CO	MPLAINT:			
PRODUCT RECEINSPECTION:		PRODUCT BEING RETURN DATE REQUESTED PR	RATE SHE	NSPECTION: Y (CIRCLE ONE)
			UPS CALL 1	'AG ISSUED: (CIRCLE ONE)
		DATE	PRODUCT	RECEIVED:
SECTION II:	INVESTIGATION			
ADVERSE EVEN	PLEASE SEE ATTACHED INSPECTION R		09/27/2015	6
ADVERSE EVEN	T FORWARDED TO PHARMACIST / NURSE FOR EVA	LUATION BY:	EDYTA FR	ACKIEWICZ
SECTION III:	CORRECTIVE ACTION:			
CORRECTIVE AC	CTION(S) COMPLETED BY:	-	DATE:	
SECTION IV:	ADVERSE EVENT REPORTS		AE #:	1648
ADVERSE EVEN ADVERSE EVEN SECTION V:	T SERIOUS: Y / N T REPORTED ON: 09/27/2015	BY: EDY	TA FRACKIE	EWICZ
	MANAGEMENT BY	Walt	DATE:	10-07-15
BY:	QA/QC DIRECTOR		DATE: _	10-06-15

cc: QA/QC Packaging

Production Shipping / Receiving

Form # VD1





CaseID: 11639546

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 $\leq_{(4)}^{(b)}$ 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

10/5/15

DSS 0CT 16 2015



VENT DATA FORM

CaseID: 11	639546
muanas	,

AE #: 1648		COMPLAINT #: 2658	
SECTION I:	PATIENT INFORMATION (IF DIFF	FERENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:			
CITY;		STATE:	
COUNTRY:	USA	ZIP CODE:	
PHONE #:	b) (6)		_
SECTION II:	PACKAGING INFORMATION:		
MFFIX Market Ma	PACKAGING LABEL HERE THE STATE OF THE STATE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
SECTION III:	CORRECTIVE ACTION:		_
0			_
CORRECTIVE ACTION	ON(S) COMPLETED BY:	DATE:	
SECTION IV:			DSS
REVIEWED BY MAN	AGEMENT BY:	DATE: 10-07-15	OCT 16 2015
BY:	Eve Bain	DATE: 10-06-15	Esc.
	QA / QC DIRECTOR		



by user-facilities, outors and manufacturers ATORY reporting

	CaseID 11658849
Afr Report # 5497	3
JF/Importer Report	-

Je 1 of 5

FDA Use Only

A. PATIENT INF Patient Identifier (6)	NOT THE REAL PROPERTY OF THE PA	3. Sex 4. Weight	1. Name (Give labeled so #1 HYLAND'S BAB		ABLETS	
	or	Female or	#2			
In confidence	Date of Birth:	Male kg:		Route Used	3. Therapy Dates	If unknown, give duration
	VENT OR PRODUCT PROBL	EM	#1 UNKNOWN		from/to (or best e	estimate)
Adverse Even	t and/or Product Problem	(e.g., defects/malfunctions)	#1 0141040444		-	
Outcomes Attribut	ted to Adverse Event		#2	edia etio el	#2	Abated After Use
(Check all that appl Death:		y or Permanent Damage	4. Diagnosis for Use (In		Stopp	ed or Dose Reduced?
E vita de contrata	(mm/dd/yyyy) Conger	ital Anomaly/Birth Defect			#1	App
		erious (Important Medical Events	6. Lot #	7. Exp. Date	#2	Yes No App
	rvention to Prevent Permanent Impairm	ent/Damage (Devices)	#1	#1		Reappeared After
B. Date of Event (mr	m/dd/yyyy) 4. Date of T	his Report (mm/dd/yyyy)		#2		roduction? Yes No V App
10/0	06/2015	10/07/2015	#2 9. NDC# or Unique ID	#2		
5. Describe Event or	Problem HILD'S FACE BECAME FLUS	HED RED AND CHILD	54973-3127-3		#2	Yes No App
TEETHING TABL					(Continue on page 3
	RECEIVE	D	D. SUSPECT ME 1. Brand Name	DICAL DEVICE		
	OCT 2 2 2015		2. Common Device Na	me	2b.	Procode
			3. Manufacturer Name	e, City and State		
	CDR		4. Model #	Lot#		5. Operator of Devi
			Catalog #	Expiratio	n Date (mm/dd/yyyy)	Health Profess
			Serial #	Unique lo	dentifier (UDI) #	Other:
		(Continue on page 3)	6. If Implanted, Give I		4	Give Date (mm/dd/yyyy)
6. Relevant Tests/L	aboratory Data, Including Dates		8. Is this a Single-use		processed and Reus	sed on a Patient?
UNKNOWN			9. If Yes to Item No. 8		ddress of Reprocess	sor
			10. Device Available		not send to FDA) Manufacturer on:	(mm/dd/yyyy)
7 Other Relevant I	History, Including Preexisting Medica	(Continue on page 3)	11. Concomitant Med	ical Products and T	herapy Dates (Excluded 2 2 2015	de treatment of event)
race, pregnancy, UNKNOWN	History, Including Preexisting Medic smoking and alcohol use, hepatic/rena	dysfunction, etc.)	E. INITIAL REPO		Margaret o	(Continue on page
	Doo	7			a.	ca
	DSS	1			- 4/	1 A
	DSS 0CT 23 2015	(Continue on page 3)	Phone # (b) (6)	E	mail Address	4. Initial Reporter Als



User Facility User Facility or Im	impó		
Contact Person		5. Phone No	umber
Date User Facility Importer Became Aware of Event (n		7. Type of Report Initial Follow-up #	8. Date of This Report (mm/dd/yyyy)
Approximate Age of Device	Patient Code Device	Problem Codes (Refer to codii	ng manual)
No Report Sent to M	dd/yyyy)	12 Location Where Event of Hospital Home Nursing Home Outpatient Treatmer Facility Other:	Outpatient Diagnostic Facility Ambulatory Surgical Facility
G. ALL MANUF	ACTURE	RS	
Name		ring Site for Devices)	2. Phone Number 310-768-0700
Address HYLAND'S, INC 154 W. 131ST LOS ANGELES, Email Address	STREET	1	3. Report Source (Check all that apply) Foreign Study Literature Consumer
STANDARD®HYLA Date Received by Manufacturer (mi 10/06/6. If IND, Give Protection of Report	7 n/dd/yyyy) 2015 col#	5. (A)NDA# IND# BLA# PMA/ 510(k)#	Health Professional User Facility Company Representative Distributor Other:
	l-day priodic itial bllow-up#	Combination Product Yes Pre-1938 Yes OTC Product Yes	
9. Manufacturer Re	port Number	 Adverse Event Term(s FLUSHED FACE, DI 	

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:

	- 4	=	
١.	nf		

DEVICE MANUFACTURERS ONLY	2. If Follow-up, What Type?
ype of Reportable Event	Correction
Death Serious Injury	Additional Information
Serious Injury Malfunction	Response to FDA Request
Manufiction	Device Evaluation
evice Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary Attached	
No (Attach page to explain why not) or	5. Labeled for Single Use?
provide code:	Yes No
event Problem and Evaluation Codes (Refer to	— coding manual)
Patient Code	-
Device	
Code	
Method -	
Results	1
Conclusions	
f Remedial Action Initiated, Check Type	8. Usage of Device
Recall Notification	Initial Use of Device
Repair Inspection	Reuse
Replace Patient Monitoring	Unknown
	9. If action reported to FDA under
Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:	
Additional Manufacturer Narrative	and / or 11. Corrected Data
	OCT 2 2 2015
	4)
	4)
	OCT 2 2 2015 OSS 23 2015

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."

PRAStaff@fda.hhs.gov valid OMB control numb
Please DO NOT RETURN this form to the above PRA Staff email address.



11	658849-01-0	0.02				
	26270717637	0-03	DATE OF COI	MPLAINT:	10/06/2015	
PRODUCT	HYLAN	ND'S BABY TEETHING TABLETS	ITE	M CODE:	BTET	
SIZE:	UNKN	OWN		LOT NO.	UNKNOWN	
REPORTER:	(b) (6)					
ADDRESS:	REFUSED TO F	PROVIDE				
	N/A					
CITY:	REFUSED TO	PROVIDE	STATE:	REFUSED	TO PROVIDE	
COUNTRY:	USA		ZIP CODE:	REFUSED	TO PROVIDE	
PHONE #:	(b) (6)					
E-MAIL:	N/A	CUSTOMER (MOTHER) CALLED TO		W D) G E A O E	DECAME FILIS	JED BED AND THAT
I ASKED HOW TH TODAY AND INFO MOTHER ALSO F DISCUSSED. I E CURRENT INFOF TEETHING TABLI ADDRESS, NAME FROM HER LAW SHE WANTS TO	IER STATES SHE BR HE CHILD WAS DOIN ORMED HER THE TA REPORTS VIEWING / EXPLAINED THE FDA RMATION. REGARDL ETS LAST MONTH A E OF CHILD, PRODU YERS. KNOW WHY THE PR THE COMPANY	THE CHILD WAS HARDLY BREATH TOUGHT THE CHILD TO THE HOSPING, SHE HESITATED, AND DID NOT BLETS CONTAINED TWICE THE AIR A VIDEO POSTED ON THE FDA WE VIDEO WAS PREPARED AND LAURESS OF MY EXPLANATION, SHE IND FOUND ISSUES WITH IT. CUST CT INFORMATION, NAME OF HOSPING CODUCT IS STILL ON THE SHELF BUT ADDITIONAL SPACE PLEASE US	TAL (D) (6) WHERE CHILD WAS A RESPOND. MOTHER STATES THE MOUNT OF BELLADONNA STATED BSITE WHERE THE RISK AND DAI NICHED IN 2010 DURING THE TIME ISTED THE VIDEO WAS CURRESOMER REFUSED TO PROVIDE AN PITAL, ETC. CUSTOMER STATED EING SOLD AND WANTS TO SPEAR	ADMITTED F E CHILD'S D O ON THE LA NGERS OF E OF THE RE NT AND THA I'V ADDITION I'D HAVE TO	OR FURTHER E JOCTOR TESTEI ABEL. THE TEETHING ECALL AND THA AT THE FDA TES NAL INFORMATI O OBTAIN THAT	TABLETS WERE TIT IS NOT STED THE ON INCLUDING HER INFORMATION
PRODUCT RECE	EIVED FOR	Y	PRODUCT BEING RETUR	RNED FOR I	NSPECTION:	Y (N)
INSPECTION:		(CIRCLE ONE)	DATE REQUESTED PR	ODUCT PE	DETI IDNED	(CINCLE ONE)
					TAG ISSUED:	(CIRCLE ONE)
SECTION II:	INVESTIGA	TION	DAT	E PRODUC		
		SEE ATTACHED INSPECTION REP	77.	E PRODUC		
SECTION II: INVESTIGATION	: PLEASE		ORT.	10/06/201		
INVESTIGATION	: PLEASE	SEE ATTACHED INSPECTION REP	ORT. JATION ON:		5	
INVESTIGATION	T FORWARDED TO	SEE ATTACHED INSPECTION REP	ORT. JATION ON:	10/06/201	5	
ADVERSE EVEN ADVERSE EVEN SECTION III:	T FORWARDED TO	SEE ATTACHED INSPECTION REP PHARMACIST / NURSE FOR EVALU PHARMACIST / NURSE FOR EVALU CTIVE ACTION:	ORT. JATION ON:	10/06/201	5	OCT 2 2
ADVERSE EVEN ADVERSE EVEN SECTION III:	T FORWARDED TO CORRECT CTION(S) COMPLETE	SEE ATTACHED INSPECTION REP PHARMACIST / NURSE FOR EVALU PHARMACIST / NURSE FOR EVALU CTIVE ACTION:	ORT. JATION ON:	10/06/201 CATHERII	5	
ADVERSE EVEN ADVERSE EVEN SECTION III: CORRECTIVE AC	T FORWARDED TO CORRECT CTION(S) COMPLETE ADVERSE E	SEE ATTACHED INSPECTION REP PHARMACIST / NURSE FOR EVALU PHARMACIST / NURSE FOR EVALU CTIVE ACTION: ED BY:	ORT. JATION ON:	10/06/201 CATHERII	5 NE DOW	
ADVERSE EVEN SECTION III: CORRECTIVE AC SECTION IV: ADVERSE EVEN ADVERSE EVEN	T FORWARDED TO CORRECT CTION(S) COMPLETE ADVERSE E	PHARMACIST / NURSE FOR EVALUATIVE ACTION: ED BY: EVENT REPORTS	ORT. JATION ON: JATION BY:	10/06/201 CATHERII	5 NE DOW	
ADVERSE EVEN ADVERSE EVEN SECTION III: CORRECTIVE AC SECTION IV: ADVERSE EVEN	T FORWARDED TO CORRECT CONCS) COMPLETE ADVERSE E	PHARMACIST / NURSE FOR EVALUED BY: EVENT REPORTS SEE ATTACHED INSPECTION REPORTS PHARMACIST / NURSE FOR EVALUED BY: EVENT REPORTS	ORT. JATION ON: JATION BY:	DATE: AE #:	5 NE DOW	DSS OCI 23

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1





CaseID: 11658849

SAE-0058-2015

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 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 $\leq_{(4)}^{(5)}$ 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.

Reviewed by

Date

OCT 2 2 2015

DSS 0CT 23 2015



EVENT DATA FORM

#: 16	49	COMPLAINT #:2659
CTION I:	PATIENT INFORMATION (IF DIFFE	ERENT FROM REPORTER ON FORM VD1)
ME:	(b) (6)	
DRESS:		
JRESS.		
Y:		STATE:
JNTRY:	USA	ZIP CODE:
ONE #:	(b) (6)	
AIL:		
CTION II:	PACKAGING INFORMATION:	
	THE PACKAGING LABEL HERE THE PACKAGING LABE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
CTION III:	CORRECTIVE ACTION:	
		OCT 2 2 20
RRECTIVE	ACTION(S) COMPLETED BY:	DATE:
CTION IV:		1011
CHON IV.	2	2/N/f
VIEWED B	Y MANAGEMENT BY:	DATE: 10-09-15 OCT 23
	Juna Three	11 10-09-15 DCT 23
:	QA / QC DIRECTOR	DATE: 10 0 1 50

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.

facilities, nd manufacturers	Mfr Report #	No.			
Y reporting	UF/Importer Re	eport #			
5					CDA 16 - 5
C. SUSPECT PRO	DUCT(S)				FDA Use Onl
. Name (Give labeled st	trength & mfr/labeler)				
#1 HYLAND'S BAB	Y TEETHING TA	ABLETS			
#2					
Dose, Frequency & R	Route Used		apy Dates (i		give duration)
#1 UNKNOWN		#1			
#2		#2			
Diagnosis for Use (In				Abated Afte	
#1 TEMP RELIEF	TEETHING PAIN		1,11,11	es No	Doesn's
#2			#2 TY	es 🗆 No	Doesn'
Lot#	7. Exp. Date				Apply After
#1	#1	-		Reappeared oduction?	
#2	#2		#1 🗆 Y	es No	Ooesn's
54973-3127-3			#2 🗆 Y	es No	Doesn's
0. Concomitant Medica	al Products and The	rapy Date	s (Exclude)	realment of	
			2b. P	rocode	
Manufacturer Name,			2b. P	rocode	
Manufacturer Name,			2b. P	5. Operator	
Manufacturer Name,	City and State	Date (mm		5. Operator	Professional
Manufacturer Name, Model # Catalog #	City and State Lot # Expiration		v(dd/yyyy)	5. Operator	
Manufacturer Name,	City and State		v(dd/yyyy)	5. Operator	Professional
Manufacturer Name, Model # Catalog # Serial #	City and State Lot # Expiration Unique Ide	ntifier (UC	√dd′yyyy) Dij#	5. Operator	Professional ser/Patient
Manufacturer Name, Model # Catalog # Serial # If Implanted, Give Date	Lot # Expiration Unique Ide	ntifier (UC	v/dd/yyyy) DI) # Ilanted, Giv	5. Operator Health Lay Us Other:	Professional ser/Patient dd/yyyy)
Manufacturer Name, Model # Catalog # Serial # If Implanted, Give Dat Is this a Single-use D Yes No	Lot # Expiration Unique Ide Ie (mm/dd/yyyy) evice that was Repr	7. If Exp	old/yyyy) Ol) # Ilanted, Given	5. Operator Health Lay Us Other:	Professional ser/Patient dd/yyyy)
Manufacturer Name, Model # Catalog # Serial # If Implanted, Give Dat Is this a Single-use D Yes No	Lot # Expiration Unique Ide Ie (mm/dd/yyyy) evice that was Repr	7. If Exp	old/yyyy) Ol) # Ilanted, Given	5. Operator Health Lay Us Other:	Professional ser/Patient dd/yyyy)
Manufacturer Name, Model # Catalog # Serial # If Implanted, Give Dat Is this a Single-use D Yes No	Lot # Expiration Unique Ide Ie (mm/dd/yyyy) evice that was Repr	7. If Exp	old/yyyy) Ol) # Ilanted, Given	5. Operator Health Lay Us Other:	Professional ser/Patient dd/yyyy)
Manufacturer Name, Model # Catalog # Serial # If Implanted, Give Dat Is this a Single-use D Yes	Lot # Expiration Unique ide ie (mm/dd/yyyy) evice that was Repr	7. If Expocessed a	v/dd/yyyy) DI) # Illanted, Giv	5. Operator Health Lay Us Other:	Professional ser/Patient dd/yyyy)
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User racing						- 1						Corre		_
3. User Facility or Impo	orter Name/	Address					Serious						ional Info	
						\perp	Malfun	ction				= '		DA Request
						1 L							e Evalua	(IOI)
							B. Device Eval	uated by I	Manufacture	?		evice Mai	nufacture	Date
			5 Bt			41			Manufacturer			,,,,,		
4. Contact Person			5. Phone N	umber			Yes		ation Summa	-	5.1	abeled for	r Cinalo	lleo?
6. Date User Facility or	. 17	7. Type of Repor	t	8. Date	of This Report	-	☐ No (Aft provide	acn page e code:	to explain wh	y not) or		_	_	
Importer Became Aware of Event (mm/		_	-	(mm/	dd/yyyy)	\mathbf{I}						Yes		No
		Initial				1 6	6. Event Proble	em and Ev	valuation Co	des (Refer to	coding	manual)		
9. Approximate	10 Event P	Follow-up #	Pafar to codi	no manus	M	41		Patient		7_		 _		
Age of Device	_	TODIGIT COURS (mg manoc	" <i>,</i>	_		Code Device				-		=
	Patient Code		·[]-				Code	L	- _		-L		
	Device Code	-				1		Method]_	7-		-	
11. Report Sent to FDA		12. Location W	here Event	Occurred	1	1		Results]_	<u> </u>	一		=
Yes		☐ Hospita	ı		utpatient iagnostic Facility	\mathbf{I}		· (courto		J	⊣ 누	=		
No (mm/dd/)	yyyy)	Home			mbulatory		Con	clusions]-[- L			
13. Report Sent to Manu	ufacturer?	Nursing Outpatie	Home ent Treatmer		urgical Facility	7	. If Remedial	Action Init	tiated, Check	Туре	8. Usag	e of Devic	e	
Yes(mm/dd/)	anna)	Facility	siit i realiiiei				Recall		Notification	,		Initial Us	e of Devi	ce
□ No (IIIIIIIIIII)	yyyy)	Other: _		(Speci	<i>₩</i>	-1 1	Repair		Inspection			Reuse		
14. Manufacturer Name	/Address	L		(0)000	.,,,	H	Replac	е [Patient Mo			Unknown		
						11	Relabe	ling	Modification Adjustment	n/ t	9. If acti	ion report C 360i(f),	list corr	A under ection/
							Other:				remo	val report	ing num	Jer:
						1 1	0. Additio	nal Manu	facturer Nam	ative	and / or	11.	Cor	rected Data
G. ALL MANUFAC	CTURER	S					_						_	
Contact Office (and it	Manufactur	ing Site for Devi	ces)	2. Phor	ne Number	٦ ۱								
Name EDYTA FRACKIEWI	C7			310-7	68-0700	\prod								
Address		Nata-			ort Source ck all that apply)									
HYLAND'S, INC.				For	eign	11								
154 W. 131ST ST				Stu	dy									
Los Angeles, ca	90061			Lite										
Email Address				✓ Cor										
STANDARD@HYLAND	S.COM				alth Professional									
Date Received by Manufacturer (mm/dd.	t/vvvv)	5.		1-	r Facility									
10/14/20		(A)NDA #		Con Rep	resentative	11								
6. If IND, Give Protocol		IND#	****		ributor									
		BLA#		Oth	er:									
7. Type of Report		PMA/ 510/k)#				-								
(Check all that apply)		510(k) # Combination												
5-day 30-day		Product	Yes			-								
7-day Periodi	NC	Pre-1938	Yes			-								
10-day / Initial	-up #	OTC Product	✓ Yes			-						Table 1	Ī	oss
9. Manufacturer Report		8. Adverse Eve	ent Term(s)	L	-	+ $+$						Marie		
54973 AE # 165	0	SEIZURES											OCT	29 21
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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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

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

OCT 2 9 20 5

CaseID: 11683168

Individual Case Safety Report



SIZE: REPORTER: ADDRESS: CITY: COUNTRY: PHONE #: E-MAIL: NATURE OF CO	THESE TABLETS MY CHILD HAS BEEN HAVING SEIZURES.	STATE: <u>N/A</u> ZIP CODE: <u>N/A</u> -MAIL AND DID NOT RESPOND TO HYLA	NOT PROVIDE	
PRODUCT RECI INSPECTION:	FOR ADDITIONAL SPACE PLEASE USE F	PRODUCT BEING RETURNED FOR DATE REQUESTED PRODUCT BE	INSPECTION:	(CIRCLE ONE)
SECTION II:	INVESTIGATION PLEASE SEE ATTACHED INSPECTION REPORT	DATE PRODUC	TAG ISSUED:	(CIRCLE ONE)
	IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION IT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION: CORRECTIVE ACTION:	NATION OF THE PARTY.	5 RACKIEWICZ	
CORRECTIVE AC	CTION(S) COMPLETED BY: ADVERSE EVENT REPORTS	DATE:	1650	
ADVERSE EVEN ADVERSE EVEN SECTION V:		BY: EDYTA FRACK DATE: DATE:	IEWICZ	

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

CaseID: 11683168





11683168-01-00-04

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 ≤ (a) 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

10/19/2015

Date

DSS OCT **2 9** 2015

683168

11683168-01-00-05

AFORM

AE #: 10	5U	COMPLAINT #: 2660	
SECTION I:	PATIENT INFORMATION (IF DIFF	ERENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:			
v354 ii		Natiba	
COUNTRY:	USA	STATE: ZIP CODE:	
PHONE #:		ZII GODE.	
E-MAIL:	(b) (6)		
SECTION II:	PACKAGING INFORMATION:		
A	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)	
	Section 1 and 1 an	(topland)	
	Section 1		
		CENTING COLORS C	
SECTION III:	CORRECTIVE ACTION:		
SECTION III.	GUNEETTE ACTION.		
CORRECTIVE	ACTION(S) COMPLETED BY:	DATE:	
SECTION IV:		1111	Dec
REVIEWED BY	MANAGEMENT BY:	DATE: 10-20-15 OC	700
	a. M	M DATE: 10-20-15	29 20
BY:	QA / QC DIRECTOR	DATE: 10 XV 13	

user-facilities, tors and manufacturers TORY reporting

Form Approved	Sel De	1169	9938	2015 erse.
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UF/importer Report #	1	10		7
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A. PATIENT INFOR	RMATION	mana.		C. SUSPECT PRO			
	Age at Time	3. S	ex 4. Weight	1. Name (Give labeled stre			
(6) (6)	of Event: 3	Months V	Female lbs	#1 HYLAND'S BABY	TEETHING I.	ABLEIS	
	Date] Male	#2			
	of Birth:	T DROPLEM	kgs	2. Dose, Frequency & Ro	oute Used	3. Therapy Dat from/to (or be	es (If unknown, give duration) est estimate)
B. ADVERSE EVEN				#1 UNKNOWN		#1	4 44 44 44
1. Adverse Event		uct Problem (e.g., a	efects/malfunctions)	#2		#2	
Outcomes Attributed t (Check all that apply)	to Adverse Event			4. Diagnosis for Use (Inc	ication)		ent Abated After Use
Death:	mm/dd/yyyy)	Disability or Per	manent Damage	#1 TEMP RELIEF T	EETHING PAI	N .	opped or Dose Reduced? Yes No Doesn't
Life-threatening			maly/Birth Defect	#2			Apply Doesn't
Hospitalization - in	and the second s		Important Medical Events)	6. Lot#	7. Exp. Date	#2 [Yes No Apply
	tion to Prevent Permar			#1	#1		ent Reappeared After eintroduction?
3. Date of Event (mm/dd	33347	4. Date of This Rep	ort (mm/dd/yyyy) 30/2015	#2	#2		Tyes T No T Doesn't
09/03/	4 /24	107	30/2013	9. NDC# or Unique ID			— — Doesn't
5. Describe Event or Pro MOTHER REPORTED (b) (6) OR (b) (6)	THAT CHILD WA		REALLY WEIRD ON HILD WAS TAKEN	54973-3127-3 10. Concomitant Medica			Yes No Apply
WEEK. CURRENTLY A FOLLOW UP APPO FEVER OF 102 DEC HOSPITAL ATTRIBUTE CARE THE CHILD TO	OINTMENT WITH GREES WHEN THE UTED SEIZURES	A NEUROLOGIS E SEIZURES OC TO THE LEVEL	CURRED.	D. SUSPECT MED	ICAL DEVICE		(Continue on page 3)
				2. Common Device Nam	е		2b. Procode
				3. Manufacturer Name,	City and State		
	1	20-					
		Receiv	ed	4. Model #	Lot #		5. Operator of Device
		Nov		Catalog #	Expiratio	on Date (mm/dd/yy	W) Health Professional
		NUV 0 3 20	15				Lay User/Patient
			J	Serial #	Unique lo	dentifier (UDI) #	Other:
		CDR (C	ontinue on page 3)	6. If Implanted, Give Da	te (mm/dd/yyyy)	7. If Explanted	d, Give Date (mm/dd/yyyy)
6. Relevant Tests/Labor	atory Data, Including	Dates		8. Is this a Single-use D	evice that was Re	eprocessed and R	eused on a Patient?
			7	9. If Yes to Item No. 8, E	inter Name and A	ddress of Reproce	essor
				10. Device Available for	Evaluation? (Do I	not send to FDA)	
				Yes No	Returned to	Manufacturer on:	(mm/dd/yyyy)
		10	ontinue on page 21	11. Concomitant Medica	al Products and Ti	herapy Dates (Ex	1
7. Other Relevant Histor	ry, Includina Preexis	ting Medical Condit	ions (e.g., allergies,				
race, pregnancy, smok	king and alcohol use, h	nepatic/renai dystunc	tion, etc.)				(Continue on page 3)
		200		E. INITIAL REPOR	RTER	XEST.	
			<u>▼</u> 1	1. Name and Address (b) (6)			Das
			0 4	(a) (a)			DSS
							DSS NOV -4 201
					(F	mail Address	
				Phone #	1 1	Ittali Address	
		(0	Continue on page 3)	Phone # (b) (6)		Itiali Address	
Submission of a rep	oort does not con	stitute an admi:	ssion that medical	Phone # (b) (6) 2. Health Professional?		maii Audiess	Initial Reporter Also Ser Report to FDA



User Facility 3. User Facility or Im	Impo		
1. Contact Person		5. Phone N	Number
5. Date User Facility Importer Became Aware of Event (n		7. Type of Report Initial Follow-up #	8. Date of This Report (mm/dd/yyyy)
Approximate	10. Event F	Problem Codes (Refer to cod	ling manual)
Age of Device	Patient	12	7-
	Code		
	Code		
1. Report Sent to F	DA?	12. Location Where Event	
Yes	dd/vyyy)	Hospital	Outpatient Diagnostic Facility
☐ No (mm/c	acryyyy)	Home	Ambulatory
3. Report Sent to M	anufacturer?	Nursing Home Outpatient Treatme	Surgical Facility
Yes	dd/yyyy)	Facility	
No	21122	Other:	(Specify)
14. Manufacturer Na	me/Address		
G. ALL MANUF	ACTURER		
G. ALL MANUF	ACTURER	S ring Site for Devices)	2. Phone Number
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G. ALL MANUF 1. Contact Office (ar Name	ACTURER		310-768-0700 3. Report Source (Check all that apply)
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Type of Reportable Event	2. If Follow-up, What Type?
Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
Device Evaluated by Manufacturer?	Device Manufacture Date (mm/yyyy)
Not Returned to Manufacturer	
Yes Evaluation Summary Attached	E. Laboladda Claste Hand
No (Attach page to explain why not) or provide code:	5. Labeled for Single Use? Yes No
Event Problem and Evaluation Codes (Refer to	o coding manual)
Patient Code	-
Device Code	-
Method	
Results -	
Conclusions	
If Remedial Action Initiated, Check Type	8. Usage of Device
Recall Notification	Initial Use of Device
Repair Inspection	Reuse
Replace Patient Monitoring	Unknown
Relabeling Modification/	9. If action reported to FDA under
Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:	21 USC 360(f), list correction/ removal reporting number:
	21 USC 360(f), list correction/ removal reporting number: and / or 11. Corrected Data
Other:	removal reporting number:
Other:	removal reporting number:

CaseID: 11609038

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."

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

SECTION I:				GOIIII E	AINT #:	2001	
TAKEN BY:		EDYTA FRACKIEWI	ICZ	DATE OF COMP	LAINT:	10/16/2015	
PRODUCT:		HYLAND'S BABY TE	EETHING TABLETS	ITEM	CODE:	BTETT40	
SIZE:		40 TABS		LC	T NO.:	A76715	
REPORTER:	(b) (6)						
ADDRESS:	N/A						
	N/A						
CITY:	N/A			STATE: (b) (6)		
COUNTRY	USA			ZIP CODE:	N/A		-
PHONE #:	(b) (6)						
E-MAIL:	N/A						
NATURE OF CO	OMPLAINT:	WHEN CHILD	WAS 3 MOS OLD ON (b) (6)	OR (b) (6) SHE WAS BREATHIN	IG REAL	LY WEIRD, MOT	HER CALLED 911
							(CIRCLE ONE)
	al Case	Safety Repo	ort	DATE REQUESTED PROD			Y (N)
ndividus		Safety Repo				RETURNED:	Y (CIRCLE ONE)
ndividus	169993			UP	S CALL		y (N)
ndividus	169993 <u>IN</u> V	Safety Repo		UP	S CALL	TAG ISSUED:	Y (N)
ndividua 1 SECTION II:	169993 <u>INN</u>	Safety Repo	ort	UP DATE P	S CALL	TAG ISSUED:	Y (N)
SECTION II: INVESTIGATION	169993 INV	8-01-00-03 /ESTIGATION PLEASE SEE ATTACH	ED INSPECTION REPORT.	DATE F	PRODUC 0/16/201	TAG ISSUED:	Y (N)
SECTION II:	169993 INV IT FORWARI	8-01-00-03 /ESTIGATION PLEASE SEE ATTACH	ED INSPECTION REPORT. // NURSE FOR EVALUATION // NURSE FOR EVALUATION	DATE F	PRODUC 0/16/201	TAG ISSUED: T RECEIVED:	Y (N)
SECTION II: ADVERSE EVEN	169993 INV	8-01-00-03 /ESTIGATION PLEASE SEE ATTACH	ED INSPECTION REPORT. // NURSE FOR EVALUATION // NURSE FOR EVALUATION	DATE F	PRODUC 0/16/201	TAG ISSUED: T RECEIVED:	Y (N)
SECTION III: ADVERSE EVEN ADVERSE EVEN SECTION III:	169993 INV NT FORWARI OCTION(S) CO	8-01-00-03 /ESTIGATION PLEASE SEE ATTACH	ED INSPECTION REPORT. // NURSE FOR EVALUATION // NURSE FOR EVALUATION	DATE F	PRODUC 0/16/201 DYTA FE	TAG ISSUED: T RECEIVED:	Y (N)
ADVERSE EVER SECTION III:	169993 INV NT FORWARI ACTION(S) CO	Safety Repo 8-01-00-03 8-01-00-03 PLEASE SEE ATTACH DED TO PHARMACIST DED TO PHARMACIST CORRECTIVE ACTION	ED INSPECTION REPORT. // NURSE FOR EVALUATION // NURSE FOR EVALUATION	DATE F	PRODUC 0/16/201 DYTA FE	TAG ISSUED: T RECEIVED: 5 RACKIEWICZ	Y (N)
DOUBLE EVEN ADVERSE EVEN SECTION III:	1 69993 INT NT FORWARI OCTION(S) CO ADV	Safety Repo 8-01-00-03 /ESTIGATION PLEASE SEE ATTACH DED TO PHARMACIST CORRECTIVE ACTION OMPLETED BY: /ERSE EVENT REPOR	ED INSPECTION REPORT. 7/ NURSE FOR EVALUATION 1: 1: 1: 1: 1: 1: 1: 1: 1: 1	DATE P JON: 1 BY: E	PRODUC 0/16/201 DYTA FE	TAG ISSUED: T RECEIVED: S RACKIEWICZ	Y (N)

cc: QA / QC Packaging

BY:

Production Shipping / Receiving

Form # VD1





CaseID: 11699938

.dverse Event SAE-0060-2015

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 (b) (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 with in specification of $\leq_{(4)}^{(5)}$ ppm.

Retention Samples:

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

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

Other investigations:

A review of the Deviation system was conducted and no Deviations were reported related to this lot of product. Of the units manufactured no other complaints have been received for Hyland's Baby Teething Tablets lot # 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

NOV -4 2015



EVENT DATA FORM

CaseID: 1	1699938
	,

AE #: 16	51	COMPLAINT #:2661	
SECTION I:	PATIENT INFORMATION (IF DIFFE	RENT FROM REPORTER ON FORM VD1)	
NAME:	(b) (6)		
ADDRESS:	N/A		
ADDINESS.	N/A		
CITY:	N/A	STATE: (b) (6)	
COUNTRY:	USA	ZIP CODE: N/A	
PHONE #:	(b) (6)		
E-MAIL:	N/A		
SECTION II:	PACKAGING INFORMATION:		
A	FFIX PACKAGING LABEL HERE Continue Cont	AFFIX COPY OF OUTER CAR (INCLUDE DRUG FACTS AND PRIN PANELS)	
SECTION III:	CORRECTIVE ACTION:		
CORRECTIVE A	ACTION(S) COMPLETED BY:	DATE:	
SECTION IV:		1 1 /	DSS
	V/	IN IH	10 27-15 NOV -4 20
REVIEWED BY	MANAGEMENT BY:	DATE:	10-21-12
BY:	Jul Bau	DATE:	10-26-15
	ØA / QC DIRECTOR		

Adverse Event Reporting Program

umer Report

CaseID: 11700316

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

porting of	FDA USE ONLY
problems and	Triage unit sequence #
rors	1022475

Y reporting of	FDA USE ONLY
uct problems and	Triage unit sequence #
e errors	422475

	r 2. Age at Time of Event of	or 3. Sex	4. Weight	#1 Dose of Amo		times	
b) (6)	Date of Birth:	✓ Female	20 _{lb}		daily		
	9 Months (b) (6)		or	#2			
In confidence	and the second	☐ Male	kg				
B. ADVERSE	EVENT, PRODUCT F	ROBLEM OR E	RROR	3. Dates of Use (If (or best estimate	unknown, give duration		t Abated After Use d or Dose Reduced?
heck all that apply	S. — Extra Santou	(e.g., defects/malfun	ctions)		- 11/02/2015	#1 🗸	res No Doesn
Adverse Eve		ferent Manufacturer		#2		#2 🗔	Apply Yes No Does
Outcomes Attri	ibuted to Adverse Event			4. Diagnosis or Re	eason for Use (Indication	on)	Apply t Reappeared After
Death:		isability or Permanen	nt Damage	1,100,000			roduction?
Life-threateni	(mm/dd/yyyy)	Congenital Anomaly/B		#2		#1	Yes No ✓ Doesr Apply
_		ther Serious (Importa		6. Lot#	7. Expiration	Date #2	Yes No Doesn
	ervention to Prevent Permane	ent Impairment/Dama	ge (Devices)	#1 A91215	#1		# or Unique ID
3. Date of Event (CD	Date of this Report	(mm/dd/yyyy)	#2	#2		-3127-3
11/02/201	5 1	1/03/2015		THE RESIDENCE AND ADDRESS.	MEDICAL DEVIC	Ε	
. Describe Event	t, Problem or Product Use I	Error		1. Brand Name			
							and the second second
				2. Common Devic	e Name		CIU
						. Ve	
See addit	cional page(s)	for compl	ete text.	3. Manufacturer N	lame, City and State	ME	V - 4 2015
			4.1	-	1		Tara and a
			1.0	4. Model #	Lot#		5. Operator of Device
			1.4				realth Profession
			0.4	Catalog #	Expiratio	n Date (mm/dd/yyyy)	Lay User/Patient
							Other:
6. Relevant Tests	Laboratory Data, Including	Dates		Serial #	Other#		
coo addit	cional page(s)	for compl	ata tavt	6. If Implanted, Gi	ive Date (mm/dd/yyyy)	7. If Explanted, C	Give Date (mm/dd/yyyy)
see addit	.ional page(s)	TOT COMPT	ete text,	9 le this a Single	-use Device that was F	Panrocassad and Pa	oused on a Patient?
				Yes No		reprocessed and K	euseu on a radent.
				9. If Yes to Item No	o. 8, Enter Name and Ad	dress of Reprocesso	r
7 Other Palevant	History, Including Preexis	ting Medical Conditi	ons (e a	100000			
allergies, race, p	oregnancy, smoking and alco	hol use, liver/kidney p	problems, etc.)				
					ONCOMITANT) M		
coo addit	ional page(s)	for compl	ata taxt	Product names a	nd therapy dates (excl	ude treatment of eve	nt)
see addit	.ional page(s)	TOT COMPT	ete text.	See addit	ional page	s) for con	mplete text.
					1 3		
				G. REPORTER	R (See confidentia	lity section on L	ack)
C PRODUCT	AVAILABILITY			1. Name and Add (b) (6)	ress		P.
the Residence of the last	e for Evaluation? (Do not se	end product to FDA)		(0)(0)			ne
☐ Yes ✓ No							23
			m/dd/yyyy)				DS DV -4
The second secon	PRODUCT(S) h. Manufacturer (from produ	ct (abol)		Phone #		E-mail	4
	n, Manufacturer (from produ nd's Teething Table			(b) (6)		(b) (6)	
Strength:				0.11-14:5			Alas Bassatiates
Manufacturer:	Hyland				ional? 3. Occupation		4. Also Reported to:
Name:				Yes No			Manufacturer User Facility
Strength: Manufacturer:					ant your identity disclo- urer, place an "X" in this		Distributor/Importe



____ (continued)

Infant started having seizures after taking Hyland Teething tablets.

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

Watch test. Took teething tablets to lab for analysis. They did a urine analysis.

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

Race: Other

Medical Conditions: none

Allergies: none

Important Information: none

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

RX Meds: none

OTC Meds: none

y user-facilities, utors and manufacturers ATORY reporting

	ISCIL 9ee (IMB MODO) 4 TO EVE
Mfr Report # 54973	7111
UF/Importer Report #	11

, age 1 of 6

FURM FUA 3500A (2/13)

PLEASE TYPE OR USE BLACK INK

FDA Use Only

A. PATIENT INF	FORMATION		C. SUSPECT PE	ARCHON POLICE	X 25	
1. Patient Identifier (b) (6)	of Event:	3. Sex 4. Weigh		d strength & mfr/labele		
(2) (0)	or1 Yes	Female	Ibs #1 HYLAND'S B	ABY TEETHING	IMPIDIO	
135	Date	✓ Male or	#2			
In confidence	of Birth:		2. Dose, Frequency	& Route Used	3. Therapy Dates from/to (or best	(If unknown, give duration) estimate)
		Problem (e.g., defects/malfunctions)	#11 TAB, AS	NEEDED, ORAL	#1	
1. Adverse Even	nt and/or Product	Problem (e.g., defects/manufactions)	#2		#2	
(Check all that app			4. Diagnosis for Use	(Indication)		Abated After Use
Death:		Disability or Permanent Damage	#1 TEMP RELIE	F TEETHING PA	N	oed or Dose Reduced? Yes No Doesn't
Life-threatenin	(mm/dd/yyyy)	Congenital Anomaly/Birth Defect	#2		#1 🗸	Yes No Apply
✓ Hospitalization	on - initial or prolonged	Other Serious (Important Medical Eve	ents) 6. Lot #	7. Exp. Date	#2	Yes No Doesn't
Required Inte	ervention to Prevent Permanent	Impairment/Damage (Devices)	#1	#1	8. Even	t Reappeared After
3. Date of Event (mi	m/dd/yyyy) 4. D	ate of This Report (mm/dd/yyyy)				Carltanhan
05/	04/2015	11/06/2015	#2	#2	#1	Yes No Doesn't
5. Describe Event or	r Problem	UO HAD A SETZIDE (b)(6)	9. NDC# or Unique II		#2 🗆	Yes No Doesn't
MOTHER CALLED WHEN HE WAS 1	ABOUT HER CHILD W	BEEN GIVING HIM BABY	54973-3127-		nerapy Dates (Exclude	rppi)
TEETHING TABL HE HAD NO KNO USED 10-15 TA OCCURRED IN T WAS GIVEN THE	LETS A WEEK PRIOR, A DWN FEVER BEFORE THE ABLETS, 1 TABLET PE THE MORNING, AND THE E DAY PRIOR. THE MO	AS NEEDED FOR TEETHING. E SEIZURE. IN ALL, SHE R DOSE. THE SEIZURE E LAST DOSE OF PRODUCT THER WAS RESPONDING TOD T THERE WAS A POSSIBLE	AY		NOV 2 7 2015	a
		LETS AND SEIZURE/BRAIN	D. SUSPECT M	EDICAL DEVICE		
BLEEDS.	Comment of the statement of		1. Brand Name		CDR	
ROLLING TO TH	HE BACK OF THE HEAD		2. Common Device	Name		Procode
		S TAKEN TO THE LOCAL AS STABILIZED, AND GIVE	N 3. Manufacturer Nam	ne, City and State		
ROCEPHIN IM.	THEY REFERRED HIM	TO THE STATE HOSPTIAL				
		S. A FEVER DEVELOPED	4. Model #	Lot#		5. Operator of Device
SUBSIDED. THE	EY DID BLOOD TESTS.	OT RELEASED UNTIL IT MRI AND CHECKED BRAIN	77.78.00.00			Health Professional
ACTIVITY WHIL	LE ASLEEP AND AWAKE	. IT WAS ALL NORMAL.	Catalog #	Expiration	on Date (mm/dd/yyyy)	Lay User/Patient
		T DETERMINED. THE MOTHE			1 -17 - 1100 0	Other:
	JUST WATCH HIM. HE HAD NO KNOWN ALLERG	IES, NOR ANY PRE-EXISTI	NG Serial #	Unique	dentifier (UDI) #	
		UNIZATION AT 9 MONTHS.	6. If Implanted, Give	Date (mm/dd/yyyy)	7. If Explanted, G	ive Date (mm/dd/yyyy)
		(Continue on page 3				
and the state of t	aboratory Data, Including Dat	es Y WHILE AWAKE AND ASLEE	D		eprocessed and Reus	ed on a Patient?
	TESTS, MRI AND XRAY				ddress of Reprocess	or
			9. If Yes to item No.	o, Enter Name and A	duress of Reprocess	or .
			10. Device Available	for Evaluation? (Do		
			Yes N	o Returned to	Manufacturer on:	(mm/dd/yyyy)
		(Continue on page 3	11. Concomitant Me	dical Products and T	herapy Dates (Exclud	le treatment of event)
7. Other Relevant H	listory Including Preexisting	Medical Conditions (e.g., allergies,	<u>"</u>			
race, pregnancy, s	smoking and alcohol use, hepat	ic/renal dysfunction, etc.)				0
NONE			E INITIAL DED	ORTER	(Continue on page 3)
		nee I	E. INITIAL REP	MANAGEMENT AND A STREET		
Toward .	- IT 004E	000	(b) (6)	13		
NOV	2 7 2015 N	OV 3 0 2015				
		0 0 0 2013				
	Mari	a. Penning	Phone #	E	mail Address	
		(Continue on page 3				
Submission of a	report does not constitu	ute an admission that medica	2. Health Profession		4	Initial Reporter Also Sen Report to FDA
	buted to the event.	utor, manufacturer or produc	Yes ✓ No	NA		Yes No V Unk



11788548	-01-00-02
Check One User Facility Importer	2. Ut/Importer Report Number

7. Type of Report Initial Follow-up #

10. Event Problem Codes (Refer to coding manual)

Hospital

12. Location Where Event Occurred

5. Phone Number

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

Outpatient Diagnostic Facility

3. User Facility or Importer Name/Address

4. Contact Person

Approximate
 Age of Device

11. Report Sent to FDA?

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

Patient Code Device Code

Report Sent to Manufacturer? Yes	Nursing Home Outpatient Treatmen Facility Other:	Ambulatory Surgical Facility t
ALL MANUFACTURER Contact Office (and Manufacture)		2. Phone Number
Name EDYTA FRACKIEWICZ	ring Site for Devices)	310-768-0700 3. Report Source
HYLAND'S, INC. 154 W. 131ST STREET LOS ANGELES, CA 90061	t.	Foreign Study Literature Consumer
Email Address		Health Professional
4. Date Received by Manufacturer (mm/dd/yyyy) 11/06/2015 6. If IND, Give Protocol # 7. Type of Report (Check all that apply)	5. (A)NDA#	User Facility Company Representative Distributor Other:
5-day 30-day 7-day Periodic	Combination Yes Pre-1938 Yes OTC Product YYes	

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

2	of	6	

DEVICE MANUFACTURERS	2. If Follow-up, What Type?
ype of Reportable Event Death Serious Injury Malfunction	Correction Additional Information Response to FDA Reque Device Evaluation
evice Evaluated by Manufacturer?	4. Device Manufacture Date (mm/yyyy)
Yes Evaluation Summary	tached
No (Attach page to explain why n	E. L. S. J. J. C. Clauda Hand
provide code:	Yes No
vent Problem and Evaluation Codes	(Refer to coding manual)
Patient Code	
Device Code	
Method -	
Results	-
Conclusions -	
Remedial Action Initiated, Check T	pe 8. Usage of Device
Recall Notification Repair Inspection Replace Patient Monit	Initial Use of Device Reuse Unknown 9. If action reported to FDA under
Relabeling Modification/ Adjustment Other:	21 USC 360(f), list correction/ removal reporting number:
Additional Manufacturer Narrat	re and / or 11. Corrected Da
DSS 7	

CaseID: 11788548

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

NOV 2 7 2015

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y user-facilities,
itors, and manufacturers
ATORY reporting

Page 3 of 6

CaseID: 11788548

FORM FDA 3500A (2/13) (continued)

					blem (conti ON FOR		FROM PO	WDERED 1	MILK.	FOLLOW	UP VISI	ITS HAVE	SHOWN	NORMAL	RESULT	rs.	
Back to Item B.5																	
	B,6.	Releva	ant Tests	s/Laborat	tory Data,	Including	Dates (con	itinued)									
Back to Item B.6																	
Back to Item B./	B.7.	Other	Relevant	: History,	Including	Preexist	ing Medical	Conditions	s (e.g., ali	lergies, race,	pregnancy,	smoking and	alcohol us	e, hepatic/n	enal dysfun	ction, etc.) ((continued)
A to item D. I I Back to Item C. IO	Con	comita	nt Medic	al Produ	cts and Th	nerapy Da	ates (Exclud	le treatment	of event)	(For continua	ition of C.10	0 and/or D.11	; please dis	itinguish)			
	Othe	er Rema		27	2015	Section 1	Nov 3	SS 0 2015	Market	Ž.							



			CHEN		COMPLAINT #:			
	178854	9-01-00	-04	DA	TE OF COMPLAINT:	11/06/2015		
PRODUCT:		HYLAND'S	BABY TEETHING TABLETS		ITEM CODE:	BTETT40		
SIZE:		40 TABS			LOT NO.:	A74414		
REPORTER:	(b) (6)							
ADDRESS:	N/A							
	N/A							
CITY:	N/A				STATE: (b) (6)			
COUNTRY:	USA			ZI	P CODE: N/A			
PHONE #:	(b) (6)							
E-MAIL:	N/A		HER CALLED ABOUT HER CHIL		75.10			
OF PRODUCT W POSSIBLE CONTHE SEIZURE LA HE WAS TAKEN STATE HOSPTIA SUBSIDED. THE SEIZURE WAS N ALLERGIES, NO	VAS GIVEN TO NECTION BE ASTED 30 MI TO THE LOCAL WHERE HO Y DID BLOOD NOT DETERM R ANY PRE-1	HE DAY PRIC TWEEN TEET NUTES, WITH CAL HOSPITA E WAS ADMIT D TESTS, ME IINED. THE ME EXISTING CO UP VISITS HA	D 10-15 TABLETS, 1 TABLET PE DR. THE MOTHER WAS RESPOD HING TABLETS AND SEIZURE/ H JERKING AND EYES ROLLING AL FOR 4 HOURS WHERE HE W. TTED FOR 2 DAYS. A FEVER DE IX AND CHECKED BRAIN ACTIVI MOTHER WAS TOLD TO JUST W DIDITIONS. HE HAD HIS LAST II AVE SHOWN NORMAL RESULT: DODITIONAL SPACE PLEASE US.	NDING TODAY AFTER S //BRAIN BLEEDS. & TO THE BACK OF THE AS STABILIZED, AND G EVELOPED AFTER THE ITY WHILE ASLEEP AND (ATCH HIM. HE WAS NO MMUNIZATION AT 9 MO S.	SHE HEARD ON THE HEAD. THE CHILD IVEN ROCEPHIN IM. SEIZURE, AND HE VO AWAKE. IT WAS A DT TAKING ANY MED NTHS. HE WAS BEI	WAS UNRESPON THEY REFERR WAS NOT RELEA LL NORMAL. TH DICATION, HAD N NG FED ON FOR	ERE WAS A ISIVE TO HIS NAME. ED HIM TO THE SED UNTIL IT E CAUSE OF THE O KNOWN	
		TOTAL	SUTTOWNE OF MOET ELENOE OO	211272102 011111110				
PRODUCT RECE	EIVED FOR		v (N)	PRODUCT BEI	NG RETURNED FOR	INSPECTION	Y (N)	
NSPECTION:	LIVEDION		(CIRCLE ONE)	11100001 021	10 (12 / 0 / 11 / 2 / 0 / 1		(CIRCLE ONE)	
				DATE REQUI	ESTED PRODUCT B	E RETURNED:		
							Y (N)	
SECTION II:	INV	ESTIGATION	ı		UPS CALL	TAG ISSUED:	(CIRCLE ONE)	
	_		! ATTACHED INSPECTION REPO	DRT.				
SECTION II: NVESTIGATION		PLEASE SEE	T			CT RECEIVED:		
NVESTIGATION ADVERSE EVEN ADVERSE EVEN	T FORWARD	PLEASE SEE	ATTACHED INSPECTION REPORTED IN THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT OF THE PORT	ATION ON:	DATE PRODUC	CT RECEIVED:		
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NVESTIGATION:	T FORWARD CTION(S) CC ADV T SERIOUS:	DED TO PHAR DED TO	ATTACHED INSPECTION REPORTS RMACIST / NURSE FOR EVALUA E ACTION: Y: T REPORTS NOV	ATION ON: ATION BY: OSS 3 0 2015	DATE PRODUCE	TRECEIVED:		

cc: QA / QC Packaging Production Shipping / Receiving

NOV 2 7 2015

Form # VD1





SAE-0063-2015

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 with in specification of $\leq_{(4)}^{(6)}$ ppm.

Retention Samples:

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

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

Other investigations:

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

11113/15

NOV 2 7 2015

DSS 3 NOV 3 0 2015

CC-0935-2015 AE-0527-2015 CaseID: 11788548

EVENT DATA FORM

NAME:	
ADDRESS: N/A	
N/A	
CITY: N/A	STATE: (b) (6)
COUNTRY: USA	ZIP CODE: N/A
PHONE #:	
E-MAIL: N/A	
SECTION II: PACKAGING INFORMAT	TION:
AFFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DIS PANELS)
The second of th	Common of the contract of the
discount of the state of the st	"
	Teething Tablets
	Control of the Contro
	The state of the s
SECTION III: CORRECTIVE ACTION:	4
CORRECTIVE ACTION(S) COMPLETED BY:	DATE:
CONTRECTIVE ACTION(O) COMPLETED BY.	DATE.
SECTION IV:	7
SECTION IV: REVIEWED BY MANAGEMENT BY:	Walf DATE: 1/-17

DISTRIBUTION: FDA

ADVERSE EVENT FILE

DSS ______ NOV 3 0 2015

FORM SAE01



PLEASE TYPE OR USE BLACK INK

user-facilities, tors and manufacturers TORY reporting

34973	
UF/Importer Report #	_

___ 1 of 5

EDA	Hea	Only
LDW	USE	Omy

Second Second 10 Month	A. PATIENT INF	CONTRACTOR OF THE		3. Sex	4. Weight	1 Name (Give labeled			
Date of Either and or Detect Product P	And the second s	of Event:	17.00		110001	the second secon	and the second s		
Nover Secret Nover Nove Nover Nove	1 1 1	4334		The second	or los	#2			
B. ADVERSE EVENT OR PRODUCT PROBLEM Adverse bear air's Product Problem (in g., adenda/amalianctional)	In confidence			Male	kgs		Route Used	3. Therapy Date	es (If unknown, give duration
Aboves Event and or Product Problem (e.g. obtechainsthructions)	B. ADVERSE EV	VENT OR PRODU	ICT PROBLE	٨				from/to (or bes	st estimate)
Death: Confinue on page 3	1. Adverse Event	t and/or Pr	oduct Problem (e.	g., defects/mali	functions)	#11 TAB TID A	1 DAI	#1	
Death:						1.4.4			
Ule-Presidency Congenital Anomalytich Detect September Sep		y)	☐ Disability o	Permanent Da	amage			Sto	
Nover a process Continue on page 3	E CONTRACT					#1 TEMP RELIEF	TEETHING PAIN	#1	
Required intervention to Prevent Permanent Impairment/Damage (Devices) Solution So						#2			n Does
3. Date of Event (mm6d/yyyy) 0/00/00000 4. Date of This Report comd9/yyyy) 11/12/2015 5. Describe Event of Problem 00/1676 AND SETZURES AFTER THIS USE OF BABY EDITING TABLETS. CHILD NOW INAS TO SES SEAL BY EDITING TABLETS. CHILD NOW INAS TO SES SEAL BY EVENCLOSISTS AND REQUIRES MEDICAL CARE. NOV 2 7 2015 Recommended to the search of t			1.1			6. Lot #	7. Exp. Date		д — Дарріу
S. Ducking rows for Problems MOTION PORTION ON BINS PHAT CHILD EXPERIENCED MOTION PORTION ON BINS PHAT CHILD EXPERIENCED BELLADONNA POSITIONS AND SETURES AFER THE USE OF BABY REPRESENCE ON BINS REPUBLICATIONS POSITIONS AND REQUIRES MEDICAL CARE. RECEIV NOV 3 7 2015 RECORDING COntinue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates NOV 2 7 2015 NOV 2 7 2015 NOV 2 7 2015 NOV 2 7 2015 NOV 3 0 2015 NOV 2 7 2015 RESIDENCE FOR THE USE OF BABY NOV 3 0 2015 NOV 2 7 2015 RESIDENCE FOR The Products and Therapy Dates (Exclude readment of event) 1. Grand Name 2. Common Device Name 2. Common Device Name 2. Common Device Name 3. Manufacturer Name, City and State NOV 3 1 2015 Gatalog # Expiration Date (mm/65/yyyy) 1. If Explanted, Give Date (mm/65/yyyy) 2. If Explanted One Date (mm/65/yyyy) 3. It is this a Single-use Device that was Reprocessed and Reused on a Patient? 1. Concomitant Medical Products and Therapy Dates (Exclude readment) 1. Device Available for Evaluation? (Do not served to Manufacturer on						#1	#1		
5. Describe Event of Problem MORTER POSTED ON 19/100 THAT CHILD EXPERIENCED BELLADONNA POISONING AND SEIZURES AFTER THE USE OF BABY TESTHING TRABLETS. CHILD NOW HAS TO BE SEEN BY NEUROLOGISTS AND REQUIRES MEDICAL CARE. RECEIV NOV 2 7 2015 RECIPION THAT CHILD EXPERENCED BELLADONNA POISONING AND SEIZURES AFTER THE USE OF BABY TESTHING TRABLETS. CHILD NOW HAS TO BE SEEN BY NEUROLOGISTS AND REQUIRES MEDICAL CARE. RECEIV NOV 2 7 2015 RECIPION THAT CHILD EXPERENCED BELLADONNA POISONING AND SEIZURES AFTER THE USE OF BABY TO Concomitant Medical Products and Therapy Dates (Exclude Reatment of event) 10. Concomitant Medical Products and Therapy Dates (Exclude Reatment of event) 10. Concomitant Medical Products and Therapy Dates (Exclude Reatment of event) 10. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common Device Name 2. Common Device Name 3. Manufacturer Name, City and State NOV 2 7 2015 Relevant Tester/Laboratory Date, Including Dates (Continue on page 3) 10. If implanted, Give Date (minddy)yyy) 1. If Explanted, in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner on Date (minddy)yyy) 1. If Explanted (in Minddeliner o						#2	#2	#1	
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Continue on page 3					Control Control Control	PERSONAL PROPERTY.			
Receive NOV 2 7 2015 A Model # Lot # S Operator of Device Model # Lot # S Operator of Device Model # Lot # S Operator of Device Model # Lot # S Operator of Device Lay UserPetent Other: Catalog # Expiration Date (mm/dd/yyyy) Serial # Unique Identifier (UDI) # Unique Identifier (UDI) # Other: Other:						D. SUSPECT ME	DICAL DEVICE		(Continue on page 3)
NOV 2 7 2015 CDR (Continue on page 3) 8. Relevant Tests/Laboratory Data, Including Dates UNKNOWN (Continue on page 3) 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on (mmidd/yyyy) To Other Relevant History, Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on (mmidd/yyyy) To Other Relevant History, Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 12. Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 13. Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 14. Name and Address (Continue on page 3) 15. Other Relevant History, Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 16. Relevant History, Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 17. Other Relevant History, Including Preexisting Medical Conditions (a.g., allergies, DNKNOWN) 18. In this a Spirate of PDA 19. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on (mmidd/yyyy) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) DSS Nov 2 7 2015 (Continue on page 3) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Concomitant Medical Products and Therapy Dates (Exclude treatment of event) To Device Available for E						277		In	
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Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates UNKNOWN (Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepaticirenal dysfunction, etc.) NOV 2 7 2015 (Continue on page 3)				110					
Continue on page 3) 6. Relevant Tests/Laboratory Data, including Dates UNKNOWN (Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnarcy, smoking and alcohol use, hepatichenal dysfunction, etc.) NOV 2 7 2015 Catalog # Expiration Date (mm/dd/yyyy)				NU	V 27 201	4. Model#	Lot #		5. Operator of Device
(Continue on page 3) 6. Relevant Tests/Laboratory Data, Including Dates UNKNOWN (Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, INKNOWN) (Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, INKNOWN) (Continue on page 3) NOV 2 7 2015 (Continue on page 3)									Health Profession
Serial # Unique identifier (UDI) # Other:					CDP	Catalog #	Expiration	Date (mm/dd/yyy)	Lay User/Patient
(Continue on page 3) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes					SDIL	Serial #	Unique Ide	entifier (UDI) #	Other:
8. Relevant Tests/Laboratory Data, Including Dates UNKNOWN 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) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 12. In Name and Address (b) (6) 13. Nov 2 7 2015 14. Initial Reporter Also Seregorial, user facility, importer, distributor, manufacturer or product Report to FDA								T7 10 F 1	C
UNKNOWN Yes No				(Continue o	n page 3)	6. If Implanted, Give D	ate (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
(Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) NOV 2 7 2015 (Continue on page 3) (Continue on page 3) (Continue on page 3) (Continue on page 3) E. INITIAL REPORTER 1. Name and Address (b) (6) Phone # Email Address (b) (6) Phone # Email Address (b) (6) 2. Health Professional? 3. Occupation 4. Initial Reporter Also Se Report to FDA		boratory Data, Includia	ng Dates				Device that was Rep	rocessed and Reu	ised on a Patient?
Yes No Returned to Manufacturer on: (mm/dd/yyyy)						9. If Yes to Item No. 8,	Enter Name and Add	fress of Reproces	sor
Yes No Returned to Manufacturer on: (mm/dd/yyyy)									
(Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) UN KNOWN (Continue on page 3) E. INITIAL REPORTER 1. Name and Address (b) (6) Phone # Email Address (b) (6) Phone # Email Address (b) (6) 2. Health Professional? 3. Occupation 4. Initial Reporter Also Se Report to FDA									
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) UN KNOWN Continue on page 3) INOV 2 7 2015 Continue on page 3)					1	Yes No	Returned to M	Manufacturer on:	(mm/dd/yyyy)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) UNKNOWN DSS				(Continue o	n page 3)	11. Concomitant Medi	cal Products and The	erapy Dates (Exclu	ide treatment of event)
NOV 2 7 2015 Continue on page 3	race, pregnancy, sm	story, Including Preexi noking and alcohol use,	isting Medical Con hepatic/renal dysfi	nditions (e.g., a					
NOV 2 7 2015 NOV 3 0 2015 (Continue on page 3) Submission of a report does not constitute an admission that medical errsonnel, user facility, importer distributor, manufacturer or product. 1. Name and Address (b) (6) Phone # Email Address (b) (6) 2. Health Professional? 3. Occupation 4. Initial Reporter Also Se Report to FDA	w / + 34 T 54 F F A T		p-	nee		E INITIAL REPO	RTER		(Conunue on page 3)
NOV 2 7 2015 (Continue on page 3) (Continue on page 3) (Continue on page 3) (Continue on page 3) (Continue on page 3) (Continue on page 3) (D) (G) (G) (D) (G) (A Initial Reporter Also Se Report to FDA			-	DOO		1. Name and Address			
NOV 2 7 2015 (Continue on page 3) (Unitial Report Also Separative an admission that medical personnel, user facility, importer distributor, manufacturer or product			N/C	V 2 0 2	015	(b) (6)		~ ~ ~	~
(Continue on page 3) Submission of a report does not constitute an admission that medical erronnel, user facility, importer, distributor, manufacturer or product		NOV 2 7	2015	11 20 5	013		(US_{\cdot}	\mathcal{A}
Submission of a report does not constitute an admission that medical errsonnel, user facility, importer, distributor, manufacturer or product						Phone #			
ersonnel, user facility, importer, distributor, manufacturer or product							777		
aused or contributed to the event							NA 3. Occupation		



4. Contact Person

Approximate
 Age of Device

Yes

No

Yes

No

Address

11. Report Sent to FDA?

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

Patient Code Device Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

EDYTA FRACKIEWICZ

HYLAND'S, INC.

1. Contact Office (and Manufacturing Site for Devices)

1. Check One 2. UF/Importer Report Number User Facility Importer 3. User Facility or Importer Name/Address

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

12. Location Where Event Occurred

Initial Follow-up #

5. Phone Number

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

Outpatient Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

2. Phone Number 310-768-0700

Foreign

Study

3. Report Source (Check all that apply)

of 5

II DEVICE MANUELOTUDEDO	CMIN
H. DEVICE MANUFACTURERS 1. Type of Reportable Event	2. If Follow-up, What Type?
☐ Death	Correction
Serious Injury	Additional Information
Malfunction	Response to FDA Request
	Device Evaluation
3. Device Evaluated by Manufacturer?	4. Device Manufacture Date
Not Returned to Manufacturer	(mm/yyyy)
Yes Evaluation Summary A	
No (Attach page to explain why no provide code:	5. Labeled for Single Use?
provide dode.	Yes No
6. Event Problem and Evaluation Codes	(Refer to coding manual)
Patient]-[
Code	
Code]-
Method -	
Results -	
Conclusions	
7. If Remedial Action Initiated, Check Ty	900 m (40 4 <u>00</u> 00000000000000000000000000000000
Recall Notification	Initial Use of Device
Repair Inspection	Reuse
Replace Patient Monito	ring Unknown 9. If action reported to FDA under
Relabeling Modification/	21 USC 360i(f), list correction/
Other:	removal reporting number:
10. Additional Manufacturer Narrativ	ve and / or 11. Corrected Data
Dec 7	
DSS =	
NOV 9 A 204E	
NOV 3 0 2015	
MAN O IT BOAR	
NOV 2 7 2015	

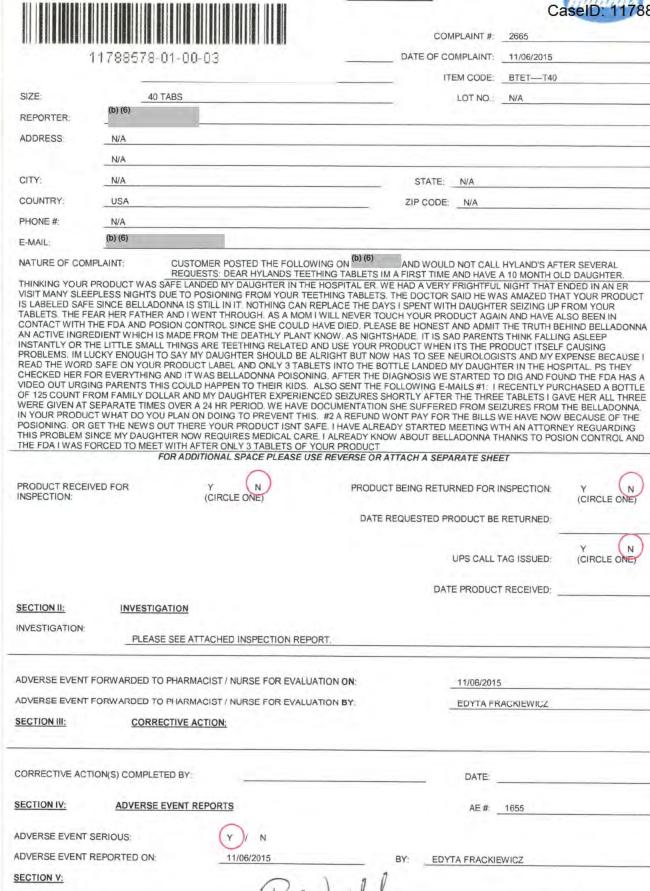
CaseID: 11788578

154 W. 131ST STREET LOS ANGELES, CA 90061 Literature ✓ Consumer Email Address Health Professional STANDARD@HYLANDS.COM User Facility Date Received by Manufacturer (mm/dd/yyyy) Company Representative (A)NDA# 11/06/2015 Distributor 6. If IND, Give Protocol# Other: BLA# PMA/ 7. Type of Report 510(k)# (Check all that apply) Combination 30-day 5-day Yes Periodic 7-day Pre-1938 Yes ✓ Initial 10-day OTC Product √ Yes Follow-up # √ 15-day 9. Manufacturer Report Number 8. Adverse Event Term(s) BELLADONNA POISONING, SEIZURES 54973 AE # 1655 This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 66

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

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

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." Please DO NOT RETURN this form to the above PRA Staff email address.



Packaging

cc: QA/QC

BY:

REVIEWED BY MANAGEMENT BY:

Production Shipping / Receiving NOV 8 0 2019





CaseID: 11788578

serious Adverse Event SAE-0064-2015

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 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 $\leq_{(4)}^{(b)}$ spm 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

NOV 2 7 2015

CC-0952-2015 AE-0537-2015













NT DATA FORM

AE #: 16	555	COMPLAINT #: 2665
SECTION I:	PATIENT INFORMATION (IF DIFFE	RENT FROM REPORTER ON FORM VD1)
NAME:	(b) (6)	
ADDRESS:	N/A	
	N/A	
CITY:	N/A	STATE: N/A
COUNTRY:	N/A	ZIP CODE: N/A
PHONE #:	N/A (b) (6)	
E-MAIL:	-	
SECTION II:	PACKAGING INFORMATION:	
А	FFIX PACKAGING LABEL HERE	AFFIX COPY OF OUTER CARTON HERE (INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)
		Teetning Tablets Total et al. The state of the state of
ECTION III:	CORRECTIVE ACTION:	-
ORRECTIVE A	ACTION(S) COMPLETED BY:	DATE:
ECTION IV:		
EVIEWED BY	MANAGEMENT BY:	DATE: 11-17-15
Y:	Eric Bain	DATE: 11-17-15
2045	QA / QC DIRECTOR	SS I

NOV 2 7 2015

DISTRIBUTION: FDA

ADVERSE EVENT FILE



d

NOV 3 0 2015

FORM SAE01



Adverse Event Reporting Program

mer Report

CaseID: 11878433
Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

Y reporting of	
ict problems and	
eerrors	

FDA USE ONLY			
riage unit equence #			
(030318		

A. PATIENT INFORMATION		2. Dose or Amount	Frequency	Route			
1. Patient Identifier 2. Age at Time of Date of Birth:	Event or 3. Sex 4. Weight 20 lb		As needed	Taken under the	tongue		
(b) (6)	✓ Male or kg	#2					
B. ADVERSE EVENT, PRODUCTION OF THE PRODUCT PR	JCT PROBLEM OR ERROR roblem (e.g., defects/malfunctions)	(or best estimate) #1 12/02/2015 -	nown, give duration) from/to	5. Event Abated A Stopped or Dose #1 Yes VN	Reduced?		
Product Use Error Problem w	vith Different Manufacturer of Same Medicin	#2 4. Diagnosis or Reason	on for Use (Indication)	— #2 ☐ Yes ☐ N	#2 Yes No Doesn't Apply		
(Check all that apply) Death: (mm/dd/yyyy)	☐ Disability or Permanent Damage	#1		8. Event Reappea Reintroduction #1 Yes N	o Doesn't		
Life-threatening	☐ Congenital Anomaly/Birth Defect ☐ Other Serious (Important Medical Events)	6. Lot#	7. Expiration Date	#2 Yes N	o Doesn't		
	ermanent Impairment/Damage (Devices)	#1	#1	9. NDC # or Uniqu			
Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)	#2	#2	54973-3127-1			
12/28/2015	12/28/2015	E. SUSPECT ME	EDICAL DEVICE				
		2. Common Device N		DEC 9	0.2045		
See additional page	(s) for complete text.	3. Manufacturer Name	e, City and State	4	9 2015		
		4. Model #	Lot#		tor of Device h Professional		
		Catalog #	Expiration Date (mm/dd/yyyy)	Jser/Patient		
6. Relevant Tests/Laboratory Data, Inc	cluding Dates	Serial #	Other#				
		6. If Implanted, Give I	Date (mm/dd/yyyy) 7. If E	Explanted, Give Date ('mm/dd/yyyy)		
		8. Is this a Single-use Yes No	Device that was Reproces	ssed and Reused on a	Patient?		
Other Relevant History, Including P	reexisting Medical Conditions (e.g.,	9. If Yes to Item No. 8, I	Enter Name and Address of	Reprocessor			
	nd alcohol use, liver/kidney problems, etc.) (s) for complete text.	Product names and the	COMITANT) MEDICA herapy dates (exclude treat				
yee addressed page	(b) for complete cent.						
PRODUCT AVAILABILITY Product Available for Evaluation? (Do	and could are disable FDA	G. REPORTER (S 1. Name and Address (b) (6)	See confidentiality sed	ction on back)			
✓ Yes No Returned to M					DEC 2		
D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from Name: hylands teething ta		Phone # (b) (6)	E-ma (b) (6)		UEC 2		
Strength: unknown Manufacturer: hylands		2. Health Professiona	17 3. Occupation	4. Also Rep	ported to:		
Name:		Yes No		111111111111111111111111111111111111111	facturer		
Strength: Manufacturer:		5. If you do NOT want y	our identity disclosed	_ =	Facility butor/Importer		





ive been giving my son hylands teething tablets for about a month now and hes been sleeping alot, being constipated, is this a serious problem $\frac{1}{2}$

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)

DSS
DEC 2 9 2015



Y reporting of uct problems and

CaseID: 11999660
Form Approved: OMB No. 0910-0291, Expires: 6/30/2015

Triage unit sequence #	1,3611	05
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Adverse Event Reporting Program Page	104 7
A. PATIENT INFORMATION 1. Patient Identifier 12. Age at Time of Event or 13. Sex 14. Weight Date of Birth:	2. Dose or Amount Frequency Route
In contidence (b) (6) In contidence (c) (b) (6) In contidence (c) (c) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	12 11520 Person to Energy
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check all that apply.	3. Dates of Use (If unknown, give duration) from/to (or best estimate) 5. Event Abated After Use Stopped or Dose Reduced?
Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine	#2 #2 Yes Mondooesny
2. Outcomes Attributed to Adverse Event (Check all that apply) Death Disability or Permanent Damage (mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth Defect Vospitalization - initial or prolonged Other Serious (Important Medical Events	4. Diagnosis or Reason for Use (Indication) #1 #2 #2 #3 #4. Diagnosis or Reason for Use (Indication) #4. Event Reappeared After Reintroduction? #1
Required Intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event/(mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) 5. Describe Event, Problem or Product Use Error Child han South	#1 640 814 #1 WWK 9. NDC # or Unique ID #2 A 58015 #2 WWK E. SUSPECT MEDICAL DEVICE 1. Brand Name 2. Common perice Name 2b. Procode
have se znees withing	3. Manufacturer Name, City and State All All All All All 4. Model # Lot # 5. Operator of Device Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other:
6. Relevant Tests/Laboratory Data, Including Dates Sol med negative	Serial # Unique Identifier (UDI) #
See new nagrin	6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8 Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and elcohol use, liver/kidney problems, etc.) My Me Carly Medical Conditions (e.g., allergies, race, pregnancy, smoking and elcohol use, liver/kidney problems, etc.)	F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event)
C. PRODUCT AVAILABILITY	G. REPORTER (See confidentiality section on back) 1. Name and Address (b) (6)
Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy)	
D. SUSPECT PRODUCT(S) 1 Name, Strength/Manufacturer (from product label) #1 Name: Strength: Strength: Strength: Strength: Social Act # about	Phone # (b) (6) (b) (6) (b) (6) (c) (c) (d) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e
Warne: Strength SS ManufactureSS	5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: Distributor/Importer

Enclosure:

Form FDA 3500 (2/13)

DSS FEB 03 2016

Individual Cas	e Safety	/ Report	á	umer Report	CONES	Form Appr	raved: OMB No.	Sel 0 12009242 0910-0291, Expires: 12/31/20 See OMB statement on revers
1 20092	42-01-00	######################################	3	Y reporting of uct problems and	Sec	age unit quence #	FDA US	EONLY
Adverse Event Reporting	Program		S	e errors	2		Le 3	6371
A. PATIENT INFORMATI 1. Patient Identifier 2. Age at Time Date of Bir (b) (6) 6 Months (b) (6)	me of Event or irth:	✓ Female	Weight 19 lb	2. Dose or Amou #1 2 tablets #2	nt	As nee		n by mouth
In confidence B. ADVERSE EVENT, PR	PODUCT PE	Male of Male	kg	3. Dates of Use (If u	inknown, giv	ve duration)	from/to 5. E	vent Abated After Use
Check all that apply: 1. Adverse Event Product Problem (e.g., defects/malfunctions) Product Use Error Problem with Different Manufacturer of Same Medicine				3. Dates of Use (If unknown, give duration) from/to (or best estimate) #1 01/31/2016 - 01/31/2016			Sto	pped or Dose Reduced? Yes No Does Apply
2. Outcomes Attributed to Adve (Check all that apply) Death:	rse Event	sability or Permanent Dar		4. Diagnosis or Rea #1 To help rel teething			8. E	Yes No Does Yent Reappeared After teintroduction? Yes No Does
(mm/dd/yyyy) Life-threatening Hospitalization - initial or pro Required Intervention to Pre	olonged 🗸 Oth		edical Events)	6, Lot# #1 B01415	7. #1	Expiration	Date #2	Yes No Does Appli DC # or Unique ID
3. Date of Event (mm/dd/yyyy)		ate of this Report (mm/	(dd/yyyy)	#2	#2			
01/31/2016 5. Describe Event, Problem or P		1/03/2016 Yor		E. SUSPECT I	WEDICAL	DEVICE		
				2. Common Device	Name			СТИ
See additional p	page(s)	for complete	e text.	3. Manufacturer Na	me, City an	nd State		EB - 4 2016
				4. Model #		Lot#		5. Operator of Devi
				Catalog #		100 CO 10		(V)(V) Lay User/Patient
6. Relevant Tests/Laboratory Da	ata, including i	Dates		Serial #		Other#	-	
				6. If Implanted, Giv	e Date (mm	/dd/yyyy)	7. If Explante	ed, Give Date (mm/dd/yyy)
				8, is this a Single-u	se Device (that was R	eprocessed an	d Reused on a Patient?
				9. If Yes to Item No.	B, Enter Nar	me and Add	ress of Reproce	essor
7. Other Relevant History, Inclu- allergies, race, pregnancy, smo See additional p	oking and alcoh	ol use, liver/kidney proble	ems, etc.)	F. OTHER (CO				
				G. REPORTER	A series	nfidential	ity section o	on back)
C. PRODUCT AVAILABI Product Available for Evaluatio Yes		urer on:		(6) (6)				
D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product label)				Phone# E-mai			E-mail	
#1 Name: Hyland's Baby ! Strength: Manufacturer:	Teeting Ta	blets			onal? 3. Oc	(b) (6) 2. Health Professional? 3. Occupation		
								The second of th
#2 Name: Strength: Manufacturer:				Yes No 5. If you do NOT wa to the manufactu				Manufacturer User Facility Distributor/Impor

CaseID: 12009242

B.5. Describe Event or Problem (continued)

Administered Hyland's Teething Tablets (2 tablets, recommended dosage) to infant baby at 7:30pm. Infant weighs 191bs. 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)

Individual Case Safety Report



ΓARY reporting of product problems and the trust use errors

1 of 1

Triage unit 192612

011610

6379/5

	CHIMATION				D. SUSPECT						N. Interest
Patient Identifier	2. Age at Time of Eve Date of Birth:	nt, or	3. Sex	4. Weight	1 Name, Strength,			200000000000000000000000000000000000000	P		
12 YEAR			Female	or ——Ib	#1 Hyland Te	ethin	g Tablets	3			
In confidence	9 mos	231	✓ Male		112						
	VENT, PRODUC	T PRO	BLEM OR ER	ROR	2. Dose or Amo	unt		Frequency		Route	0
Check all that apply:					#1		- 1				
1. Adverse Event	No. of the Control of		g., defects/malfunct	Acres and the second se							
	rror Problem with	Differe	nt Manufacturer o	Same Medicine	#2						
Outcomes Attribute (Check all that appl)					3. Dates of Use (If	unknow	n aive duration	1 from/to (or	5 Event	t Abated Afte	er I lee
Death:	"	П	isability or Permane	ont Damana	best estimate)	urmitowi	i, give duration	i) iioniiio (di	Stopp	ped or Dose	Reduced?
	(mm/dd/yyyy)	=			#1				#1 🔲	Yes 🔲 No	Doesn't Apply
Life-threatening	Salating and the salati		ongenital Anomaly/		#2					Yes No	
3.37.7.3	- initial or prolonged		The TOTAL TO BY	tant Medical Events)	4. Diagnosis or Re	ason for	Use (Indication	on)	#2	Yes No	Apply
Required Interv	rention to Prevent Perm	anent Im	ipairment/Damage ((Devices)	#1	111070	A CONTRACTOR	*		t Reappeared roduction?	d After
3. Date of Event (mm)	/dd/yyyy)	100	te of this Report (n	nm/ad/yyyy)	=-				_	Yes No	Doesn't
			1/08/2016		#2						Apply
5. Describe Event, Pr	roblem or Product Use	Error			6. Lot #		7. Expiration	Date	#2	Yes No	Doesn't Apply
	d son was heal				#1		#1		9. NDC	# or Unique	11.7
	sits at the ti him Hylands Te				#2		#2			1440	
recommended b	y a family mem	ber.	Son was giv	ren two	E. SUSPECT	MEDIC	AL DEVIC	F			
	ithin three ho				1. Brand Name						TIL
and child was	taken to the	ER.	He improved	and was not							CTU
	ospital. Doc her is concern				2. Common Device	Name				CCD	1 9 2016
	lla donna in p				3. Manufacturer Name, City and State						
video of a NI	H case study b	y the	FDA. Son I	nas twin							
	nts monitor al possible aller			ucea to						200	
		-			4. Model #		Lot#				or of Device
					Catalog #		Evole	tion Date /	mm/dd/yyyy)		h Professional
					Catalog #		LAPIN	tion bate (illivaa yyyy)	Lay U	Jser/Patient
					Serial #		Other	#		Other	r.
										1	
					6. If Implanted, Given	e Date (mm/dd/yyyy)	7. If E	cplanted, Gi	ive Date (mm	n/dd/yyyy)
					8. Is this a Single-	na Bard	and the same in	40.000	· Lack Harris	A July Barri	
					Yes		ice that was H	eprocessed	and Heuse	on a Patie	entr
					9. If Yes to Item No	-	er Name and	Address of I	Reprocesso	or	
5.754.4743											
6. Relevant Tests/Lab	boratory Data, Includi	ng Dates									
				0 1							
					F. OTHER (C	ONCO	MITANT) N	EDICAL	PRODUC	CTS	
				- 1	Product names ar	d therap	y dates (excl	ide treatmer	nt of event)		
7 Other Palevent His	story, including Preexi	eting Me	adlesi Conditions	la a alleroine							
race, pregnancy, sm	noking and alcohol use,	liver/kidi	ney problems, etc.)	org., anergies,	G. REPORTE	R (See	confiden	tiality sec	ction on	back)	
					1. Name and Address	188					
					(b) (6)			-			
				0.00							
					17.0			- 10			
					76) 765° *			E-mail			
C. PRODUCT A	VALLABILITY				2. Health Profession	nal? 3	Occupation	_	1/2	4. Also Repo	orted to:
THE RESIDENCE OF THE PERSON NAMED IN	Evaluation? (Do not s	end pron	duct to FDA)		Yes N	0	ALL MANY			Manufa	acturer
					5. If you do NOT w		Identity dies	osed		User F	
Yes No	Returned to M	Manufacto		m/dd/yyyy)	to the manufact						utor/importer

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

PLEASE TYPE OR USE BLACK INK



The FDA Safety Information and Adverse Event Reporting Program

ort	Rep
ort	Rep

CaseID: 12197698

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

	See OMB state
porting of &	FDA USE ONLY
product use errors	Triage unit sequence #
product use errors	1,441037

A DATIENS	INFORMATION			2. Dose or Amo	ount Freque	ency Route	į.
	fier 2. Age at Time of	Event or 3. Sex	4. Weight	#1		ency Koute	
b) (6)	Date of Birth:		nale 16 lb.				
	6 Months (b)(6)		40	#2			
In confidence		☐ Mal	e				
		UCT PROBLEM C	R ERROR	3. Dates of Use (If (or best estimate	funknown, give duratio		t Abated After Use d or Dose Reduced?
Check all that ap		Problem (e.g., defects/n	nalfunctions)		- 03/17/2016	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Yes No Does
			turer of Same Medicine	#2		Wa 🗔	Yes No Does
	tributed to Adverse E	vent			eason for Use (Indicat	ion)	Apply
(Check all that	t apply)	Distance in Day	and Daniel	#1 Teething		8. Even	t Reappeared After troduction?
Death:	(mm/dd/yyyy)	Disability or Perm		#2		#1 🔲	Yes ☐ No ☑ Does Apply
Life-threate		Congenital Anon		6. Lot#	7. Expiratio	n Data #2 🗆	Ves No Does
		ed [/] Other Serious (In Permanent Impairment/	nportant Medical Events)	#1	#1	772	# or Unique ID
3. Date of Event			port (mm/dd/yyyy)	#2	#2	5. NDC	# Of Dividue ID
03/17/20		03/19/201	And the second property of the second	E. SUSPECT	MEDICAL DEVIC	E	
	ent. Problem or Produ		u .	1. Brand Name			
				2. Common Devic	e Name		
				4,4500000000000000000000000000000000000			CTU
Soo addi	tional name	alel for cor	mplete text.	2 Manufactures N	lame, City and State	MA	R 2 1 2016
see addi	cional page	e(S) TOT CO	upiece cext.	3. Manufacturer N	ame, City and State	IVI.	IN & A LUIN
				1			
				4. Model #	Lot#		5. Operator of Devic
							Health Profession
				Catalog #	Evniratio	n Date (mm/dd/yyyy)	Lay User/Patient
				Catalog w	Expiratio	in Date (minutaryyyy)	
6. Relevant Test	ts/Laboratory Data, In	cluding Dates		- 6-4-1#	Out and		Other:
TO CHARLENGE AND		Julius Parios		Serial #	Other#		
				-			
See addi	tional page	e(s) for con	plete text.	6. If Implanted, Gi	ve Date (mm/dd/yyyy)	7. If Explanted, G	Give Date (mm/dd/yyyy)
					use Device that was I	Reprocessed and Re	used on a Patient?
				Yes No			
				9. If Yes to Item No	. 8, Enter Name and Ad	dress of Reprocessor	
7. Other Relevan	nt History, Including F	Preexisting Medical Co and alcohol use, liver/kid	inditions (e.g.,				
	, ,, - 2,		niej prosicino, stary	E OTHER (CO	ONCOMITANT) M	EDICAL PRODI	ICTS
					nd therapy dates (excl		
See addi	tional page	e(s) for com	plete text.	0.140.7.1.00.00.00.00.00			•
				400000000000000000000000000000000000000			
				G. REPORTER 1. Name and Addr	(See confidentia	lity section on b	ack)
	T AVAILABILITY			Name (b) (6)	435		
Product Availab	ele for Evaluation? (De	o not send product to FL	DA)	Address:		116	
Yes N	lo Returned to M	Manufacturer on:	(mm/dd/yyyy)	100		117	
D. SUSPECT	PRODUCT(S)		V-2144-21111	City:		State: ZI	P;
	th, Manufacturer (fron			Phone #		E-mail (b) (6)	
1 Name: Hyla Strength:	and teething tal	blets				24 617	
- Manufacturer:				2. Health Professi	onal? 3. Occupation	4	. Also Reported to:
2 Name:				Yes No			Manufacturer
Strength:	nee			5. If you do NOT wa	ant your identity disclo	sed	User Facility

B.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.

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

Blood panel showed mild dehydration

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

Race: Other

Medical Conditions:

Allergies:

Important Information:

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

Individual Case Safety Report

PLEASE TYPE OR USE BLACK INK



12470569-01-00-01

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Form Approved: OMB No. 0910-0221, Express -09(30/2018
Caso ID state and 1/60/06/20.

	FDA USE ONLY
Triage unit sequence #	662552
FDA Rec.	
Date	

Note: For date prompts	s of "dd-mmm-yyyy" p	lease use 2-digit	day, 3-letter n	nonth] 3.	Dose or Amount	Frequency		Route		
abbreviation, and 4-dig		11-Jul-2015.			#1	135 Tablet(s)	Every 6 hour	5	Taken by r	nouth	
A. PATIENT INF						4.4					
1. Patient Identifier 2 b) (6)		Month(s)	3. Sex	4. Weight	#2						
	6 Week(s)		Female	25	#2						
0	r Date of Birth (e.g.,	08 Feb 1925)	=	✓ Ib	4 Da	ates of Use /From/Ti	o for each) //f unk	nown	o Event	Abated Aff	ne Hen
In Confidence			Male	☐ kg		ates of Use (From/To ve duration, or best e		n-yyyy)			Reduced?
5.a.Ethnicity (Check	5.b.Race (Check	k all that apply)				08-Jun-2016 - 11-J	un-2016		#1 V Y	es No	Doesn' apply
single best answer)	☐ Asian ☐	American India	n or Alaskan i	Nativa	#2 5 Di	agnosis or Reason	for Una Vindicatio	en l	#2 Ye	- DNo	Doesn'
Hispanic/Latino		ican American	Whi	1000	1 7	eething	ior use (maicano	(i)		s No	☐ apply
✓ Not Hispanic/Lati	요즘 프레이어 그			ie	#1					Reappeare oduction?	
B. ADVERSE EVE	L Hadive Havi	alian or Other Pa	icinc Islander	-	#2				#1 V Ye	s 🗆 No	Doesn'
1. Check all that appl		PROBLEM							- L	- Цпе	— арріу
	Table of the Control of the	Secret Section				the Product	7. Is the Produ		#2 Ye	s No	Doesn's
✓ Adverse Event		em (e.g., defect			W. 1	mpounded?	Over-the-Co				
Product Use Erro	or Problem with	Different Manuf	acturer of Sai	me Medicine	-	-	#1 / Yes	□ No	4		
2. Outcome Attribute	d to Adverse Event	(Check all that a	pply)		#2		#2 Yes	No			
Death Include da	te (dd-mmm-vvvv):		7.3			oiration Date (dd-mn			#:	2	
Life-threatening	- (22	Disability	or Permanent	Damage	1000	SUSPECT MED	ICAL DEVICE				
Hospitalization - in	nitial or prolonged	Congenita	Anomaly/Birt	h Defects	1. Br	and Name					
✓ Other Serious (Im					11 -			(A) (A) (A)	×		
Required Interven	ntion to Prevent Perm	anent Impairmer	t/Damage (De	evices)	2. Co	mmon Device Name	e	LIL	12	b. Procod	e
3. Date of Event (dd-n	mmm-yyyy)	4. Date of this	Report (dd-mi	тт-уууу)			111	MIK	2016	2.11.1	-
11-Jun-2016		14-Jun-201	6		3. Ma	nufacturer Name, C	ity and State	114 70	Luic		
5. Describe Event, Pro	oblem or Broduct Lie	o Error			1						
See additional			t .		4. Mo	del#	Lot#		11	Operato	r of Device
0.15/0000510000	2-3-1-1				1		100			,. Operato	TOI DOVICE
										Health	Professional
Relevant Tests/Labo	oratory Data Includi	na Datas			Catal	log #	Expiration	Date (dd-n	nmm-yyyy)	Lay U	ser/Patient
. Noteralli restarcas	oratory Data, merati	ing Dates					1			Other	
										Outer	
					Seri	ial#	Unique Ide	ntifier (UD)I) #		
Other Relevant History	ory, Including Preex	isting Medical	Conditions (e	g.							
allergies, pregnancy,	smoking and alcohol	use, liver/kidney	problems, etc	2.)	6. If Ir	mplanted, Give Date	(dd-mmm-yyyy)	7. If Exp	lanted. Giv	e Date (do	i-mmm-yyyy,
See additional p	page(s) for co	mplete text	6.60		1000	inprainted, entre eath	(44 ///////////////////////////////////			2 - 27 - 6 - 6	2227
					8. Is t	this a single-use de	vice that was		T.Var. I	T. No.	
DROBUGT AVA	II ADII ITW					processed and reus			Yes [No	
C. PRODUCT AVA 2. Product Available fo		at sound product t	o EDA)		9. If Y	es to Item 8, Enter N	ame and Address	of Reproc	essor		
	Name of the last o		J FDA)								
✓ Yes No	Returned to Ma	nufacturer on: -	(dd-mmm-y	vvv)	E (OTHER (CONC	OMITANT) ME	DICAL	PRODU	OTC.	
D. SUSPECT PRO			0000		Produ	uct names and there	apy dates (Exclui	de treatme	ent of event)		
. Name, Manufacturer					See	additional page	(s) for compl	ete text			
1 - Name and Strength Iylands baby tee			# or Unique II	D		REPORTER (See	e confidentialit	y section	i on back)		
,	oneng control				(b) (6)	me and Address					
		1.									
W - 441 - 271 - 125											
#1 - Manufacturer/Comp lylands Inc.	pounder	#1- Lot #									
lytands Inc.		A15116									
#2 - Name and Strength	1	#2 - NDC	# or Unique ID)		try; us		ZIP	P/Postal Cod	e (b) (6)	11 11
		1 1 2 2 2 2	200 400 400		Phone (b) (6)	9.#3	E-mail: (b) (6)				
					-						
DSS	3					alth Professional?	3. Occupation		14. A	Iso Repor	ted to:
2 - Manufacturer/Comp	pounder	#2- Lot #				Yes No				Manufac	turer/
JUN 15 21	Ote	1			5 14	ou do NOT west	us identification			Compou User Fac	
- 0 2	410					ou do NOT want yo the manufacturer, p				200	or/Importer
					1					P. SHIPPIN	miniporte!

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 251bs 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

Individual Case Safety Report



The FDA Safety Information and

ar	Rej	por		10	
		ing		/	
tp	rob	lem	s an	d	
err	ors				

7	CaseID: 1248034	(
Form Approved	: OMB No. 0910-0291, Expires: 09/30/2018	
	See PRA statement on reverse.	

Triage unit sequence #

Adverse Event Re					la p			Route		
Note: For date prompts			day, 3-letter m	onth	3. Dose or A	mount	As Needed	Taken by n	nouth	
abbreviation, and 4-digi		01-Jul-2015.			#1		or Haraban			
A. PATIENT INFO		***		12.00.1.12						
1. Patient Identifier 2.			3. Sex	4. Weight	#2					
(b) (6)	Week(s	Day(s)		21	#2					
0	r Date of Birth (e.g.,	08 Feb 1925)	Female	V 1b		· ·		lo Edward	Abatad After Use	
			✓ Male	☐ kg	4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy) 9. Event Abated After Use Stopped or Dose Reduced					
In Confidence		0.200 0.001			#1 01-Apr-20			#1 🗆 Ye	es No Doesn	
5.a.Ethnicity (Check single best answer)	5.b.Race (Chec	k all that apply)			#2				- Dosen	
	Asian	American India	n or Alaskan N	Vative	4		for Use (indication)	#2 Ye	s No apply	
Hispanic/Latino	Black or Af	rican American	✓ Whit	le	#1	ing			Reappeared After	
✓ Not Hispanic/Lati	ino Native Hav	vailan or Other Pa	acific Islander					- 1 10000	oduction?	
B. ADVERSE EV				100	#2			#1 V Ye	s No apply	
1. Check all that appl		THOOLEM					Participation of the Control of the	#2 🗆 v	s No Doesn	
	The second second		re de descri		6. Is the Produ Compounde	5.4	7. Is the Product Over-the-Counter?	#2 10	apply	
✓ Adverse Event		lem (e.g., defect				No.	#1 7 Yes No			
Product Use Erro	or Problem with	Different Manuf	acturer of Sar	ne Medicine			#2 Yes No	-		
2. Outcome Attribute	ed to Adverse Event	(Check all that a	ipply)		#2 Yes	No No		1	10	
		1 -0.04			B. Expiration D		CONTRACTOR OF MANAGEMENT	6 #	2	
	ate (dd-mmm-yyyy):	☐ Disability	or Permanent	Damage		C - G - G - G - G - G	ICAL DEVICE			
Life-threatening	antal as solla seco		al Anomaly/Birt	1 1 1 1 1 1 1	1 Brand Name	9				
✓ Other Serious (In	initial or prolonged			Dolone			C	TU		
Required Interver	ntion to Prevent Perr	nanent Impairme	nt/Damage (De	evices)	2. Common De	wies No.	0.00	Per manufacture	2b. Procode	
A A A A A A A A A A A A A A A A A A A					12. Common Di	evice Mail	e JUN I	7 2016	D. Procode	
3. Date of Event (dd-mmm-yyyy) 4. Date of this Report (dd-mmm-yyyy)					3. Manufacture	er Name, C	City and State	-		
04-May-2016		16-Jun-20	16							
5. Describe Event, Pr	roblem or Product L	Jse Error			1					
See additional			xt.		4. Model #		Lot#		Operator of Device	
	Andrew Andrews									
					4-10-3				Health Professiona	
6. Relevant Tests/Lab	oraton/ Data Inclus	ding Dates			Catalog # Expiration Date (d			-mmm-yyyy)	Lay User/Patient	
See additional			t.				1 1 1 1 1 1 1 1		Other	
are appreciately	- A							-0.0	T 47.7 1 1	
					Serial#		Unique Identifier (U	(IDI) #		
7 Other Polavent III-	tony Including Dec	avisting Medical	Conditions /	9.0	1					
Other Relevant His allergies, pregnancy	, smoking and alcoh	ol use, liver/kidne	y problems, et	(c.)	6 If Implement	Give Det	e (dd-mmm-yyyy) 7. If Ex	oplanted. Gi	ve Date (dd-mmm-yyy	
See additional					o. ii impianted	, Give Dai	a (adminingyyy)			
					8 Is this a sin	ale-usa d	evice that was	TIME	1.60	
					reprocesse	d and reus	evice that was sed on a patient?	Yes	No	
C. PRODUCT AV				-5-	9. If Yes to Item	n 8, Enter f	lame and Address of Repro	ocessor		
2. Product Available		not send product	to FDA)							
Yes No	Returned to M	Manufacturer on:			1			-		
	_		(dd-mmm-	уууу)			OMITANT) MEDICA			
D. SUSPECT PR					Product name	s and the	rapy dates (Exclude treatmets) for complete te.	nent of even	0	
1/-Name, Manufacture		ength (from pro	duct label) C # or Unique	ID	200		ee confidentiality section	-	0	
Hylands Teethin		#1-140	o a or ornique		1 Name and (b) (6)	Address	oo oomidamidii y oodii	J. J. Duoi		
5	20.00				(D) (6)				- 1	
									1/1	
					1				N	
#1 - Manufacturer/Con	mpounder	#1- Lot ;	#							
Hylands									(b) (P)	
#2 - Name and Streng	oth	#2 - NID(C# or Unique I	ID.	Country: US			IP/Postal Co	ode: (b) (b)	
#E - Marile and Streng	gui.	#2 - ND(o ar or ornique i		Phone #: (b) (6)		E-mail: (b) (6)			
					12.121		127			
							3. Occupation	[4.	Also Reported to:	
40.14		un la	31		Yes	No		1	Manufacturer/	
#2 - Manufacturer/Cor	mpounder	#2- Lot	**					- 1	Compounder	
					5. If you do N	OT want y	our identity disclosed	7 1	User Facility	
					to the man	uracturer,	please mark this box:	v	Distributor/Importer	



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

14 OSS 1414

PLEASE TYPE OR USE BLACK INK



orting of oblems and

Frequency

Controppi	Case(Date) 249 1395							
FDA USE ONLY								
Triage unit sequence #								
FDA Rec. Date	664/10							

Route

late. For data area	pts of "dd-mmm-yyyy"	nlease use 2-digit da	v. 3-letter month	3.	Dose or Amount	Frequency	Route			
vote: For date prom	digit year; for example	01-Jul-2015	At a minet that in	#1	2 Tablet(s)		Taken by	mouth		
A. PATIENT IN		, 01-uu-2010.		7.						
OF A STATE OF THE PARTY OF THE		o) [] Marather	a say 4. Weight			ļ				
. Patient Identifier i) (6)	2. Age Year((s) Day(s)	3. Sex 16	#2						
	or Date of Birth (e.g. (b) (6)	g., 08 Feb 1925)	Female / lb	g	ive duration, or best	o for each) (If unknown, estimate) (dd-mmm-yyy,	() Stop	t Abated After Use ped or Dose Reduced?		
In Confidence 5.a.Ethnicity (Chec	ck Espession	eck all that apply)		-	01-Mar-2016 - 17-A	Apr-2016	#1 🗸	Yes No Doesn't		
single best answer)			2,2000000000000000000000000000000000000	#2	to down to the H	for the Andrews	#2 🗖	Doesn't		
	Asian	American Indian	The state of the s	5. Diagnosis or Reason for Use (indication) She is teething and I used to to help						
Hispanic/Latin	☐ Black or /	African American	✓ White		calm her and ease		10.Ever	nt Reappeared After stroduction?		
✓ Not Hispanic/I	Latino Native Ha	awaiian or Other Paci	fic Islander	-				— Decen's		
B ADVERSE F	VENT, PRODUC			#2			#1 🔲	Yes No apply		
1. Check all that a					the Product	7. Is the Product	_	Yes No Doesn'		
✓ Adverse Even		oblem (e.g., defects/r		1	ompounded?	Over-the-Counter				
Product Use E	Error Problem wit	th Different Manufac	turer of Same Medicine	#1	Yes V No	#1 🗸 Yes	No			
				#2	Yes No	#2 Yes	No			
2. Outcome Attrib	outed to Adverse Eve	nt (Check all that ap)	oly)	11	piration Date (dd-m		11.14	#2		
	e date (dd-mmm-yyyy)	Disability or	Permanent Damage		SUSPECT ME	DICAL DEVICE				
Life-threatenin			Anomaly/Birth Defects	1, 8	Brand Name					
Other Serious	n - initial or prolonged (Important Medical E	-	manife and selected	11			CTI			
Required Inte	rvention to Prevent Pe	ermanent Impairment	Damage (Devices)	20	ommon Device Nar	ne	0111	2b. Procode		
3. Date of Event (eport (dd-mmm-yyyy)	+ 2.0	CHILIDA DEVICE 1461	LIIIN	2 2 2010	2007-0193		
3. Date of Event (ии-ліпп-уууу)	1 2 40 3 5 5 7	18 - 1 - 10 - 10 - 10 - 10 - 10 - 10 - 1	3. N	lanufacturer Name,	City and State	# & LUIO			
17-Mar-2016		21-Jun-2016	5							
5. Describe Event	, Problem or Produc	t Use Error		4.8	Model #	Lot#		5. Operator of Device		
See addition	al page(s) for	complete text		7.0		7.7		S. Sperator of Device		
								Health Professiona		
				Car	talog #	Expiration Date	(dd-mmm-vv			
	Laboratory Data, Inc			11		Expiration Date	(== annu-yy)			
	al page(s) for							Other:		
				· e	erial#	Unique Identifi	er (UDI)#			
				1	***	and a second	367 37 55	U		
7. Other Relevant	History, Including Prancy, smoking and alc	reexisting Medical C	problems etc.				45	Oher Bet 122		
allergies, pregna	ancy, smoking and alco al page(s) for	complete teve	problems, etc.)	6.1	f Implanted, Give D	ate (dd-mmm-yyyy) 7.	If Explanted,	Give Date (dd-mmm-yyy)		
see addition	ar page(s) for	complete cext								
				8. 1	s this a single-use	device that was used on a patient?	Yes	☐ No		
	AVAIL A BULLEY			11		Name and Address of F				
C. PRODUCT	AVAILABILITY ble for Evaluation?(D	o not soud area	EDAT	3,						
			, run							
✓ Yes ☐	No Returned to	Manufacturer on: -	(dd-mmm-yyyy)	-	OTHER (CON	COMITANT) MEDI	CAL PRO	DUCTS		
D CHERCE	PRODUCTS		(www.minuryyyy)	Pro	oduct names and th	erapy dates (Exclude to	reatment of ev	ent)		
D. SUSPECT	turer/Compounder,	Strength (from produ	uct label)	Se	e additional pa	ge(s) for complete	text.			
#1 - Name and Stre	ength	#1 - NDC	# or Unique ID			See confidentiality s	ection on ba	ick)		
Teething Tab	lets			1.1	Name and Address (6)					
	111			(0)	10/			A		
	1)							Code (b) (6)		
#1 - Manufacturer/	Compounder	#1- Lot #		1				4 00		
Hylands Baby	Target American	B51615						20		
nyidnus baby		851615		C	ountry: US		7IP/Postal	Code (b) (6)		
#2 - Name and St	rength	#2 - NDC	# or Unique ID		ione #:	E-mail:	Lii /i Ustal	6		
		100	CATE DISCHOOL	111177	(6)	(b) (6)				
				Access	**					
				2.	Health Professiona	17 3. Occupation		4. Also Reported to:		
the subject of	10 manual and installation	#2- Lot #		-	Yes No			Manufacturer/		
#2 - Manufacturer	Compounder	#2- LOT#		-	W	Constant and the standard		Compounder User Facility		
				5.	If you do NOT want	your identity disclose r, please mark this bo	c 🔽	Distributor/Importer		
					to the manufacture	, piease mark mis DO	. 1	☐ Distributor/Importer		

CaseID: 12491395

B.5. Describe Event or Problem (continued)

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 and and 2 tablets the morning of the seizure. We brought her to children's hospital and she was admitted and they did and EEG and found nothing wrong with our little girl.

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

Normal growth and development evaluation and an EEG

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 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

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

RX Meds: None

OTC Meds: None

Individual Case Safety Report





A A	1260652	0-01-00-01			10	0111	FDA Rec.	U	100	77	
Note: For date prom	pts of "dd-mmm-yyyy"	please use 2-digit	day. 3-letter m	onth	113.	Dose or Amount	Date Frequency		Route		
abbreviation, and 4-	digit year; for example,		say, o lane, it	TO THE T	#1	2 Tablet(s)	Once a day		Taken by	mouth	
A. PATIENT IN 1. Patient Identifier							4.				
(b) (6)	2. Age Year(s		3. Sex	4. Weight 18.15	#2						
	or Date of Birth (e.g		Female	✓ Ib							
In Confidence	(b) (6)		✓ Male	☐ kg	4. Da	ates of Use (From/ ve duration, or besi	To for each) (if unkr estimate) (dd-mmn	nown, n-vvvv)	9. Event	Abated Aft	ter Use Reduced
5.a.Ethnicity (Chec		ck all that apply)	1	1 3	#1 2	23-Jul-2016 - 23-		42376	1000	es V No	☐ Does
single best answer)	Asian [American India	n or Alaskan N	lative	#2 5. Dia	agnosis or Reaso	n for Use (indication	7)	#2 🗆 Ve	es No	apply
☐ Hispanic/Latino ☐ Black or African American ☑ White						Teething	Total Carlo			Reappeare	- apply
Not Hispanic/L	L Ivauve Hav	vailan or Other Pa	cific Islander						Reintr	oduction?	
	VENT, PRODUC	PROBLEM			#2				#1. Ye	es No	✓ Doesn
1. Check all that ap			divisite in Catholic III		9.1	the Product	7. Is the Produc		#2 🗌 Ye	es No	Doesn apply
Product Use E		Different Manuf				Yes V No	#1 Ves	Inter?			265.4
A STATE OF THE STA				ne medicine		Yes No	#2 Tyes	П №			
The Park Street Committee of the Committ	uted to Adverse Even		oply)			piration Date (dd-n			#	2	
Death Include	date (dd-mmm-yyyy):		or Permanent D	Damage			DICAL DEVICE		1"		
	- initial or prolonged		Anomaly/Birth		1. Br	and Name					
	(Important Medical Eve										
	vention to Prevent Perr		C EL VENDO		2. Co	mmon Device Nar	ne		CTU	b. Procode	e
3. Date of Event (do	d-mmm-yyyy)	4. Date of this i		nm-yyyy)	3. Ma	nufacturer Name,	City and State	JH	282		
23-Jul-2016		27-Jul-201	6				-17 2010 01010	201	- 20 /	U16	
	Problem or Product L		4.0		4. Mo	del #	Lot#				
see addiciona	l page(s) for o	complete tex	E.,		4. IVIO	del #	Lot #		1	5. Operato	r of Device
										Health	Professiona
6. Relevant Tests/La	aboratory Data, Includ	ing Dates			Catal	og#	Expiration D	ate (dd-m	тт-уууу)	Lay Us	er/Patient
See additional	l page(s) for c	omplete text								Other:	
					Seri	al#	Unique Iden	tifier (UD	0 #		
7. Other Relevant Hi	istory, Including Pree	visting Madical (onditions /o				10000	ever deser			
allergies, pregnand	cy, smoking and alcoho	il use, liver/kidney	problems, etc.)"	R. IF In	nplanted, Give Da	to della mana sana v	7 If Evol	anted Giv	o Data (da	-mmm-yyyy
See additional	page(s) for co	implete text			0.1111	iipianteu, Give Da	te (dd-mmm-yyyy)	/. II Espi	anteu, Giv	e Date (Du	-rumm-yyyy
					8. ls t	his a single-use d	evice that was sed on a patient?	П	Yes [No	
C. PRODUCT AV		W-100	-				Name and Address	of Reproce		1.04	
Acres 1	for Evaluation?(Do n	ol send product to	FDA)								
✓ Yes □ No	Returned to Ma	anufacturer on: -	Idd mmm in	660							
D. SUSPECT P	RODUCTS		(dd-mmm-y)	(799)	F. C	OTHER (CONC oct names and the	OMITANT) ME rapy dates (Exclude	DICAL	PRODUC	CTS	
1,-Name, Manufactur	rer/Compounder, Stre	ngth (from produ	ict label)		See a	additional page	e(s) for comple	te text			
Hylands Teethi		#1 - NDC	# or Unique ID			REPORTER (Some and Address	ee confidentiality	section	on back)		
					(b) (6)	ne and Address				-	0-
										0	0
#1 - Manufacturer/Cor	mpounder	#1- Lot #								0	201
Hylands				-							2010
#2 - Name and Streng	gth	#2 - NDC #	or Unique ID		Count		1 =	ZIP/	Postal Cod	e(b)(6)	
					Phone (b) (6)	#.	E-mail:				
					2 Has	Ith Professional?	3 Occupation				
#2 Manufacture	ministrativa di Arri					Yes No	o. Occupation		4. A	Iso Report	
#2 - Manufacturer/Con	mpounder	#2- Lot #				10.0				Manufact Compoun	nder
					5. If yo	ou do NOT want y	our identity disclos please mark this b	ox:		User Faci	ility r/Importer
							and the second second	, DO 1	1.6.1	סוטטווופוע	THIDOLIGI

eporting of problems and

Triage unit

FDA USE ONLY

B.5. Describe Event or Problem (continued)

Gave 6 month old son 2 Hylands Teething Tablets aprox 6:30pm (b) (6) Within 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 effecting him.

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

(b) (6) blood work done at (b) (6)

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:

Individual Case Safety Report



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PLEASE TYPE OR USE BLACK INK

l' reporting of ct problems and errors

FDA USE ONLY	
Triage unit sequence #	
FDA Rec. 1074018	

Note: For date prompts of "dd-mmm-yyyy" ple	ase use 2-digit day, 3-letter m	onth	3. Dose or Amoun	t Frequency	Route	
abbreviation, and 4-digit year; for example, 0	I-Jul-2015.		#1	4		
A. PATIENT INFORMATION						
1. Patient Identifier 2. Age Year(s)	Month(s) 3. Sex	4. Weight				
(b) (6) 5 Week(s)	Day(s)	18	#2			
or Date of Birth (e.g., 0	R Feb 1925	✓ lb				
of bate of birth (e.g., a	✓ Male		4. Dates of Use (From	n/To for each) (If unkn	own, 9. Ev	ent Abated After Use
In Confidence	[V]	kg		st estimate) (dd-mmm	-yyyy) Sto	opped or Dose Reduced?
5.a.Ethnicity (Check 5.b.Race (Check	all that apply)		#1		#1 [.	Yes No Doesn'
single best answer)		mělicom	#2			apply Doesn'
Hispanic/Latino	American Indian or Alaskan N		5. Diagnosis or Reas The baby was Te) #2 L	Yes No apply
✓ Black or Afric	can American White	e	#1	centary		ent Reappeared After
Not Hispanic/Latino Native Hawa	iian or Other Pacific Islander		-		Re	eintroduction?
B. ADVERSE EVENT, PRODUCT I	PROBLEM		#2		#1 🗸	Yes No Doesn't
1. Check all that apply			C In the Decident	Territoria.	10.5	
✓ Adverse Event ☐ Product Proble	um form alabada (malbumatana)		6. Is the Product Compounded?	7. Is the Production Over-the-Cou		Yes No Doesn't
	m (e.g., defects/malfunctions)	e memoral	#1 Yes No		V-10-1	
Product Use Error Problem with D	ifferent Manufacturer of Sam	ie Medicine			□ No	
2. Outcome Attributed to Adverse Event (Check all that apply)		#2 Yes No		∐ No	
	an mac appryy		8. Expiration Date (dd	-mmm-yyyy) #1		#2
Death Include date (dd-mmm-yyyy):	Disability or Permanent D		E. SUSPECT MI	EDICAL DEVICE		10000
Life-threatening] <u></u>		1. Brand Name			
Hospitalization - initial or prolonged	Congenital Anomaly/Birth	Defects				
Other Serious (Important Medical Events						
Required Intervention to Prevent Perma	nent Impairment/Damage (Dev	rices)	2. Common Device N	ame	Page 1 11	2b. Procode
3. Date of Event (dd-mmm-yyyy)	. Date of this Report (dd-mm	іт-уууу)			CTU	300,720,72
01-Aug-2016	13-Aug-2016		3. Manufacturer Nam	e, City and State	110 4 F 20	10
		- V		A	UG 1 5 20	10
5. Describe Event, Problem or Product Use			1 00-1-14	77.24		
See additional page(s) for co	mplete text.		4. Model #	Lot#		5. Operator of Device
			0.11			Health Professional
6. Relevant Tests/Laboratory Data, Includin	o Dates	-	Catalog #	ate (dd-mmm-yy	m-yyyy) Lay User/Patient	
See additional page(s) for com				11.00		
	4-7-7-7-7-7-7-7-7-7-7-7-7-7-7-7-7-7-7-7		1 1			Other:
			Serial #	Unique Iden	tifier (UDI) #	
7.00-01-00-			1.0			
 Other Relevant History, Including Preexist allergies, pregnancy, smoking and alcohol u 	iting Medical Conditions (e.g.	3.				
See additional page(s) for com	plete text.	´	6. If Implanted, Give D	ate (dd-mmm-yyyy)	7. If Explanted,	Give Date (dd-mmm-yyyy)
	V. Inc. Collect					
		1	8. Is this a single-use reprocessed and re	device that was	□ V	ELW.
a propular with the in-			the transfer of the same of th		Yes	∐ No
C. PRODUCT AVAILABILITY	And Annual Control		9. If Yes to Item 8, Ente	r Name and Address of	f Reprocessor	
2. Product Available for Evaluation? (Do not	send product to FDA)					
✓ Yes No Returned to Man	ufacturer on:					
W ANNUAL CONTRACTOR	(dd-mmm-yy	yy)	F. OTHER (CON	COMITANT) ME	DICAL PRO	DUCTS
D. SUSPECT PRODUCTS			Product names and the	nerapy dates (Exclude	treatment of ev	rent)
 Name, Manufacturer/Compounder, Streng #1 - Name and Strength 						
Hyland's Baby Teething Tablets	#1 - NDC # or Unique ID		G. REPORTER (See confidentiality	section on ba	ack)
			1. Name and Address (b) (6)			
7						
4.7						
#1 - Manufacturer/Compounder	#1- Lot #	-				
			Country. US		(7000	o (h) (6)
#2 - Name and Strength	#2 - NDC # or Unique ID			TE mail.	ZIP/Postal	Code: (6) (6)
	The second second		Phone #: (b) (6)	E-mail:		
				777		
		li	2. Health Professiona	? 3. Occupation	- 1	4. Also Reported to:
#2 Manufacture Co.	46.1374		Yes No			Manufacturer/
#2 - Manufacturen Compounder	#2- Lot #				_	Compounder
			5. If you do NOT want	your identity disclos	ed	User Facility
AUG 1 5 2016				r, please mark this be		☐ Distributor/Importer

B.5. Describe Event or Problem (continued)

I started giving my baby Hyland's Baby Teething Tablet 2 weeks after he turned 4 months.

(b)(6)

he had multiple seizures and I took him straight to the Children's Hospital. He had a EEG done for 48 hours, a 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



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1	126894	40-01-00-0	1	0,	FDA Rec.	758	92
Note: For date prom	pts of "dd-mmm-yyyy"	please use 2-digit	day, 3-letter month	3. Dose or Amount	Frequency	Route	
abbreviation, and 4-	digit year, for example,	The state of the s		#1 2 Tablet(s)	As Needed	Taken i	by mouth
A. PATIENT IN	And the second second second second				-		
1. Patient Identifier (b) (6)			3. Sex 4. Weight	#2	i		
	Week(s	. =	Female 19	#2			
In Confidence	or Date of Birth (e.g.	, 08 Feb 1925)	Male kg	4. Dates of Use (From/To give duration, or best e		200	nt Abated After Use pped or Dose Reduced?
5.a.Ethnicity (Chec	C. C. Tanana Carlina	ck all that apply)		#1 15-Aug-2016 - 23-A	ug−2016	#1 🗸	Yes No Doesn
single best answer)	Asian	American India	an or Alaskan Native	5. Diagnosis or Reason	for Use (indication)	#2	Yes No Doesn
Hispanic/Latin	Black or At	rican American	✓ White	Teething pain		10.Eve	ent Reappeared After
✓ Not Hispanic/L	atino Native Hav	valian or Other Pa	acific Islander			Rei	ntroduction?
B. ADVERSE E	VENT, PRODUCT	PROBLEM		#2		#1	Yes No Doesn apply
1. Check all that a	pply			6. Is the Product	7. Is the Product	#2	Yes No Doesn
✓ Adverse Even	Product Prot	olem (e.g., defect	s/malfunctions)	Compounded?	Over-the-Counter	_	apply
Product Use E	rror Problem with	Different Manua	acturer of Same Medicine	#1 Yes V No	#1 🗸 Yes	No	
2.0.4	end to Advisor Proces	1 (OK - +1) - 11 15 -1 -	2214	#2 Yes No	#2 Yes	No	
	uted to Adverse Even	t (Check all that a	ippiy)	B. Expiration Date (dd-mr)	пт-уууу) #1		#2
Life-threatenin	date (dd-mmm-yyyy): g - initial or prolonged (Important Medical Eve	Congenita	or Permanent Damage	E. SUSPECT MED 1. Brand Name	ICAL DEVICE		
Required Inter	vention to Prevent Perr	nanent Impairme	nt/Damage (Devices)	2. Common Device Name	e C	71 t	2b. Procode
3. Date of Event (o	ld-mmm-yyyy)	4. Date of this	Report (dd-mmm-yyyy)			10	10.10.000
23-Aug-2016		24-Aug-201	16	3. Manufacturer Name, C	ity and State 16 2	5 2016	
5 Describe Event	Problem or Product L	lea Error					
See additiona	al page(s) for (complete tex	kt.	4, Model # Catalog #	Lot #	(44	5. Operator of Device
6. Relevant Tests/L	aboratory Data, Includ	ding Dates			Expiration Date	s (dd-////////-yy)	Lay User/Patient Other:
				Serial #	Unique Identifi	ier (UDI)#	
allergies, pregnan	listory, including Pree icy, smoking and alcohol 1 page(s) for c	ol use, liver/kidne	y problems, etc.)	6. If Implanted, Give Date	(dd-mmm-yyyy) 7.	If Explanted,	Give Date (dd-mmm-yyy)
				8. Is this a single-use de reprocessed and reus	vice that was	☐ Yes	□No
C. PRODUCT A	VAILABILITY			9. If Yes to Item 8, Enter N			
2. Product Available	e for Evaluation?(Do I	Mary Company		3. Il tes to item 6, Eliter N	and and Address of f	Reprocessor	
✓ Yes □ N	Returned to M	anufacturer on:	(dd-mmm-yyyy)	F. OTHER (CONC	OMITANTA MEDI	CAL DROP	NICTS
D. SUSPECT F	RODUCTS		(ac miningy)	Product names and ther	SERVICE MANAGEMENT OF THE PARTY		
1. Name, Manufactu	rer/Compounder, Stre			See additional page	(s) for complete	text.	
#1 - Name and Stren Hyland's Teeth			C# or Unique ID	G. REPORTER (Se 1. Name and Address (b) (6)	e confidentiality s	ection on ba	ick)
#1 - Manufacturer/Co	ompounder	#1- Lot #					
Hyland's		B70415		and Company of the Co			
#2 - Name and Stree	ngth	#2 - NDC	# or Unique ID	Country: US	16.	ZIP/Postal	Code:(b) (6)
	7			Phone #: (b) (6)	E-mail: (b) (6)		
	F			2. Health Professional?	3. Occupation		A DEPOSITOR OF THE PARTY OF THE
	DSS			Yes No	and the same of th		4. Also Reported to: Manufacturer/
#2 - Manufacturer/Co		#2- Lot #		F 10	CONTROL DE CO		Compounder
	AUG 2 5 2016			5. If you do NOT want yo to the manufacturer, p			User Facility Distributor/Importer

porting of roblems and

Gasel D: 12689440

FDA USE ONLY

CaseID: 12689440

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

 $\underline{\mathtt{OTC}}$ Meds: Infant Motrin Concentrated drops (1.25mL, rare occasions) Infant Tylenol (2.5 mL, only when fever is high)

Individual Case Safety Report

12800110



reporting of problems and errors

FDA USE ONLY				
Triage unit sequence # 67(0113				
FDA Rec.				

Casel Diatenze 930/2018

Note: For date promp	ots of "dd-mmm-yyyy" ple	ease use 2-digit	day, 3-letter mo	onth	3.	Dose or Amou	nt Fre	quency		Route		
abbreviation, and 4-d	ligit year; for example, 0	1-Jul-2015.			#1	3 Tablet(s	Fou	r times a	day	Taken by	mouth	
A. PATIENT IN	FORMATION											
1. Patient Identifier (6)	2. Age Year(s) Week(s)	Month(s) Day(s)	3. Sex	4. Weight	#2							
	or Date of Birth (e.g., (08 Feb 1925)	√ Female	Пв								
In Confidence	(b) (6)		☐ Male	✓ kg	g	ates of Use (Fro ive duration, or b 6 Months	om/To for e est estima	each) (If unkno ate) (dd-mmm-	own, -yyyy)	Stoppe		Reduced?
5.a. Ethnicity (Check single best answer)	5.b.Race (Check	all that apply)		244	#2					#1 🗸 Y	es No	apply
Hispanic/Latino	, = -	American India	n or Alaskan Na	201	5. Di	iagnosis or Rea To soothe infa					es No	— арріу
Not Hispanic/La					#1						Reappeare oduction?	
C.D.	Native Hawa	iian or Other Pa	cinc Islandel		#2					#1 🗆 Ye	s TNo	Doesn't
	VENT, PRODUCT	PROBLEM	_		1							apply
1. Check all that ap				-	20.00	the Product	1 1 1 1 1 1 1 1	s the Product		#2 Y	es No	Doesn't
✓ Adverse Event	Product Proble	m (e.g., defects	/malfunctions)	1		ompounded?		over-the-Cou		-		-PP-7
Product Use Er	rror Problem with D	ifferent Manufa	cturer of Sam	e Medicine	#1-1-	Yes N	10 #	1 ✓ Yes	☐ No			
2 Outcome Attribu	ited to Adverse Event (Chock all that a	anha!	-	#2 [- V		☐ No			
		Crieck all that ap	(Vidia		8. Ex	piration Date (d	ld-mmm-y	(YYY) #1		#	12	
	date (dd-mmm-yyyy):	C Disability	r Permanent D	amane	E.	SUSPECT N	MEDICA	L DEVICE				
Other Serious (- initial or prolonged Important Medical Event	Congenital	Anomaly/Birth	Defects	1. Bi	rand Name					0.00	
Required Interv	ention to Prevent Perma	nent Impairmen	VDamage (Dev	ices)	2. Co	ommon Device	Name			12	b. Procod	le
3. Date of Event (do	d-mmm-yyyy)	4. Date of this F	Report (dd-mm							ALLA	0.0	
24-Aug-2016		25-Aug-201	6		3. Ma	anufacturer Nar	ne, City a	nd State			20 50	116
5. Describe Event, F	Problem or Product Us	e Error				- 4-14		1 - 2 21				
See additiona	1 page(s) for co	mplete tex	t.		4. IVI	odel#		Lot#				or of Device
					Cata	ilog#		Contration D	see Palat w			
Relevant Tests/La	boratory Data, Includir	ng Dates						Expiration Da	ate (dd-m	тт-уууу)	☐ Lay U:	ser/Patient
					Ser	rial#		Unique Ident	lifier (UD	1) #		
Other Relevant Hi	story, Including Preexi	sting Medical C	onditions (e.g									
	cy, smoking and alcohol page(s) for con			,	6. If I	mplanted, Give	Date (dd	ттт-уууу)	7. If Exp	lanted, Gi	re Date (da	d-mmm-yyyy,
					8. Is	this a single-us processed and	se device reused or	that was	E	Yes [No	
	for Evaluation?(Do no		FDA)		9, If	Yes to Item 8, En	ter Name	and Address o	f Reproc	essor		
✓ Yes No	Returned to Mar	nufacturer on." -	(dd-mmm-yy	(vv)	E	OTHER (CO	NCOMI	TANT) ME	DICAL	PRODU	CTS	
D. SUSPECT P	RODUCTS		11.000			uct names and						
Name, Manufactur	rer/Compounder, Stren				See	addltional p	page(s)	for comple	te text			
Name and Streng		#1 - NDC	# or Unique ID		G.	REPORTER	(See co	nfidentiality	section	on back		
yrand's Baby '	Teething Tablets	54973-	3127-1		1 Na (b) (6)	ame and Addres	SS				-	
		24373-	2121-1		2.7.5.7							16
												USO
#1 - Manufacturer/Co	mpounder	#1- Lot #									77	DSS 6 2 6 20
Hyland's	10000	A60714									U	26 20
		11/2/2019			Cour	ntry: US			[7IP	/Postal Co	de (b) (6)	4 41
#2 - Name and Streng	gth	#2 - NDC	or Unique ID		Phon			E-mail:	1210	. 55101 501		
					(b) (6)		E	(b) (6)				
					2 11-	alth Drofossian	12 2 A	cupation				
						ealth Profession Yes No	air 3. 00	cupation		4. /	Also Repo	
2 - Manufacturer/Co	mpounder	#2- Lot #		-	L	Ties Tivo	11				Manufac	
					5 16	you do NOT wa	nt vous le	antitu disales	had	-	Compou	E 1-20 MIN.
						the manufactur					540 N. YOU	or/Importer
				- 11	1						T DISTIIDUT	ommporter

B.5. Describe Event or Problem (continued)

My 15 month old took 3 teething tabs (as directed) and 30 min later had a seizure. (b)(6) after that had a second seizure and required sedation and hospitalization.

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, very healthy

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

RX Meds: None

OTC Meds: None

Individual Case Safety Report



FDA 3300ASE PDA 2720379U-486 Department: CDER

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
FDA Received Date	03-Sep-2016	CTU Received Date	03-Sep-2016 19:45:05
Report Type	Spontaneous	Report Classification	
Assign To	User		
User/Group			
Forward to Department	CDER		

Contact		7.0 1.00		500.00
Source Form Type	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Generated by: system Generated on: 03-Sep-2016 19:45:06 Page 1 of 4

tion A – About the Problem What kind of problem was it?				
Miliat fringl of muchlow was it?			and the second s	
(Check all that apply)	N N	bad side effect (including new or worsen		
(Check an that apply)		rrectly which could have or led to a prob	lem	
		vith the quality of the product	Contraction of the Contraction o	
	Had problems after	switching from one product maker to an	other maker	
Did any of the following happen?	Hospitalization – adı	mitted or stayed longer		
(Check all that apply)	Required help to pre	event permanent harm (for medical devi	ces only)	
	Disability or health	problem		
	Birth defect			
	Life-threatening			
	Death			
	Other serious/impor	tant medical incident		
Date of Death				
Other serious/important medical	Severe urticaria in in	fant	_	
incident Date the problem occurred	27-Aug-2016			
us what happened and how it		e as many details as nossibb	s).	
ME, Televalle lesis of Impolato				
Blood tests, cbc, pt, ptt,				1 of 1
Blood tests, cbc, pt, ptt, tion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you	Orajel Teething swal			1 of 1
Blood tests, cbc, pt, ptt, tion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes	Orajel Teething swal			1 of 1
Blood tests, cbc, pt, ptt, tion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether				1 of 1
Blood tests, cbc, pt, ptt, ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				1 of 1
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Blood tests, cbc, pt, ptt, ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date	Church & Dwight Yes			1 of 1
Blood tests, cbc, pt, ptt, ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number	Church & Dwight Yes 01-Nov-2018			1 of 1
ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per	Church & Dwight Yes 01-Nov-2018 Gp6006			1 of 1
ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g)	Church & Dwight Yes 01-Nov-2018 Gp6006	bs		1 of 1
ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity	Yes 01-Nov-2018 Gp6006 7.5 % percent 1 Other	If Other If Other		1 of 1
ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency	Yes 01-Nov-2018 Gp6006 7.5 % percent 1 Other 4 times a day	If Other		1 of 1
tion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started	Yes 01-Nov-2018 Gp6006 7.5 % percent 1 Other	If Other If Other		1 of 1
Blood tests, cbc, pt, ptt, ion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used Date the person first started taking or using the product	Yes 01-Nov-2018 Gp6006 7.5 % percent 1 Other 4 times a day Topical 17-Aug-2016	If Other If Other		1 of 1
tion B - About the Products Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.) Is the Product Over-the-Counter? Expiration date Lot number NDC number Strength (for example, 250 mg per 500 ml or 1g) Quantity Frequency How was it taken or used	Yes 01-Nov-2018 Gp6006 7.5 % percent 1 Other 4 times a day Topical	If Other If Other		1 of 1

340	
product?	Department: CDER
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
ıy was the person using the pro	oduct? (such as what condition was it supposed to treat)
Teething	
tion C - About the Medical De	vice
Name of 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?	
y implanted medical devices ON	NLY (such as pacemakers, breast implants, etc.)
ate the implant was put in	Date the implant was taken out (If relevant)
	Televant)
her identifying information (Th	
her identifying information (Th m)	ne model, catalog, lot, serial, or UDI number, and the expiration date, if you can loca
ber identifying information (Th m)	
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tion D - About the Person Who	ne model, catalog, lot, serial, or UDI number, and the expiration date, if you can loca
	ne model, catalog, lot, serial, or UDI number, and the expiration date, if you can local or the expiration date if you can local or the expiration date if you can local or the expiration date if you can local or the expiration date.
ction D - About the Person Who Person's Initials Sex	ne model, catalog, lot, serial, or UDI number, and the expiration date, if you can local be to the problem [6] [6] [6] [6] [6] [6]
ction D - About the Person Who Person's Initials Sex Age (specify unit of time for age)	ne model, catalog, lot, serial, or UDI number, and the expiration date, if you can local or the expiration date if you can local or the expiration date if you can local or the expiration date if you can local or the expiration date.
rtion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth	Had the Problem (b) (c) Male 5 Month(s)
etion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight	the model, catalog, lot, serial, or UDI number, and the expiration date, if you can local the Problem (b) (6) (6) (7.2 kg(s)
rtion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth	Had the Problem (b) (6) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino
etion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight	Had the Problem (b)(6) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino American Indian or Alaskan Native
etion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Had the Problem (b) (6) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander
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etion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Had the Problem (b) (6) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White
etion D - About the Person Who Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Had the Problem (6) (6) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian
Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Had the Problem (a) (b) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino Mative Hawaiian or Other Pacific Islander Asian White Black or African American
Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Had the Problem (b) (6) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino American Indian or Alaskan Native Native Hawaiian or Other Pacific Islander Asian White
Person's Initials Sex Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Choose all that apply)	Had the Problem (a) (b) Male 5 Month(s) 7.2 kg(s) Not Hispanic/Latino Mative Hawaiian or Other Pacific Islander Asian White Black or African American
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Negas list all allered to the	FDA 33769861PDA2729376	PU-41
rease ust an anergies (such as to o	rugs, foods, pollen or others)	
None		
		-1
ist any other important informat	on about the person (such as smoking, pregnancy, alcohol use, etc.)	13
None	mana ye and take a superior and the country of the	
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ist all current prescription medic	ations and medical devices being used.	
is an current prescription incure	anons and incorear actives being asca.	
ist all over-the-counter medicatio	us and any vitamins, minerals, supplements, and herbal remedies being used.	
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OTHER (CONCOMITANT) MEI	ICAL DRODUCTS	
AND DESCRIPTION OF THE PARTY OF	ICAL PRODUCTS 1 of 1	
Product Name		
Strength	ICAL PRODUCTS 1 of 1	
Product Name Strength Therapy Start Date		
Product Name Strength		
Product Name Strength Therapy Start Date Therapy End Date	If Other	
Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Filling	g Out This Form	
Product Name Strength Therapy Start Date Therapy End Date ection E - About the Person Filling	If Other	
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Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code	g Out This Form	
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Product Name Strength Therapy Start Date Therapy End Date Section E = About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date Did you report this problem to the company that makes the product (the manufacturer/compounder)? If you do NOT want your identity	g Out This Form (b) (6) 03-Sep-2016	
Product Name Strength Therapy Start Date Therapy End Date Section E - About the Person Fillin Last name First name Number/Street City State/Province Country ZIP or Postal code Telephone number Email address Today's date Did you report this problem to the company that makes the product (the manufacturer/compounder)?	(b) (c) (d) (d) (d) (e) (d) (e) (e) (e) (e) (e) (e) (e) (e) (e) (e	

Generated by: system Generated on: 03-Sep-2016 19:45:06 Page 4 of 4

Department: CDER

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:

Form Approved: OMR No. 0910-6391 Expires: 09/30/2018 See PRA statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

	FDA USE ONLY	
Triage unit sequence #		
FDA Rec.		
Date		

abbreviation, and 4		y" please use 2-digit day, 3-letter month	3. Dose or Amount	Frequency	Route
	-digit year; for examp	le, 01-Jul-2015.	#1 3 Tablet(s)	Every 6 hours	Taken by mouth
	NFORMATION		23 - 23 0		
1. Patient Identifier		r(s) Month(s) 3. Sex 4. Weight			
(b) (6)		(1) Inditation 5. Sex	#2		
	Wee	(0)			
	or Date of Birth (e	e.g., 08 Feb 1925)			
	(b) (6)	Male kg	4. Dates of Use (From/)	o for each) (If unknow) estimate) (dd-mmm-yy	9. Event Abated After Use Stopped or Dose Reduce
In Confidence		Kg	#1 17-Aug-2016 - 18-	and the second of the second o	#1 Ves No Do
5.a.Ethnicity (Che		heck all that apply)	#2	0.210	#1 V Yes INO app
single best answer	7 Asian	American Indian or Alaskan Native	5. Diagnosis or Reason	for Use (indication)	#2 Yes No Do
Hispanic/Latin	no 🗀		Teething	tar and financially	— — ар
		African American White	#1		10.Event Reappeared After Reintroduction?
Not Hispanic/	Latino Native F	lawaiian or Other Pacific Islander	-		D-
B. ADVERSE	EVENT, PRODU	CT PROBLEM	#2		#1 ☐ Yes ☐ No ☑ app
1. Check all that a	apply		6. Is the Product	17 to the Dundwet	#2 Tyes TNo Do
			Compounded?	7. Is the Product Over-the-Counter	
Adverse Ever		roblem (e.g., defects/malfunctions)	III D No	#1 7 Yes	7 No
Product Use I	Error Problem w	ith Different Manufacturer of Same Medicine			
0.0.4		ant (Charle all that parks)	#2 Yes No	#2 Yes	No
2. Outcome Attrib	outed to Adverse Ev	ent (Check all that apply)	8. Expiration Date (dd-m	mm-yyyy) #1 31-Ma	ar-2018 #2
Death Include	e date (dd-mmm-yyyy		E. SUSPECT MED	DICAL DEVICE	
Life-threatening	ng	Disability or Permanent Damage	1. Brand Name	TO THE PENIOR	
	n - initial or prolonged	Congenital Anomaly/Birth Defects	I State State		
	s (Important Medical E				
	And the second s	ermanent Impairment/Damage (Devices)	2. Common Device Nar	0.0	2b. Procode
			2. Common Device Nar	lie	ZD. Procode
3. Date of Event (aa-mmm-yyyy)	4. Date of this Report (dd-mmm-yyyy)	3. Manufacturer Name,	City and State	
19-Aug-2016		01-Sep-2016			
Describe 5	Deables & Deables	t Use Saver	+		
	t, Problem or Produc		4. Model #	Lot#	5. Operator of De
See addition	ar page(s) for	complete text.	-5 112.71.71.21		S. Operator of De
					Health Profess
			Catalog #		
Relevant Tests/I	Laboratory Data, Inc	luding Dates	Jatalog #	Expiration Date	(dd-mmm-yyyy) Lay User/Patie
		complete text.			Other:
	47 40 131 355	2.75	5-4-5		
			Serial #	Unique Identifi	ier (UDI) #
			41		4-
	History, Including P	annualities Manual Canaditions (a.a.	II		
allergies pregna	nev smokina and air	ohol use liver/kidney problems etc.)			
		reexisting Medical Conditions (e.g., ohol use, liver/kidney problems, etc.)	6. If Implanted, Give Da	te (dd-mmm-yyyy) 7.	If Explanted, Give Date (dd-mmm-
		complete text.	6. If Implanted, Give Da	te (dd-mmm-yyyy) 7.	If Explanted, Give Date (dd-mmm-
			200		G. Children
			8. Is this a single-use of reprocessed and reu	levice that was sed on a patient?	Yes No
See additiona	al page(s) for AVAILABILITY	complete text.	200	levice that was sed on a patient?	Yes No
See additiona	al page(s) for AVAILABILITY		8. Is this a single-use of reprocessed and reu	levice that was sed on a patient?	Yes No
See additiona C. PRODUCT A 2. Product Availab	AVAILABILITY ble for Evaluation?(L	complete text. Do not send product to FDA)	8. Is this a single-use of reprocessed and reu	levice that was sed on a patient?	Yes No
See additiona	AVAILABILITY ble for Evaluation?(L	complete text.	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter	levice that was ised on a patient? Name and Address of R	Yes No
C. PRODUCT A 2. Product Availab V Yes	AVAILABILITY ble for Evaluation?([] No Returned to	Complete text. Do not send product to FDA) Do Manufacturer on:	8. Is this a single-use of reprocessed and reu	levice that was sed on a patient? Name and Address of R	Yes No
C. PRODUCT A 2. Product Availab V Yes	AVAILABILITY Tole for Evaluation?(I) No Returned to	Complete text. Do not send product to FDA) Do Manufacturer on:	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter	levice that was ised on a patient? Name and Address of R COMITANT) MEDI Prapy dates (Exclude to	Yes No Reprocessor ICAL PRODUCTS reatment of event)
C. PRODUCT A 2. Product Availab V Yes D. SUSPECT 1. Name, Manufact	AVAILABILITY ple for Evaluation?([] No Returned to PRODUCTS turer/Compounder, S	Complete text. Do not send product to FDA) Do Manufacturer on:	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONO Product names and the See additional pages of the page of th	levice that was sed on a patient? Name and Address of Recommendation of Parapy dates (Exclude the (s) for complete	Yes No Reprocessor ICAL PRODUCTS reatment of event)
C. PRODUCT A 2. Product Availab V Yes D. SUSPECT 1. Name, Manufact #1 - Name and Stre	AVAILABILITY ble for Evaluation?(I No Returned to PRODUCTS turer/Compounder, Sength	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONO Product names and the See additional pages of the page of th	levice that was sed on a patient? Name and Address of Recommendation of Parapy dates (Exclude the (s) for complete	Yes No Reprocessor ICAL PRODUCTS reatment of event)
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C. PRODUCT A 2. Product Availab Yes D. SUSPECT 1. Name, Manufact 41 - Name and Stre Infant Teethi	AVAILABILITY Dole for Evaluation?(I) No Returned to PRODUCTS turer/Compounder, Sength ing Tablets Compounder	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONO Product names and the See additional pages of the page of th	levice that was sed on a patient? Name and Address of Recommendation of Parapy dates (Exclude the (s) for complete	Yes No Reprocessor ICAL PRODUCTS reatment of event)
C. PRODUCT A 2. Product Availab V Yes D. SUSPECT 1. Name, Manufact 11 - Name and Stre 11 - Name Teethi	AVAILABILITY Dole for Evaluation?(I) No Returned to PRODUCTS turer/Compounder, Sength ing Tablets Compounder	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03	8. Is this a single-use of reprocessed and reuse of reprocessed and reuse of reprocessed and reuse of reproduct names and the See additional page G. REPORTER (S. 1, Name and Address (b) (6)	levice that was sed on a patient? Name and Address of Recommendation of Parapy dates (Exclude the (s) for complete	Yes No Reprocessor ICAL PRODUCTS reatment of event) a text. ection on back)
C. PRODUCT A 2. Product Availab Yes D. SUSPECT 1. Name, Manufact 41 - Name and Stre Infant Teethi 41 - Manufacturer/ Homelab Inc	AVAILABILITY Dole for Evaluation?(I No Returned to PRODUCTS turer/Compounder, Sength ing Tablets Compounder (Canada)	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONO Product names and the See additional page G. REPORTER (S. 1, Name and Address (b) (6)	levice that was sed on a patient? Name and Address of the common of the	Yes No Reprocessor ICAL PRODUCTS reatment of event)
C. PRODUCT A 2. Product Availab Yes D. SUSPECT 1. Name, Manufact 41 - Name and Stre Infant Teethi 41 - Manufacturer/ Homelab Inc	AVAILABILITY Dole for Evaluation?(I No Returned to PRODUCTS turer/Compounder, Sength ing Tablets Compounder (Canada)	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03 #1-Lot # 41116	8. Is this a single-use of reprocessed and reuse of reprocessed and reuse of reprocessed and reuse of reproduct names and the See additional page G. REPORTER (S. 1, Name and Address (b) (6)	levice that was sed on a patient? Name and Address of Recommendation of Parapy dates (Exclude the (s) for complete	Yes No Reprocessor ICAL PRODUCTS reatment of event) a text. ection on back)
C. PRODUCT A 2. Product Availab Yes D. SUSPECT 1. Name, Manufact 41 - Name and Stre Infant Teethi 41 - Manufacturer/ Homelab Inc	AVAILABILITY Dole for Evaluation?(I No Returned to PRODUCTS turer/Compounder, Sength ing Tablets Compounder (Canada)	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03 #1-Lot # 41116	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONC Product names and the See additional page G. REPORTER (S. 1, Name and Address (b) (6) Country: US Phone #: (b) (6)	levice that was sed on a patient? Name and Address of Recommendates (Exclude the (s) for complete ee confidentiality see Conf	Yes No Reprocessor ICAL PRODUCTS reatment of event) a text. ection on back)
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C. PRODUCT A 2. Product Availab Yes D. SUSPECT 1. Name, Manufact #1 - Name and Stre Infant Teethi #1 - Manufacturer/ Homelab Inc #2 - Name and Stre #2 - Name and Stre	AVAILABILITY Dole for Evaluation?(I) No Returned to PRODUCTS turer/Compounder, sength ing Tablets Compounder (Canada)	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03 #1- Lot # 41116 #2 - NDC # or Unique ID	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONC Product names and the See additional page G. REPORTER (S. 1, Name and Address (b) (6) Country: US Phone #: (b) (6)	levice that was sed on a patient? Name and Address of Recommendates (Exclude the (s) for complete ee confidentiality see Conf	Yes No Reprocessor ICAL PRODUCTS reatment of event) a text. ection on back) ZIP/Postal Code: (b) (6)
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C. PRODUCT A 2. Product Availab Yes D. SUSPECT 1. Name, Manufact #1 - Name and Stre Infant Teethi #1 - Manufacturer/ Homelab Inc #2 - Name and Stre #2 - Name and Stre	AVAILABILITY Dole for Evaluation?(I) No Returned to PRODUCTS turer/Compounder, sength ing Tablets Compounder (Canada)	complete text. Do not send product to FDA) Do Manufacturer on: (dd-mmm-yyyy) Strength (from product label) #1 - NDC # or Unique ID 59779-860-03 #1- Lot # 41116 #2 - NDC # or Unique ID	8. Is this a single-use of reprocessed and reu 9. If Yes to Item 8, Enter F. OTHER (CONC Product names and the See additional page of the See additional p	Revice that was sed on a patient? Name and Address of Recommendation of Recommendat	Yes

CTCASEIPDA2721292U-273 Department: CDER

B.5. Describe Event or Problem (continued)

My daughter (b) (6) had to be rushed to (b) (6) 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 (0)(6) was the CVS brand Homeopathic theeting tablets. Upon inspection at the emergency was the CVS brand Homeopathic theeting tablets. Upon inspection at the emergency room , it was discovered that the CVS pills contained Belladona . Belladona is a highly toxic substance that was once used to poison people, Although the percentagage of Belladona per the label is 0000000003%. There has been no significant clinical testing to verifythat 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 Enforcemnt 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 forgein 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)

<u>Medical Conditions:</u> 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)

RX Meds: None

OTC Meds: CVS Homeopathic Infants Teething Tablets , No other medication