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:

8238934	8291771	8291776	8308768	8341495	8349109	8403771
8411015	8475966	8478591	8525521	8555594	8730938	8733145
8737450	8745080	8745181				

Run by: **STEPPERH**

Date - Time: **04-NOV-2016 08:01 AM**

Total number of cases (Esub): 17

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8238934

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 09-Nov-2011 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 10-Nov-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-7906069 **Application #:**

Patient Information:

Age: 273 DAY **Sex:** Male **Weight:** 8.62 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT		MG/	Oral	2 tablets every 3-4-hours po	TEETHING	09-Nov-2011	09-Nov-2011

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT		NA	NA	112867		54973-3127-1	HYLAND

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Agitation	NA
Irritability	NA
Rash erythematous	NA
Rash papular	NA

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Preferred Term (MedDRA Â Version: **18.0** **ReC**

Event/Problem Narrative:

Hylands Teething Tablets Child took Hylands Teething Tablets, 2 tablets every 3 - 4 hours for one day. Child developed a red bumpy raised rash covering entire back from neck to waist, spreading to his sides and shoulders. Child became irritable and agitated as well. Child had no change in diet, laundry detergent, new clothing or any other circumstances preceding this incident. WILSONJ: |*********| 2011-11-10-08.48.14 |*********| USFDAMWVOLUNTARY_195958_9423_20111110.xml Route To: AERS : Electronic

Relevant Medical History:

No preexisting medical conditions. Child was teething. Child is caucasion. No other mitigating factors.

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

Relevant Laboratory Data:

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

Concomitant Products:

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

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FOIA Case Report Information

Case ID: 8238934

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8291771

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** N **Country:** USA **Event Date:** 27-Jul-2007 **Outcomes:** DS,HO,OT **Application Type:** ANDA

FDA Rcvd Date: 30-Nov-2011 **Mfr Rcvd Date:** 21-Nov-2011 **Mfr Control #:** US-ABBOTT-11P-163-0876437-00 **Application #:** 088058

Patient Information:

Age: 33 YR **Sex:** Male **Weight:** 136.2 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	VICODIN					BACK PAIN		
2	HYDROCHLOROTHIAZIDE					HYPERTENSION	22-Aug-2003	10-Jun-2008
3	HYLANDS TEETHING TABLETS						Apr-2009	
4	HYLANDS TEETHING TABLETS						2007	
5	HYLANDS TEETHING TABLETS						2007	
6	HYLANDS TEETHING TABLETS						Feb-2009	
7	HYLANDS TEETHING TABLETS					SUPPLEMENTATION THERAPY	2007	
8	HYLANDS TEETHING TABLETS						Nov-2007	
9	LISINOPRIL					HYPERTENSION		10-Jun-2008

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	VICODIN		NA	NA				
2	HYDROCHLOROTHIAZIDE	4 Year	NA	NA				
3	HYLANDS TEETHING TABLETS		NA	NA				
4	HYLANDS TEETHING TABLETS		NA	NA				

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	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
	Product Name	**Interval 1st Dose to Event**	**DeC**	**ReC**	**Lot#** **Exp Date**	**NDC #** **MFR/Labeler**		
5	HYLANDS TEETHING TABLETS		NA	NA				
6	HYLANDS TEETHING TABLETS		NA	NA				
7	HYLANDS TEETHING TABLETS		NA	NA				
8	HYLANDS TEETHING TABLETS		NA	NA				
9	LISINOPRIL		NA	NA				

Event Information:

Preferred Term (MedDRA Â© Version: 17.0)	ReC
Activities of daily living impaired	NA
Adverse drug reaction	NA
Alanine aminotransferase increased	NA
Anxiety	NA
Arthralgia	NA
Aspartate aminotransferase increased	NA
Back pain	NA
Blood cholesterol increased	NA
Blood glucose increased	NA
Blood triglycerides increased	NA
Cellulitis	NA
Chest pain	NA
Diabetes mellitus	NA
Dizziness	NA
Dyspnoea	NA
Emotional disorder	NA

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Preferred Term (MedDRA Â Version:	18.0	ReC
Emotional distress		NA
Fall		NA
Fatigue		NA
Fear		NA
Glucose urine present		NA
Glycosylated haemoglobin increased		NA
Head injury		NA
Hypoaesthesia		NA
Injury		NA
Joint injury		NA
Ligament sprain		NA
Low density lipoprotein increased		NA
Memory impairment		NA
Nausea		NA
Nervousness		NA
Osteoarthritis		NA
Pain		NA
Pain in extremity		NA
Productive cough		NA
Rash		NA
Rash pustular		NA
Sleep apnoea syndrome		NA
Snoring		NA
Spinal compression fracture		NA
Stab wound		NA
Thyroid neoplasm		NA
Upper respiratory tract infection		NA

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Urinary tract infection	NA
Vision blurred	NA
Wrist fracture	NA

Event/Problem Narrative:

Spontaneous report from the USA of LIGHTHEADED, NAVICULAR BONE FRACTURE, CHEST PAIN, COMPRESSION FRACTURE DEFORMITY OF T12, DEGENERATIVE JOINT DISEASE, STABBED IN THE ABDOMEN, PHYSICAL PAIN/DISCOMFORT AND SUFFERING, EMOTIONAL PAIN AND SUFFERING, EMOTIONAL INJURY, SUSTAINED SEVERE AND PERMANENT PHYSICAL INJURIES, FRIGHT, NERVOUSNESS and ANXIETY/WORRY/APPREHENSION and non-serious NAUSEOUS, THYROID NODULE, URINARY TRACT INFECTION, FALL, WRIST INJURY, PAIN, CHEST PAIN, OBSTRUCTIVE SLEEP APNEA, SNORING, BACK PAIN, CELLULITIS OF RIGHT FOOT, RASH ON LEGS, FOOT AND ELBOWS, DRUG REACTION, BLOOD GLUCOSE 234, AST 56, ALT 135, A1C 8.2, CHOLESTEROL 245, LDL 52, FELL DOWN THE STAIRS, RIGHT HAND PAIN, LEFT GREAT TOE PAIN, BACK PAIN WORSENED, PUSTULAR ERUPTION ON FOOT, AIR PURIFIER DROPPED ON HEAD, BLURRED VISION, FORGETFULNESS, RASH, COUGH WITH SPUTUM, DIFFICULTY TAKING A DEEP BREATH, GENERALIZED ACHES TO ANKLES AND KNEES, FATIGUE, GLUCOSE 231, AST 63, ALT 99, A1C 8.7, TRIGLYCERIDES 250, URINE GLUCOSE 1000, DIABETES MELLITUS WORSENED, LEG PAIN, NUMBNESS, UPPER RESPIRATORY INFECTION, FALLING, SPRAINED ANKLE, BACK PAIN THAT INTERFERED WITH NORMAL DAILY FUNCTIONS, TRIGLYCERIDES 288, CHOLESTEROL 238, GLUCOSE 165 and ALT 105 with VICODIN (HYDROCODONE/ACETAMINOPHEN). On unknown dates, the patient experienced PHYSICAL PAIN/DISCOMFORT AND SUFFERING, EMOTIONAL PAIN AND SUFFERING, EMOTIONAL INJURY, SUSTAINED SEVERE AND PERMANENT PHYSICAL INJURIES, FRIGHT, NERVOUSNESS and ANXIETY/WORRY/APPREHENSION. On 27 Jul 2007, the patient experienced LIGHTHEADED and NAUSEOUS. On 27-JUL-2007, the patient became light beaded and nauseous after taking Vicodin. The lightheadedness and nausea resolved the same day, and Vicodin use continued. On 27 Jul 2007, the LIGHTHEADED and NAUSEOUS resolved. On 09 Aug 2007, the patient experienced THYROID NODULE. On 09-AUG- 2007, magnetic resonance imaging (MRI) revealed a thyroid nodule. Thyroid-stimulating hormone {TSH) was within normal limits (WNL), andit was Ultimately determined that that thyroid nodule was of no consequence. On 02 Oct 2007, the patient experienced URINARY TRACT INFECTION. On 11 Oct 2007, the patient experienced FALL, WRIST INJURY, PAIN and NAVICULAR BONE FRACTURE. On 11-OCT-2007, the patient fell, injured his wrist, and was in pain. An x-ray revealed a possible subtle fracture along the neck of the navicular bone, and the wrist was splinted. The information regarding resolution and other treatment could not be deciphered. On 26 Nov 2007, the patient experienced TRIGLYCERIDES 288, CHOLESTEROL 238, GLUCOSE 165 and ALT 105. On 26-NOV-2007, lab work was repeated and revealed TSH WNL, triglycerides 288 (30-200), cholesterol 238 (less than

200), glucose 165 (65-115), AST 45 (13-40}, and ALT 105 (10-50). On 09-JAN-2008, his A1C was 6,2 (4.8-6.0). On 14-JAN-2008, the patient's medical records note controlled diabetes mellitus. On 12 Mar 2008, the patient experienced CHEST PAIN. On 12-Mar-2008, the patient experienced chest pain. Troponins, cardiac markers, electrocardiogram (EKG) and a chest x-ray were within normal limits. He was treated with Aspirin (acetylsalicylic acid) 325 mg. On 02 Jun 2008, the patient experienced OBSTRUCTIVE SLEEP APNEA, SNORING and BACK PAIN. Medical records from 02-JUN-2003 note sleep apnea, snoring, and continued back pain from previous falls. He was advised to schedule a sleep study to further evaluate the sleep apnea, but the consumer refused. On 03 Jun 2008, the patient experienced CELLULITIS OF RIGHT FOOT. On 03-JUN-2008, he was diagnosed with cellulitis of the right foot and treated with Augmentin (amoxicillin and clavulanate). On 10 Jun 2008, the patient experienced RASH ON LEGS, FOOT AND ELBOWS and DRUG REACTION. On 10-JUN-2008, the patient was re-evaluated as a rash had spread to his legs, fact, and elbows. He was diagnosed with a drug reaction, and treatment with lisinopril and HCTZ were discontinued. He was started on Norvasc (amlodipine besylate)and treated with clobetasol and another undecipherable medication. On (b) (6) the patient experienced CHEST PAIN and BLOOD GLUCOSE 234. On (b) (6) he was hospitalized for chest pains. He requested discharge on (b) (6) prior to seeing a cardiologist as he felt his questions were not being answered. His blood glucose during hospitalization was 234. On 20 Oct 2008, the patient experienced AST 56, ALT 135, A1C 8.2, CHOLESTEROL 245 and LDL 52. On 20-OCT-2008, an EKG was within normal limits and blood work revealed glucose 151 (65-118), AST 56 (13-40), ALT 135 (10-50), A1C 8.2 (4.8-6.0), cholesterol 245 (less than 200), triglycerides 201 (30-200), low density lipoprotein (LDL) 152 (less than 100), Metformin and another undecipherable mediation were started. On 27 Jan 2009, the patient experienced FELL DOWN THE STAIRS, RIGHT HAND PAIN, LEFT GREAT TOE PAIN, BACK PAIN and COMPRESSION FRACTURE DEFORMITY OF T12. On 27-JAN-2009, the patient fell down the stairs and experienced right hand, left great toe, and back pain. X-rays revealed no fractures of the toe or hand. Thoracic spine x-ray revealed a mild compression fracture deformity of T12. On 28 Jan 2009, the patient experienced DEGENERATIVE JOINT DISEASE. Computed tomography (CT) scan of the thoracic spine performed on 28-JAN-2009 showed mild degenerative joint disease (DJD) of T9-T10, T10-T11, and a compression fracture deformity of T12 which appeared chronic in nature. No acute findings were noted. The patient was treated with Vicodin, Flexeril, and Motrin (ibuprofen) and was off of work. He was switched to Tramadol in FEB-2009 and was 30% improved by MAR-2009. He started physical therapy {PT) on 30-MAR-2009. On 20 Apr 2009, the patient experienced BACK PAIN WORSENED and PUSTULAR ERUPTION ON FOOT. On 20-APR-2009, he returned to work and his back pain worsened. Flexeril was restarted as was Lodine (etodolac). He also developed a pustular eruption on his foot that was treated with Bactrim (sulfamethoxazole and trimethoprim) DS for 7 days. In (b) (6) the patient experienced STABBED IN THE ABDOMEN, AIR PURIFIER DROPPED ON HEAD, PAIN, BLURRED VISION, FORGETFULNESS, RASH, COUGH WITH SPUTUM, DIFFICULTY TAKING A DEEP BREATH, GENERALIZED ACHES TO ANKLES AND KNEES and FATIGUE. Medical records from (b) (6) show that the patient was stabbed in the abdomen and had an air purifier dropped on his head. He was experiencing pain, blurred vision, forgetfulness, rash, a cough with sputum, difficulty taking a deep breath,

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generalized aches to the ankles and knees, and fatigue. Tetanus and diphtheria toxoids were administered. A CT scan of the head was negative. On 13 Jul 2009, the patient experienced GLUCOSE 231, AST 63, ALT 99, A1C 8.7 and TRIGLYCERIDES 250. On 13-JUL-2009, blood work revealed glucose 231 (65-115), AST 63 (13-40), ALT 99 (10-50}, A1C 8.7 (4.8-6.0), triglycerides 250 (30-200), and high-density lipoprotein (HDL) 28 (greater than 40). On 16 Jul 2009, the patient experienced URINE GLUCOSE 1000. On 16-JUL-2009, urinalysis revealed glucose 1000 and ketones 5 (negative). Treatment with Bactrim, Loctine, and Flexeril were discontinued and the patient was started on started simvastatin 20 mg, metformin 500 mg, Lantus Solostar (insulin glargine (rDNA origin)) 15 units Subcutaneously (SQ) at night, and he got a glucometer to check his glucose at home. On 27 Jul 2009, the patient experienced DIABETES MELLITUS WORSENED. On 27-JUL-2009, the patient's diabetes worsened. Aspirin 81 mg daily and glucagon for acute hypoglycemic events were added to his diet, exercise and weight loss were stressed. On 25-AUG-2009, Metformin was discontinued and Janumet (metformin and sitagliptin) was added. On 17 Sep 2009, the patient experienced LEG PAIN and NUMBNESS. On 17-SEP-2009, he had a sleep study that confirmed obstructive sleep apnea. On 23 Sep 2009, the patient experienced BACK PAIN. On 23-SEP-2009, the patient was evaluated for continued back pain and leg painand numbness. A thoracic spine x-ray showed that his spine was stable, and an MRI revealed that the chronic compression fracture was unchanged. On 30 Oct 2009, the patient experienced UPPER RESPIRATORY INFECTION. On 30-OCT-2009, the patient was diagnosed with a URI and treated with Tamiflu (oseltamivir phosphate) and Zofran (ondansetron). On 01 Nov 2009, the patient experienced FALLING and SPRAINED ANKLE. On 01-NOV-2009, he was evaluated after falling while drunk and spraining his ankle. An x-ray of his ankle showed no fracture. He was placed in an air cast, given crutches, and treated with Etodolac. By 10-NOV-2009, his ankle was 98% improved. On 04 Jan 2010, the patient experienced BACK PAIN THAT INTERFERED WITH NORMAL DAILY FUNCTIONS. On 04-JAN-2010, he was evaluated for continued back pain that interfered with his normal daily functions and working. He reported drinking 3-4 beers daily to help with the pain. He restarted PT on 06-JAN-2010. On 21-JAN-2010, he reported feeling better overall and that PT was going well. It was also reported that as a result of events due to product use, the patient experienced physical pain/discomfort and suffering, emotional pain and suffering, emotional injury, sustained severe and permanent physical injuries, and experienced fright, nervousness, and anxiety/worry/apprehension. It was alleged that the products were unreasonably dangerous and defective. Except where noted, the outcome and current status of the events were not reported. It is not noted when or if product use was discontinued in response to any of the reported events. It was also reported that HYDROXYCUT products were negligently manufactured, contained manufacturing defects, were not effective and were not made in accordance with product specifications or performance standards. HYDROCHLOROTHIAZIDE, LISINOPRIL (LISINOPRIL DIHYDRATE) and HYDROXYCUT were also considered suspect. The patient was treated with AUGMENTIN, NORVASC, CLOBETASOL, METFORMIN, FLEXERIL, MOTRIN, TRAMADOL, LODINE, BACTRIM, TETANUS TOXOID, DIPHTHERIA TOXOID, SIMVASTATIN, LANTUS SOLOSTAR, JANUMET, TAMIFLU, ZOFRAN and ETODOLAC.

********** Laboratory information/comments 11 Oct 2007: Wrist X-ray: Possible subtle fracture along the neck of the navicular bone. 12-Mar-2008: Cardiac Markers: WNL 12-Mar-2008:

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Troponins: WNL 27 Jan 2009: Toe and wrist x-ray: WNL 27 Jan 2009: Thoracic spine X-ray: Mild compression fracture deformity of T12 28 Jan 2009: CT thoracic spine: Mild DJD T9-T10, T10-T11, compression fracture deformity of T12 which appears chronic in nature, no acute findings. 23 Sep 2009: Thoracic spine: Stable 23 Sep 2009: MRI Thoracic spine: Chronic compression fracture unchanged. 01 Nov 2009: Ankle x-ray: No fracture.

Relevant Medical History:

On 04-JAN-2007, after starting the product, the patient experienced recurrent plantar fasciitis and foot pain which was treated with an injection of lidocaine, Marcaine and Celestone Soluspan (betamethasone injectable suspension). On an unspecified date in FEB-2007, the patient fell and injured his back. He was diagnosed with thoracolumbar Strain and treated with Flexeril (cyclobenzaprine hydrochloride) and another undecipherable medication, On 05-FEB-2007, he developed an unspecified viral infection with symptoms of fatigue and body aches. On 08-FEB-2007, he was diagnosed with pharyngitis after developing a headache, coughing and a sore throat. Treatment included amoxicillin. On an unspecified date in Jun-2007, the consumer experienced myalgia (resolved on an unknown date). On 15-JUN-2007, an abdominal ultrasound revealed poss ble fatty infiltration of the liver. On 21-JUN-2007, the patient's ALT was 226 (10-50) and his AST was 138 (13-40). On 27-JUN-2007, the patient was evaluated for burning stomach pain and diagnosed with gastritis. Treatment included omeprazole 20 ng. On 28-JUN-2007, a gastroenterologist confirmed the patient's fatty liver disease and recommended weight loss, decreasing alcohol intake, and rechecking the liver function tests in 3 months. POSSIBLE ASEPTIC MENINGITIS (REQUIRED HOSPITALIZATION) (Started (b) (6)) LOWER BACK STRAIN (Started 2003) SHOULDER INSTABILITY (Started 2003) WORK ACCIDENT HIT BY FORKLIFT (Started 2003) ABDOMINAL PAIN ACHILLES TENDON AVULSION (SUBSEQUENT MILD SPURRING) ALCOHOL USE (WEEKLY TO TWICE MONTHLY) BULGING CERVICAL DISCS CHEWING TOBACCO USE DORSAL CALCANEAL SPUR DYSPEPSIA EARACHES ECZEMA FATTY LIVER FRACTURED LUMBAR SPINE GERD HAND LACERATION HAND PAIN HEADACHES HYPERCHOLESTEROLEMIA HYPERTENSION HYPERTRIGLYCERIDEMIA INCREASED ALT INCREASED AST INSOMNIA LOWER BACK PAIN MILD HEPATOMEGALY MOTOR VEHICLE ACCIDENT PHARYNGITIS PLANTAR FASCITIS RECURRENT UTI RENAL CALCULI SHOULDER PAIN SMOKER (1/2 TO 1 PPD FOR 10-20 YEARS) SUBCONJUNCTIVAL HEMORRHAGE TINEA PEDIS ULNAR STYLOID FRACTURE UPPER RESPIRATORY INFECTION

Disease/Surgical Procedure	Start Date	End Date	Continuing?
HOSPITALISATION	(b) (6)		UNKNOWN
MENINGITIS ASEPTIC	(b) (6)		UNKNOWN
ACCIDENT AT WORK	2003		UNKNOWN
JOINT INSTABILITY	2003		UNKNOWN
MUSCLE STRAIN	2003		UNKNOWN
ABDOMINAL PAIN			UNKNOWN

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ALANINE AMINOTRANSFERASE INCREASED	UNKNOWN
ALCOHOL USE	UNKNOWN
ASPARTATE AMINOTRANSFERASE INCREASED	UNKNOWN
BACK PAIN	UNKNOWN
CONJUNCTIVAL HAEMORRHAGE	UNKNOWN
DYSPEPSIA	UNKNOWN
EAR PAIN	UNKNOWN
ECZEMA	UNKNOWN
EXOSTOSIS	UNKNOWN
GASTROOESOPHAGEAL REFLUX DISEASE	UNKNOWN
HEADACHE	UNKNOWN
HEPATIC STEATOSIS	UNKNOWN
HEPATOMEGALY	UNKNOWN
HYPERCHOLESTEROLAEMIA	UNKNOWN
HYPERTENSION	UNKNOWN
HYPERTRIGLYCERIDAEMIA	UNKNOWN
INSOMNIA	UNKNOWN
INTERVERTEBRAL DISC PROTRUSION	UNKNOWN
LACERATION	UNKNOWN
MUSCULOSKELETAL PAIN	UNKNOWN
NEPHROLITHIASIS	UNKNOWN
PAIN IN EXTREMITY	UNKNOWN
PHARYNGITIS	UNKNOWN
PLANTAR FASCIITIS	UNKNOWN

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ROAD TRAFFIC ACCIDENT	UNKNOWN
SPINAL FRACTURE	UNKNOWN
TENDON RUPTURE	UNKNOWN
TINEA PEDIS	UNKNOWN
TOBACCO USER	UNKNOWN
ULNA FRACTURE	UNKNOWN
UPPER RESPIRATORY TRACT INFECTION	UNKNOWN
URINARY TRACT INFECTION	UNKNOWN

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

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Weight	300	POUNDS			
SGOT	45				
HbA1C	6.2		4.8	6.0	
Cholesterol	245				
Urine ketone body	5 negative				
SGOT	138				
TSH	wnl				
Glucose	151				
Triglycerides	201				
SGOT	63				
Triglycerides	250				
Urine glucose	1000				
Ultrasound abdomen	possible fatty infiltration of liver				
Chest X-ray	WNL				
Low density lipoprotein cholesterol	152			100	
High density lipoprotein cholesterol	28			40	
SGPT	165		10	50	
Cholesterol	238				
SGPT	105				
EKG	wnl				

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Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
SGPT	99				
Computerised tomogram head	Negative				
Sleep study	moderate obstructive sleep apnea				
SGPT	226				
SGOT	56				
TSH	WNL				
Glucose	231				
MRI	thyroid nodule				
SGPT	135				
HbA1C	8.2				
SGOT	80		13	40	
Triglycerides	288		30	200	
Glucose	165				
EKG	WNL				
HbA1C	8.7				

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ATARAX				PRODUCT USED FOR UNKNOWN INDICATION			
2	CLONIDINE				PRODUCT USED FOR UNKNOWN INDICATION			
3	DIOVAN				PRODUCT USED FOR UNKNOWN INDICATION			
4	LIPITOR				PRODUCT USED FOR UNKNOWN INDICATION		Jun-2007	
5	PLENDIL				PRODUCT USED FOR UNKNOWN INDICATION			
6	TENORETIC				PRODUCT USED FOR UNKNOWN INDICATION			

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Reporter Source:

Study Report?: No

Sender Organization: ABBOTT

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8291776

Case Information:

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

FDA Rcvd Date: 06-Dec-2011 **Mfr Rcvd Date:** 21-Nov-2011 **Mfr Control #:** US-JUTA GMBH-2011-20420 **Application #:** 077034

Patient Information:

Age: 65 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	CITALOPRAM HYDROBROMIDE		20 MG/	Unknown	20 mg, daily	DEPRESSION		
2	HYLANDS TEETHING TABLETS				unknown	WEIGHT DECREASED		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	CITALOPRAM HYDROBROMIDE		NA	NA	UNCOMFIRMED			WATSON
2	HYLANDS TEETHING TABLETS		NA	NA				

Event Information:

Preferred Term (MedDRA Â© Version: 17.0)	ReC
Cerebral vasoconstriction	NA
Drug interaction	NA

Case ID: 8291776

Event/Problem Narrative:

Date of initial report: 21-NOV-2011 A literature report from the J Med Case Reports, entitled " Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: a case report," describes a 65 year old Caucasian woman on longstanding citalopram who developed reversible cerebral vasoconstriction syndrome two weeks after beginning to take Hydroxycut. Both citalopram and Hydroxycut were discontinued. Patient received treatment with nimodipine. At follow up, there was significant improvement of her left visual field deficit and CT angiography six weeks after discharge showed marked resolution of cerebral vasoconstriction. " A 65-year-old Caucasian woman presented to her local hospital with sudden-onset, bifrontal, pounding headache described as “getting hit in the head with an axe.” The headache was the worst of her life and did not improve after she took acetaminophen, caffeine, and butalbital. There was hyperacusis, photophobia and nausea. Noncontrast head computed tomography (CT) and brain magnetic resonance imaging (MRI) at the time of admission were normal and she was treated with prednisone for presumed intractable migraine. Aside from a similar but milder headache one week prior to her current presentation, she reported only a sparse past history of migraines that ceased after her hysterectomy and no family history of migraines or strokes. She had hyperlipidemia treated with simvastatin 40mg daily, lumbar spinal compression fractures, multiple miscarriages and depression that had been treated for several years with citalopram 20mg daily. On further questioning, our patient reported taking the weight-loss supplement Hydroxycut beginning two weeks prior to her thunderclap headache. On admission, her body mass index was 22.3, and she was normotensive on lisinopril 10mg daily. She had not previously been on lisinopril, which was presumably initiated at the outside hospital for prednisone-induced hypertension. We held the lisinopril for the duration of her hospitalization given her normal to low blood pressures. Her fasting lipid panel revealed cholesterol 223mg/dL, triglycerides 141mg/dL, high density lipoprotein 61mg/dL, low density lipoprotein 134mg/dL, very low density lipoprotein 28mg/dL and lipoprotein(a) 6mg/dL. Two days after admission, she developed bilateral leg weakness and left-sided visual disturbances that she described as “blank lines.” A repeat MRI revealed areas of restricted diffusion consistent with acute infarcts in the bilateral anterior cerebral artery territories and in her right occipital lobe (Figure 1). The following investigations were unrevealing: hypercoagulability studies, rheumatic and vasculitic screening labs, magnetic resonance venography, transthoracic echocardiogram with bubble contrast, and Holter monitoring. LA lumbar puncture, performed while our patient was being treated with prednisone, revealed 0 white blood cells (WBC), 48 red blood cells (RBC), cerebrospinal fluid (CSF) protein 27mg/dL, glucose 81mg/dL and no xanthochromia. CT angiography (CTA) was obtained, which revealed multifocal segmental cerebral artery vasoconstriction, most prominent in the bilateral anterior and posterior cerebral arteries (Figures 2A and 2B). We made the diagnosis of RCVS and began treatment with nimodipine 30mg three times daily. Over the subsequent days, her headache resolved and her vision and leg weakness improved. Our patient’s blood pressures at admission and prior to starting nimodipine were 92-116/54-58mmHg on no antihypertensive medications. After beginning nimodipine for RCVS, her systolic blood pressures ranged from the high 80s to low 100s (mmHg). We administered intravenous fluid bolus as needed to keep her systolic blood pressure above 90mmHg, in an effort to balance maintaining adequate cerebral perfusion while continuing nimodipine treatment for RCVS. Our patient tolerated this well without any

Case ID: 8291776

clinical decline or symptomatic hypotension. She was discharged on nimodipine and advised not to take Hydroxycut and citalopram, which had been discontinued when a diagnosis of RCVS was first suspected. At the time of discharge, her systolic blood pressures remained in the 90s to low 100s mmHg. Therefore, she was advised to measure her blood pressure at home and take nimodipine only if systolic blood pressure was over 100mmHg. Following discharge, our patient experienced no headaches and no recurrence of her presenting symptoms. At a follow-up appointment, she had no residual leg weakness and significant improvement of her left visual field deficit, although she reported that her vision had not returned to her baseline. CTA performed six weeks after discharge showed marked resolution of cerebral vasoconstriction, confirming the diagnosis of RCVS (Figures 2C and 2D)." See article for further details.

Relevant Medical History:

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Case ID: 8291776

Literature Text: Cvetanovich GL, Ramakrishnan P, Klein JP, Rao VR, Rooper AH. Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: a case report. Journal of Medical Case Reports. 2011;5(1)

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8308768

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 20-Dec-2011 **Outcomes:** OT **Application Type:** NDA

FDA Rcvd Date: 22-Dec-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8003445 **Application #:** 999999

Patient Information:

Age: 0 DAY **Sex:** Male **Weight:** 59.42 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	UNSPECIFIED INGREDIENT		BID	Oral	3 tablets	TEETHING	19-Dec-2011	20-Dec-2011

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	UNSPECIFIED INGREDIENT		NA	NA	113314			HYLAND

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Toxicity to various agents	NA

Event/Problem Narrative:

Used Hylands teething tablets and experienced problems consistent with belladonna toxicity. Initially, the baby was extremely sleepy. However, the symptoms progressed to extreme agitation -more than usual- and he has been constipated -no bm since using the product-. WILSONJ: |*********| 2011-12-22-08.02.58 |*********| USFDAMWVOLUNTARY_198335_11359_20111221.xml Route To: AERS : Electronic

Case ID: 8308768

Relevant Medical History:

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8341495

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** Y **Country:** USA **Event Date:** 13-Aug-2011 **Outcomes:** LT **Application Type:** NDA

FDA Rcvd Date: 18-Jan-2012 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8052713 **Application #:** 999999

Patient Information:

Age: 152 DAY **Sex:** Female **Weight:** 8.16 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BABY TEETHING		1X	Oral	2 tablets	TEETHING	13-Jan-2012	13-Jan-2012

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	BABY TEETHING		NA	NA	113211		5497331271	HYLAND

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Depressed level of consciousness	NA
Eye movement disorder	NA
Hypopnoea	NA
Hypotonia	NA
Pallor	NA

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8341495

Event/Problem Narrative:

45 minutes after giving my 5 month old daughter 2 of the recommended -2-3- tablet she became limp, eyes rolled in head, difficult to arrouse, shallow breathing and pale. My husband was able to get a response from her and was very close to calling 911. WILSONJ: |*********| 2012-01-18-08.58.30 |*********| USFDAMWVOLUNTARY_199758_12646_20120118.xml Route To: AERS : Electronic

Relevant Medical History:

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Case ID: 8341495

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8349109

Case Information:

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

FDA Rcvd Date: 23-Jan-2012 **Mfr Rcvd Date:** 16-Jan-2012 **Mfr Control #:** PHHY2012US003686 **Application #:** 077040

Patient Information:

Age: 65 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	CITALOPRAM		20 MG/		20 mg, UNK	DEPRESSION		
2	HYLANDS TEETHING TABLETS				UNK	WEIGHT DECREASED		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	CITALOPRAM		Yes	Unk				NOVARTIS
2	HYLANDS TEETHING TABLETS		Yes	NA				

Event Information:

Preferred Term (MedDRA Â® Version: 17.0)	ReC
Cerebral vasoconstriction	Unk
Headache	Unk
Hyperacusis	Unk
Muscular weakness	Unk
Nausea	Unk
Photophobia	Unk
Visual impairment	Unk

Case ID: 8349109

Event/Problem Narrative:

Case number PHHY2012US003686 is an initial literature report received on 16 Jan 2012. The authors discuss reversible cerebral vasoconstriction syndrome in a patient taking citalopram and hydroxycut. Medical history of the patient included migraines, hyperlipidemia, lumbar spinal compression fractures and multiple miscarriages. The patient was started on citalopram (manufacturer unknown) 20mg daily, unknown route and duration for depression from an unknown date years ago. The patient was also on Hydroxycut unknown dose, route and duration for weight loss from an unknown date. On an unknown date the patient reported bifrontal, pounding headache, hyperacusis, photophobia, nausea and was hospitalzied. Noncontrast head computed tomography (CT) and brain magnetic resonance imaging (MRI) at the time of admission were normal and she was treated with prednisone for presumed intractable migraine. Two days after admission, she developed bilateral leg weakness and left-sided visual disturbances that she described as blank lines. A repeat MRI revealed areas of restricted diffusion consistent with acute infarcts in the bilateral anterior cerebral artery territories and in her right occipital lobe. CT angiography (CTA) was obtained, which revealed multifocal segmental cerebral artery vasoconstriction, most prominent in the bilateral anterior and posterior cerebral arteries. The patient was diagnosed with reversible cerebral vasoconstriction syndrome (RCVS) and began treatment with nimodipine 30mg three times daily. Over the subsequent days, her headache resolved and her vision and leg weakness improved. Our patients blood pressures at admission and prior to starting nimodipine were 92-116/54-58mmHg on no antihypertensive medications. The patient tolerated the treatment without any clinical decline or symptomatic hypotension. She was discharged on nimodipine and advised not to take Hydroxycut and citalopram, which had been discontinued when a diagnosis of RCVS was first suspected. Following discharge, the patient experienced no headaches and no recurrence of her presenting symptoms. The authors concluded that the patient on longstanding citalopram developed RCVS two weeks after beginning to take the weight-loss supplement Hydroxycut.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
ABORTION SPONTANEOUS			UNKNOWN
HYPERLIPIDAEMIA			UNKNOWN
MIGRAINE			UNKNOWN
SPINAL COMPRESSION FRACTURE			UNKNOWN

Case ID: 8349109

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

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Computerised tomogram	Normal				N
Angiogram	Abnormal				Y

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	SIMVASTATIN	40 MG/		40 mg, UNK				

Reporter Source:

Study Report?: No

Sender Organization: SANDOZ

503B Compounding Outsourcing Facility?:

Literature Text: Cvetanovich GL, Ramakrishnan P, Klein JP, Rao VR, Ropper AH. Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: a case report. J Med Case Reports. 2011;5:548

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8403771

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 11-Feb-2012 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 13-Feb-2012 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8133816 **Application #:**

Patient Information:

Age: 209 DAY **Sex:** Male **Weight:** 8.62 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	HYLAND'S TEETHING TABLETS		QID	Sublingual	2-3 tablets, 4 times per day, sl	PAIN, DISCOMFORT	11-Feb-2012	11-Feb-2012

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	HYLAND'S TEETHING TABLETS		NA	NA	113631		54973-3127-1	HYLAND

Event Information:

Preferred Term (MedDRA Version: 18.0)	ReC
Poisoning	NA
Seizure	NA

Event/Problem Narrative:

My son had 3 of Hyland's Teething Tablets. This was the first time he had the product. (b) (6) later he had what we -my husband and I- believe to have been a seizure. The "seizure episode" consisted of about 3 short -5-10 second- seizures. We took him to the Emergency Room where the doctor could neither confirm nor deny that a seizure had occurred. The doctor warned us about the possible risks involved with this product. I have since found out that the tablets contain Belladonna, a poison, and are associated with many possible side effects, including seizures. I am shocked at the popularity of this product, which is growing, and the lack of knowledge among parents, as well as the lack of warnings on the labels. I understand that this product has been recalled in the past and may not be regulated buy the FDA, but parents desperately need to be warned about this product if it is going to stay on the shelves!!!! Please do something! WALKERC: |*********| 2012-02-13-11.36.00 |*********| USFDAMWVOLUNTARY_201263_13984_20120212.xml Route To: AERS : Electronic

Case ID: 8403771

Preferred Term (MedDRA Â Version: **17.0** **ReC**

Relevant Medical History:

My son has never had a seizure before or any health problems that may cause seizures or be associated with them. He was a full-term, perfectly healthy child and I have no doubt that this product caused him to have a seizure.

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8411015

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 14-Feb-2012 **Outcomes:** **Application Type:** NDA

FDA Rcvd Date: 17-Feb-2012 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8143995 **Application #:** 999999

Patient Information:

Age: 0 DAY **Sex:** Female **Weight:** 7.26 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	HYLAND'S TEETHING TABLETS		QID		2-3 tablets per time			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	HYLAND'S TEETHING TABLETS		NA	NA				HYLAND

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Irritability	NA
Somnolence	NA

Event/Problem Narrative:

We gave my 7-month old daughter Hyland's teething tablets last night and this morning. After we gave her the tablets, we noticed that she got very sleepy and were not concerned as it was almost 9:30pm and close to her bedtime. This morning, my daughter woke up ~7:30am and was very irritable so we gave her 2 more tablets around 9am. She fell asleep about 5 minutes later. Our baby girl had always able to play for at least 3 or 4 hours before taking her late morning/early afternoon nap. We also call our pediatrician and they have never heard of this product. Needless to say, we discarded the entire box. WILSONJ: |*********| 2012-02-16-08.43.51 |*********| USFDAMWVOLUNTARY_201467_14167_20120216.xml Route To: AERS : Electronic

Case ID: 8411015

Relevant Medical History:

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8475966

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 20-Mar-2012 **Outcomes:** CA,DE,DS,HO,LT,OT,RI **Application Type:**

FDA Rcvd Date: 26-Mar-2012 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8234070 **Application #:**

Patient Information:

Age: 60 DAY **Sex:** Male **Weight:** 4.99 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	HYLAND'S BABY TEETHING TABLETS		QID	Oral	2 or 3 tablets under tounge	TEETHING	02-Mar-2012	23-Mar-2012
2	HYLAND'S BABY TEETHING TABLETS							

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	HYLAND'S BABY TEETHING TABLETS		NA	NA			54973-3127-1	
2	HYLAND'S BABY TEETHING TABLETS		NA	NA			64679-0434-02	

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Hypopnoea	NA
Irritability	NA
Product quality issue	NA
Pyrexia	NA
Staring	NA

Case ID: 8475966

Preferred Term (MedDRA Â Version: **17.0** **ReC**

Event/Problem Narrative:

My son had a fever that i couldn't get him to break. It was 101.2..then he was cooing at me and then he stopped out of no where and his breathing got shallow then he was staring at me but it was as if he was staring through me. He was also very cranky and fussy. This was very unlike him. At first I thought it was from teething so I gave him hylands baby teething tablets. I just found out today that these tablets were recalled back in Oct of 2010 because of an ingredient called belladonna. I check the bottle of the teething tablets that I have been giving him and it contains the same ingredient called belladonna and it is now march of 2012. I don't know what to do with the teething tablets now. I don't want to throw them out just in case it is the reason he is having this symptoms. I would like to know what I should do. the website wouldn't let me continue until i clicked every box here and at the end. This is the first time I am contacting anyone about this. I do not mind if you tell the manufacturers my information. WILSONJ: |*********| 2012-03-26-08.48.14 |*********| USFDAMWVOLUNTARY_203797_16200_20120324.xml Route To: AERS : Electronic Route To: DQRS : : Paper

Relevant Medical History:

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

Relevant Laboratory Data:

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

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8475966

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8478591

Case Information:

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

FDA Rcvd Date: 27-Mar-2012 **Mfr Rcvd Date:** 13-Mar-2012 **Mfr Control #:** US-MYLANLABS-2012S1005812 **Application #:** 077042

Patient Information:

Age: 65 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	CITALOPRAM			Unknown	20mg daily	DEPRESSION		
2	HYLANDS TEETHING TABLETS			Unknown		WEIGHT DECREASED		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	CITALOPRAM		Yes	NA				MYLAN
2	HYLANDS TEETHING TABLETS	2 Week	Unk	NA				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Cerebral vasoconstriction	NA
Drug interaction	NA

Case ID: 8478591

Event/Problem Narrative:

Cvetanovich GL, Ramakrishnan P, Klein JP, Rao VR, Ropper AH. Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: A case report. J-Med-Case-Rep 2011; 5 No. 548 A 65-year-old woman developed reversible cerebral vasoconstriction syndrome (RCVS) during concomitant therapy with citalopram and Hydroxycut, a herbal weight-loss supplement. The woman, who had depression, had been receiving citalopram 20mg daily [route not stated] for several years. She presented with a sudden-onset "thunderclap" headache, accompanied by nausea, photophobia and hyperacusis. She had taken butalbital, paracetamol [acetaminophen] and caffeine, with no improvement. Intractable migraine was suspected. The woman received prednisone and lisinopril. Further investigation revealed that she had commenced the weight-loss supplement Hydroxycut [route and dosage not stated] 2 weeks earlier. Lisinopril was discontinued. On hospital day 2, she developed a left visual field deficit and weakness in both legs. An MRI demonstrated lesions in the right occipital lobe and bilateral anterior cerebral artery territories. She had a WBC count of 0 and a RBC count of 48. CT angiography (CTA) showed multifocal segmental vasoconstriction, particularly in the bilateral anterior and posterior cerebral arteries, and a diagnosis of RCVS was made. Citalopram was discontinued, and she began receiving nimodipine. Her headache resolved over the next few days, and her vision and leg weakness improved. She was advised not to take Hydroxycut and citalopram, and was discharged. At last follow-up, she had no residual leg weakness and improvement of her visual field deficit. Six weeks after discharge, a repeat CTA revealed marked resolution of cerebral vasoconstriction.

Relevant Medical History:

Sparse past history of migraines that ceased after her hysterectomy, no family history of migraine. Body mass index 22.3.

Disease/Surgical Procedure	Start Date	End Date	Continuing?
ABORTION SPONTANEOUS			NO
COMPRESSION FRACTURE			UNKNOWN
DEPRESSION			YES
HYPERLIPIDAEMIA			YES
HYSTERECTOMY			NO

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

Case ID: 8478591

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
CT scan	Normal	NA			
Holter monitoring	Unrevealing	NA			
Cholesterol	223	mg/dL			
Very low density lipoprotein cholesterol	28	mg/dL			
Low density lipoprotein cholesterol	134	mg/dL			
Transthoracic echocardiogram	Unrevealing	NA			
RBC count	48	UNK			
CSF protein	27	mg/dL			
Lipoprotein (a)	6	mg/dL			
WBC count	0	UNK			
MRI	(admission) Normal	NA			
Triglycerides	141	mg/dL			
CT angiography	Multifocal cerebral artery vasoconstriction	NA			
High density lipoprotein cholesterol	61	mg/dL			
CSF glucose	81	mg/dL			

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	SIMVASTATIN		Unknown	40mg daily	HYPERLIPIDAEMIA			

Reporter Source:

Study Report?: No

Sender Organization: MYLAN

503B Compounding Outsourcing Facility?:

Literature Text: Cvetanovich GL, Ramakrishnan P, Klein JP, Rao VR, Ropper AH. Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: A case report. J-Med-Case-Rep 2011; 5 No. 548

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8525521

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** Y **Country:** USA **Event Date:** 19-Apr-2012 **Outcomes:** **Application Type:** NDA

FDA Rcvd Date: 23-Apr-2012 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-8304302 **Application #:** 999999

Patient Information:

Age: 4 YR **Sex:** Male **Weight:** 6.8 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT		QID	Oral	2 to 3 tabs	TEETHING	13-Apr-2012	20-Apr-2012

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT		NA	NA			54973-3127-1	

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Rash generalised	NA

Event/Problem Narrative:

full body rash with bumps after ingestion of the product Triage Quality Control: WILSONJ: |*********| 2012-04-23-08.25.44 |*********| USFDAMWVOLUNTARY_205479_17645_20120421.xml Route To: AERS : Electronic

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8525521

Relevant Medical History:

teething tablets were recalled from the fda and still on shelves at babies r us

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8555594

Case Information:

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

FDA Rcvd Date: 25-Apr-2012 **Mfr Rcvd Date:** 17-Apr-2012 **Mfr Control #:** US-ROXANE LABORATORIES, INC.-2012-RO-01078RO **Application #:** 077043

Patient Information:

Age: 65 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	CITALOPRAM				20 mg	DEPRESSION		
2	HYLANDS TEETHING TABLETS					PHYTOTHERAPY		
3	LISINOPRIL				10 mg	HYPERTENSION		
4	PREDNISONE					MIGRAINE		
5	SIMVASTATIN				40 mg	HYPERLIPIDAEMIA		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	CITALOPRAM		Yes	NA				ROXANE
2	HYLANDS TEETHING TABLETS	2 Week	Yes	NA				
3	LISINOPRIL		Yes	NA				
4	PREDNISONE		Unk	NA				ROXANE
5	SIMVASTATIN		Unk	NA				

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Cerebral infarction	NA
Cerebral vasoconstriction	NA

Case ID: 8555594

Hypertension	NA
Hypotension	NA

Event/Problem Narrative:

Published Literature Case Report Events: Reversible cerebral vasoconstriction syndrome, Acute infarcts in the bilateral anterior cerebral artery and in her right occipital lobe, Prednisone induced hypertension, Hypotension A 65-year-old Caucasian woman presented to her local hospital with sudden-onset, bifrontal, pounding headache described as getting hit in the head with an axe. The headache was the worst of her life and did not improve after she took acetaminophen, caffeine, and butalbital. There was hyperacusis, photophobia and nausea. Noncontrast head computed tomography (CT) and brain magnetic resonance imaging (MRI) at the time of admission were normal and she was treated with prednisone for presumed intractable migraine. Aside from a similar but milder headache one week prior to her current presentation, she reported only a sparse past history of migraines that ceased after her hysterectomy and no family history of migraines or strokes. She had hyperlipidemia treated with simvastatin 40 mg daily, lumbar spinal compression fractures, multiple miscarriages and depression that had been treated for several years with citalopram 20 mg daily. On further questioning, our patient reported taking the weight-loss supplement Hydroxycut beginning two weeks prior to her thunderclap headache. On admission, her body mass index was 22.3, and she was normotensive on lisinopril 10 mg daily. She had not previously been on lisinopril, which was presumably initiated at the outside hospital for prednisone induced hypertension. We held the lisinopril for the duration of her hospitalization given her normal to low blood pressures. Her fasting lipid panel revealed cholesterol 223 mg/dL, triglycerides 141 mg/dL, high density lipoprotein 61 mg/dL, low density lipoprotein 134 mg/dL, very low density lipoprotein 28 mg/dL and lipoprotein (a) 6 mg/dL. Two days after admission, she developed bilateral leg weakness and left-sided visual disturbances that she described as blank lines. A repeat MRI revealed areas of restricted diffusion consistent with acute infarcts in the bilateral anterior cerebral artery territories and in her right occipital lobe. The following investigations were unrevealing: hypercoagulability studies, rheumatic and vasculitic screening labs, magnetic resonance venography, transthoracic echocardiogram with bubble contrast, and Holter monitoring. LA lumbar puncture, performed while our patient was being treated with prednisone, revealed 0 white blood cells (WBC), 48 red blood cells (RBC), cerebrospinal fluid (CSF) protein 27 mg/dL, glucose 81 mg/dL and no xanthochromia. CT angiography (CTA) was obtained, which revealed multifocal segmental cerebral artery vasoconstriction, most prominent in the bilateral anterior and posterior cerebral arteries. We made the diagnosis of reversible cerebral vasoconstriction syndrome (RCVS) and began treatment with nimodipine 30 mg three times daily. Over the subsequent days, her headache resolved and her visionand leg weakness improved. Our patient s blood pressures at admission and prior to starting nimodipine were 92-116/54-58 millimeters per mercury (mmHg) on no antihypertensive medications. After beginning nimodipine for RCVS, her systolic blood pressures ranged from the high 80s to low 100s (mmHg). We administered intravenous fluid bolus as needed to

Case ID: 8555594

keep her systolic blood pressure above 90 mmHg, in an effort to balance maintaining adequate cerebral perfusion while continuing nimodipine treatment for RCVS. Our patient tolerated this well without any clinical decline or symptomatic hypotension. She was discharged on nimodipine and advised not to take Hydroxycut and citalopram, which had been discontinued when a diagnosis of RCVS was first suspected. At the time of discharge, her systolic blood pressures remained in the 90s to low 100s mmHg. Therefore, she was advised to measure her blood pressure at home and take nimodipine only if systolic blood pressure was over 100 mmHg. Following discharge, our patient experienced no headaches and no recurrence of her presenting symptoms. At a follow-up appointment, she had no residual leg weakness and significant improvement of her left visual field deficit, although she reported that her vision had not returned to her baseline. CTA performed six weeks after discharge showed marked resolution of cerebral vasoconstriction, confirming the diagnosis of RCVS. Author's Comments: RCVS is the term for a group of rare syndromes characterized by multifocal narrowing of the cerebral arteries that resolves over the course of days to weeks. Patients present with sudden, severe thunderclap headaches that may be accompanied by neurologic deficits. Clinical situations associated with the development of RCVS include pregnancy or the postpartum period and various medications and illicit drugs. RCVS is diagnosed on the basis of this clinical presentation, exclusion of other causes of thunderclap headache such as subarachnoid hemorrhage andcerebral vasculitis by cerebrospinal fluid analysis, documentation of multifocal vasoconstriction of the cerebral arteries by angiography, and of reversibility of the vasoconstriction within 12 weeks of onset, although there may be permanent neurologic injury if stroke occurs secondary to vasospasm. Treatment has included calcium channel blockers or magnesium, and discontinuation of potential triggers for RCVS, particularly adrenergic or serotonergic compounds. We report the case of a patient on longstanding citalopram who developed RCVS two weeks after beginning to take the weight-loss supplement Hydroxycut, and we review the literature identifying factors associated with development of RCVS. This case illustrates the cardinal features of RCVS: thunderclap headache, lack of subarachnoid hemorrhage by CSF and radiographic analysis, ostensible exclusion of cerebral vasculitis by CSF and systemic testing, and angiographic demonstration of multifocal segmental cerebral artery vasoconstriction that resolves with time or calcium channel blocker treatment. It also exemplifies ischemic strokes as complications of RCVS, emphasizing the delicate balance between maintenance of adequate cerebral perfusion pressure to avoid watershed infarcts while using calcium channel blockers to mitigate against worsening vasoconstriction. The other aspect of RCVS treatment is identification and discontinuation of the potential triggers of RCVS. The clinical settings for RCVS include pregnancy and the postpartum state, serotonergic and sympathomimetic drugs and tumors, direct or neurosurgical trauma, hypertension, primary headache disorders such as migraine and other miscellaneous conditions such as hypercalcemia and porphyria. Regardless of etiology, RCVS is thought to occur due to perturbation of cerebral vascular tone. Although amphetamine-related weight-loss supplements and selective serotonin reuptake inhibitors including citalopram have been associated with RCVS, Hydroxycut has not previously been implicated. It is impossible to prove causality, but the temporal relationship between the patient's initiation of Hydroxycut and development of RCVS and the rapid reversal of symptoms and vasospasm following cessation implicates the supplement as a contributing cause in this case. Citalopram may have acted in concert

Case ID: 8555594

with the newly initiated Hydroxycut to cause this patient's RCVS, though the fact that she tolerated citalopram well for several years before developing RCVS argues against the antidepressant drug as the sole trigger.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
ABORTION SPONTANEOUS			UNKNOWN
ANGIOGRAM			UNKNOWN
DEPRESSION			UNKNOWN
ELECTROCARDIOGRAM			UNKNOWN
HYPERLIPIDAEMIA			UNKNOWN
HYSTERECTOMY			UNKNOWN
LUMBAR PUNCTURE			UNKNOWN
MIGRAINE			UNKNOWN
NUCLEAR MAGNETIC RESONANCE IMAGING			UNKNOWN
PHYTOTHERAPY			UNKNOWN
SPINAL COMPRESSION FRACTURE			UNKNOWN

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8555594

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization: ROXANE

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8730938

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 23-Sep-2010 **Outcomes:** HO **Application Type:**

FDA Rcvd Date: 04-Aug-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-7655894 **Application #:**

Patient Information:

Age: 121 DAY **Sex:** Male **Weight:** 4.08 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT					TEETHING	01-Sep-2010	23-Sep-2010

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT		NA	NA				HYLAND

Event Information:

Preferred Term (MedDRA Version: 18.0)	ReC
Crying	NA
Hyperhidrosis	NA
Lethargy	NA
Product quality issue	NA
Respiratory rate decreased	NA
Seizure	NA
Staring	NA
Unresponsive to stimuli	NA

Case ID: 8730938

Preferred Term (MedDRA Â Version: **17.0** **ReC**

Event/Problem Narrative:

On (b) (6) upon arriving home from work at approximatley 5:45 pm I gave my son Hyland's teething tablets somewhere between that time and 8pm. The night was normal as always and he was acting as he always did. Around 8pm, after bottle feeding him, i walked away from my son for a breif moment upon returning to him quickly due to a strange sounding cry, i found him sweating...i picked him up and immediatley felt something was not right. He suddenly felt lathargic and become un responsive, he breathing had slowed drastically. He had a blank stare in his eyes. I immediatley called my mother in law to come over who lived a few blocks away and ran to my neighbors house for help in panic. She immediatley called 911. They thought he had a seizure and he was taken by ambulance to the hospital. They did ask if he had any medicine and i told him yes teething tablets, i even showed them the bottle. He ended up being ok, after running test to rule out seizues. Today his daycare was mentioning the teething tablets and how she cant find them anywhere. I mentioned to her they were recalled last year. I came into work and decided to look the tablets up to see why they were recalled and if and when they would be back. The first article i read explained why they we recalled "varying amounts of belladonna, a potentially toxis ingredient" once reading the side affects I realized they matched the exact incident we went through the same night he took these. Had i read this article sooner i would have reported! I will never recommended anyone buy this product if it goes back onto the shelf and would never purhcase again,I am just thankful my son is ok. wilsonj: |*********| 2011-08-04-08.38.01 |*********| USFDAMWVOLUNTARY_190102_4543_20110803.xml Route To: AERS : Electronic Route To: DQRS : : Paper

Relevant Medical History:

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

Relevant Laboratory Data:

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

Case ID: 8730938

Preferred Term (MedDRA Â Version: **19.0** **ReC**

Concomitant Products:

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

Reporter Source:

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

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8733145

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 01-Nov-2009 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 26-Jul-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-7635492 **Application #:**

Patient Information:

Age: 182 DAY **Sex:** Female **Weight:** 23.5 LB

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	HYLAND TEETHING TABLETS			Oral	1 TABLET 4-6HRS	IRRITABILITY	01-Nov-2009	01-May-2010

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

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Cardiac murmur	NA

Event/Problem Narrative:

My child used the Highland Teething Tablets during her entire teething process. When (b) (6) was only a few months old, heart murmurs that were not discovered at birth, were discovered. I dont know if the murmurs resulted from the tablets or not, but I definitely would like to know. wilsonj: |*********| 2011-07-26-09.25.30 |*********| USFDAMWVOLUNTARY_189640_4180_20110726.xml Route To: AERS : Electronic

Case ID: 8733145

Relevant Medical History:

I had gestational diabetes during my pregnancy. I smoked a cigarette maybe every three days.

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8737450

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** Y **Country:** USA **Event Date:** 27-Jul-2011 **Outcomes:** HO,LT,RI **Application Type:**

FDA Rcvd Date: 01-Aug-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-7647694 **Application #:**

Patient Information:

Age: 2 YR **Sex:** Female **Weight:** 10.89 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BABY ORAJEL INSTANT TEETHING PAIN RELIEF		QID	Dental	PEA SIZED AMT TO AFFECTED AREA 4X/DAY	TEETHING	27-Jul-2011	27-Jul-2011

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	BABY ORAJEL INSTANT TEETHING PAIN RELIEF		NA	NA	1083	31-Mar-2013			

Event Information:

Preferred Term (MedDRA Version: 19.1)	ReC
Methaemoglobinaemia	NA
Oxygen saturation decreased	NA

Event/Problem Narrative:

Patient had tube of empty orajel at her home hours prior to presenting to ER blue with O2 sats in the 80s. She was intubated, eventually found to have methemoglobinemia and treated with methylene blue. She was life-flighted to (b) (6) via helicopter and has fully recovered. wilsonj: |*********| 2011-08-01-11.30.39 |*********| USFDAMWVOLUNTARY_189906_4378_20110729.xml Route To: AERS : Electronic

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8737450

Relevant Medical History:

no underlying medical hx no daily meds no drug allergies.

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

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
ABG	NORMAL				
METHEMOGLOBIN LEVEL	46	%			
CBC	UNREMARKABLE				
VBG	NORMAL				
CMP	UNREMARKABLE				

Concomitant Products:

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

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8745080

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** N **Country:** USA **Event Date:** 10-Jan-2010 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 23-Sep-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-7774542 **Application #:**

Patient Information:

Age: 0 DAY **Sex:** Male **Weight:** 13.15 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT\CHAMOMILE							

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	BELLADONNA EXTRACT\CAMOMILE EXTRACT\CHAMOMILE		NA	NA				HYLAND

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Hypersomnia	NA
Hypopnoea	NA
Lethargy	NA
Lip discolouration	NA
Seizure	NA

Case ID: 8745080

Preferred Term (MedDRA Â Version: **18.0** **ReC**

Event/Problem Narrative:

Our son first had a seizure close to the time that we gave him Hylands Teething Tablets. He since then off and on has had over 25 seizures. He is currently only 2 years old. We have had an EEG, EKG and soon will have an MRI. We have reported to his neurologist that we assume this relationship. We are very concerned about this being related to his seizures. His seizures are like this: He becomes very lethargic, lips start turning blue and has extreme shallow breathing. His eyes are glassy, he is over heated, he is not 'present' during the 30 second-1 minute seizures. After it is over he sleeps very hard until he has recovered.

Relevant Medical History:

None.

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

Relevant Laboratory Data:

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

Concomitant Products:

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

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8745080

Reporter Source:

Study Report?: No

Sender Organization:

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8745181

Case Information:

Case Type: DIRECT **eSub:** Y **HP:** Y **Country:** USA **Event Date:** 21-Aug-2011 **Outcomes:** **Application Type:**

FDA Rcvd Date: 25-Aug-2011 **Mfr Rcvd Date:** **Mfr Control #:** US-FDA-7708740 **Application #:**

Patient Information:

Age: 0 DAY **Sex:** Male **Weight:** 12.25 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	HYLAND'S BABY HOMEOPATHIC TEETHING TABLETS		Q8H	Oral	2-3 TABS, EVERY 8 HOURS, PO	TEETHING	21-Aug-2011	23-Aug-2011

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	HYLAND'S BABY HOMEOPATHIC TEETHING TABLETS		NA	Yes	112833		54973-3127-1	HYLAND

Event Information:

Preferred Term (MedDRA Version: 17.0)	ReC
Abdominal discomfort	NA
Abnormal behaviour	NA
Diarrhoea	NA
Flatulence	NA
Irritability	NA
Restlessness	NA

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8745181

Event/Problem Narrative:

watery diarrhea of 24 hours duration. resolved within 24 hours of discontinuing product. Initially received 2 doses of 3 tablets 12 hours apart on 8/21/2011. Watery diarrhea began 8/22 at 5 am with fussiness and abdominal discomfort, gas, restlessness, irritability. Bland diet started -BRAT- with pediatric electrolytes orally, tablets discontinued immediately. Diarrhea resolved within 24 hours. A single dose of 2 tablets was then administered on 8/23 at 9 pm and diarrhea resumed at 9 am on 8/24/2010. Patient is not lactose intolerant as the manufacturer suggested. wilsonj: |*********| 2011-08-25-08.09.02 |*********| USFDAMWVOLUNTARY_191269_5462_20110824.xml Route To: AERS : Electronic

Relevant Medical History:

White male, NKDA, no other medications being used at the time, lactose TOLERANT.

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Case ID: 8745181

Literature Text:

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 04-Nov-2016 08:03 AM
Total Number of Cases (Non-Esub): 172
Total Number of Pages: 438
Print Job Number: 12979

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:

7662960	7662973	7662994	7663044	7664436	7664660	7664963	7664990
7665261	7665361	7665383	7665414	7665509	7665512	7665552	7665603
7665769	7665775	7665784	7665927	7665929	7665937	7666052	7666143
7666176	7666215	7666246	7666248	7666261	7666263	7666284	7666316
7666359	7666379	7667610	7667612	7667724	7667738	7667743	7667750
7667922	7668156	7668251	7668314	7668473	7668607	7668850	7668887
7668927	7668946	7668979	7669030	7669046	7669964	7669976	7670100
7670493	7670496	7670892	7673718	7674000	7675902	7676016	7677527
7679619	7682004	7682299	7682451	7684270	7686705	7686853	7688673
7691191	7698915	7699366	7706677	7706830	7707066	7707821	7723951
7733265	7733404	7739553	7739701	7743142	7744127	7750625	7750696
7754115	7756415	7756528	7758002	7763555	7764708	7777563	7786988
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7906444	7907505	7915981	7933934	7942346	7966799	7988073	7998999
8007694	8008866	8047188	8060254	8148601	8247199	8267907	8275969
8285750	8315407	8325043	8400982	8455449	8503620	8505962	8610311
8666988	8708045	8736052	8858739	8901795	8901821	8994666	9026575
9028016	9037214	9046531	9053810	9233387	9275279	9275377	9275491
9282572	9282598	9282606	9282612	9282625	9282632	9282641	9282648

9282654	9282659	9282670	9282690	9282725	9282737	9282744	9282750
9282756	9282761	9282767	9282776	9282791	9282797	9282809	9282818
9410071	9410124	9410139	9410150				

Failed Case Id's for Images:

Total Failed Cases: 0

CaseID: 7662960

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

Individual Safety Report

7067398-X-00-01

Adverse Event Reporting Program

NTARY reporting of
, product problems and
luct use errors

ssion - Page 1 /2

FDA USE ONLY
Triage unit sequence # 433476

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/01/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

I have used Hyland's Teething tablets periodically with my daughter for some time now. I am not sure of the exact date I bought them or how often I have given them to her; however, I have noticed that she has begun having some constipation issues for the last month or so and her facial skin has become quite flushed. I have read about the Hyland's recall and feel that she has experienced some of the adverse affects associated with the undetermined amount of belladonna in the product evidenced by the constipation and skin flushing. I want it noted that she experienced some of these issues. I am not sure if they will go away with the

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets Hyland's
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	every 4 hours	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 7/2010 to 10/2010
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Relieve teething discomfort
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108422	#1
#2	#2

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

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)* DSS
OCT 26 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

Individual Safety Report

7067398-X-00-02

MEDWATCH

fessionals of adverse events and product problems

B5. Describe event or problem continued

discontinue of use or if these are going to be chronic issues. Quite frankly I only bought them because I thought they were safe. Had I known the FDA didn't approve of them I never would have bought them. I don't like the fact that I a able to buy something in a store in the medicine section that is not considered safe enough by the FDA to approve. I shouldn't be able to purchase things that are not safe.

DSS

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CDER

CaseID: 7662973

U.S. Department of Health and Human Services

Individual Safety Report

7067399-1-00-01

Adverse Event Reporting

...UNTARY reporting of ...nts, product problems and ...roduct use errors

...mission - Page 1

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

FDA USE ONLY

Triage unit sequence # 433475

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 1 Years	☑ Female ☐ Male	29 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☑ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - Initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/20/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

My daughter has been using the hylands tething tablets that have been recaled and she has goten sick from them she has the side efects of sleeping alot and muscle weeknes like shes falling all the time now when shes walking cuz shes so tifed from these this has been going on for two weeks now of her wanting to sleep all the time I talked to poison control tonite and the told me I have to take her in tomarow and have her looked at because she has symptoms of this poison or whatever it is

More

6. Relevant Tests/Laboratory Data, Including Dates

She goes in tomarow for this

More

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

She is only one and a half years old she is white

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands teething 3 tablets Hylands tablets
#2

2.	Dose or Amount	Frequency	Route
#1		As needed	
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 --
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108862	#1
#2 107806	#2

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands

2. Common Device Name
Teething tablets

OTC

3. Manufacturer Name, City and State
Hylands los angeles, ca 90061

4. Model #	Lot # 108862	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

U.S. Department of Health and Human Services

CDER

CaseID: 7662994

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

Individual Safety Report

7067400-5-00-01

...TARY reporting of product problems and ...ct use errors

...Program

...Submission - Page 1

FDA USE ONLY

Triage unit sequence # 433479

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 18 Months	☐ Female ☑ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/12/2008	10/25/2010

5. Describe Event, Problem or Product Use Error

We took our son to the doctor after witnessing a dramatic impairment in the use of his leg for a period of several hours, on June 12, 2008. We had witnessed two similar instances of this type of temporary paralysis about 4 and 5 months earlier that did not last quite as long. We did not seek medical attention for the first two instances as they did not last as long and we thought maybe his leg was just asleep, or had a muscle spasm. When we took him to the doctor she seemed highly concerned, especially after I modeled for her the type of dramatic immobility we had observed. She did not observe anything unusual during her examination but

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hyland's Teething Tablets — Hyland's Incorporated

#2

2.	Dose or Amount	Frequency	Route
#1	2-3 Tablets	as needed	po
#2			

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

#1 summer 2009 to June 2010

#2

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

#1 teething pain

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 106881	#1
#2	#2

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's teething tablets

2. Common Device Name
teething tablets

3. Manufacturer Name, City and State
Hyland's Inc. Los Angeles, CA 9[illegible]

OTC

4. Model #	Lot # 106881	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

Infant's Tylenol

DSS
OCT 26 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

suspected that it was brain or spinal cord related. She asked for time to consult with some specialists. We took him back one week later for follow-up and she did a SED rate, ordered X-rays of the leg, foot, and hip -all came back normal- and referred us to a pediatric neurologist for a next day appointment. Neurologist ordered blood work, an electrolyte panel to check for potassium deficiency, did an EKG to check for heart irregularities, and did an EEG. All tests came back normal. We opted to hold off on doing an MRI after further discussion with the neurologist. He believed our son had had three focal seizures but was unable to determine the cause. We wondered at the time of the incident if anything could have been triggered by the recent Tylenol recalls because we recalled given him Tylenol on at least two of the instances to help ease teething pain. Our doctor did not feel that the Tylenol recall was in any way linked to the symptoms we were observing. In hindsight I am now wondering if these episode were not linked rather, to the Hyland's teething tablets recall, known specifically to cause seizures among other effects. We did frequently use the tablets as directed during periods of intense teething pain and all of these episodes of seizure activity happened during intense teething periods.

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OCT 26 2010

CaseID: 7663044

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

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Individual Safety Report

7067401-7-00-01

The Adverse Event Reporting Program

...RY reporting of ...duct problems and ...se errors

... - Page 1 / 2

FDA USE ONLY

Triage unit sequence # 433478

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Our Son In confidence	17 Months	☐ Female ☑ Male	30 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/28/2009	10/25/2010

5. Describe Event, Problem or Product Use Error

On February 28th 2009 at approximately 930pm I called EMS on my Son who at the time was 17 months old. He had been seeming tired most the day, and not himself. Around 930pm he became very lathargic, white or flushed in the face, unresponsive & completely limp. He didnt snap out of this for approx 20 minutes. When EMS arrived to our home they didn't notice anything serious enough to have him taken in because he eventually was able to stand up, walk around, and they assumed he had a short fainting spell from a viral illness. He remained tired the next day, much more than usual but didn't have another limp, lathargic, unresponsive spell until

More

6. Relevant Tests/Laboratory Data, Including Dates

Blood tests were taken in both Hospitals. EKG, EEG, Echo were also preformed.

More

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

None

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Homeopathic Tablets Highland's
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 Tablets	4 times a day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/01/2009 -- 03/10/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teeting of 2 year Molars
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date
#1 101986	#1
#2	#2

9. NDC # or Unique ID
54973-7504-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's Teething Tablets

2. Common Device Name
Teething Tablets

3. Manufacturer Name, City and State
P&S Laboratories Los Angeles, CA 90 51

OTC

4. Model #	Lot # 101986	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☑ Other: Child

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 Addr... of Reprocessor

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
OCT 26 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
Email (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 2

B5. Describe event or problem continued

(b) (6) - (b) (6) days after our initial call into EMS. It was the same symptoms as (b) (6) nights before. I rushed him into (b) (6) Hospital where they began running a battery of tests, hooked him up to an IV and began administering fluids. He was found to be dehydrated slightly and was transported via Ambulance to (b) (6) Childrens Hospital for further testing based on my observations the past few days. Once admitted into Childrens Hospital he experienced 1 additional limp spell, remained very lathargic and experienced trouble walking. We remained in the Hospital for 4 additional days and finally released without any answers. He was seen by Cardiologists, Neurologists, and Pediatrians whose tests all came back normal to rule out heart, brain, or bacterial infections. It was assumed all of these disturbing symptoms were from a Viral Illness which ran it's course. I followed up with our Pediatrician for the 2nd time on this issue and he advised it could also have been night terrors. Today, October 25th 2010 we saw the Recall on Teething Tablets. The exact Teething Tablets I've gave my Son. We are very surprised & disturbed to read the symptoms of Belladonna poisoning are the exact symptoms my Son displayed, All of these symptoms were communicated & documented before, during & after our Stay in the Hospital in (b) (6) My son WAS taking these exact Teething Tablets at this time included in the Recall! We still have the Bottle. He has not taken them since that time.

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OCT 26 2010

CaseID: 7664436

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

Individual Safety Report

7068098-2-00-01

The FDA Safety Information and Adverse Event Reporting Program

LUNTARY reporting of ents, product problems and product use errors

bmission - Page 1 CDER

FDA USE ONLY

Triage unit sequence # 433667

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 9 Months	☐ Female ☑ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
	10/24/2010

5. Describe Event, Problem or Product Use Error

(b) (6) has had severe constipation since we started using the tablets 3 months ago. We have to use liquid suppositories to help him have bowel movements. We have changed his diet several times to try and fix this problem. Now we know it could have been the teething tablets we were using 3-4 times a day. Hopefully stopping their use will fix the problem.

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Teething Tablets no strength listed Hyland's

#2 A

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	up to 4 times dail	sl
#2			

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

#1 07/01/2010 -- 10/24/2010

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Teething pain

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108867	#1
#2	#2

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name OTC

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Other Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7664660

U.S. Department of Health and Human Services

Individual Safety Report

7068043-X-00-01

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

FDA USE ONLY
Triage unit sequence # 433537

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	9.5 Months	☑ Female ☐ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/24/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

My daughter has had ongoing severe issues with constipation since starting to use Hyland Teething tablets at 5 months. I thought it was related to starting solids. After reading the recent FDA recall I realized her symptoms are most likely related to the teething tablets. She very recently also started showing signs of labored breathing.

More

6. Relevant Tests/Laboratory Data, Including Dates

N/A

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More

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

NONE

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland Teething tablets n/a Hyland
   #2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	3x day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 06/01/2010 -- 10/24/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething pain
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 unknown	#1	unknown
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: n/a
2. Common Device Name: n/a
3. Manufacturer Name, City and State: n/a

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

CaseID: 7664963

U.S. Department of Health and Human Services

Individual Safety Report

7068247-6-00-01

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n - Page 1 of 2

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

FDA USE ONLY
Triage unit sequence # 433662

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 14 Months	☐ Female ☑ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/30/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

I gave my son 2 Hyland's teething tablets before bed, and a couple hours later he woke up crying. I got him out of bed and he was jerking his head/arms, staring blankly, couldn't stand -he knows how to walk-, and just not being himself. I thought it was from Motrin earlier that day, but after I read the effects of this product on the recall website, I am positive this is what caused my son to have this reaction. I kept him up and gave him water, and then put him back down to bed. He was better in the morning, but that night was pretty scary. I was very close to taking him the hospital, but my husband was out of town and I had nobody to

More

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

He has a dairy sensitivity and acid reflux.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets Homeopathic Hyland's
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4x/day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/01/2010 -- 09/30/2010 (1-2 x per month)
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething irritability
#2

6. Lot #	7. Expiration Date
#1 106226	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's Teething Tablets

2. Common Device Name
Hyland's Teething Tablets OTC

3. Manufacturer Name, City and State
Hyland's, Inc. Los Angeles, CA 90061

4. Model #	Lot # 106226	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☑ Other: parent

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

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

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*
Hyland's Teething Tablets

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

watch my other sleeping son.

DSS
OCT 27 2010

CaseID: 7664990

U.S. Department of Health and Human Services

CDER

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

MEDWATCH

Individual Safety Report

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Adverse E...

7068268-3-00-01

ge 1 / 2

FDA USE ONLY

Triage unit sequence # 433660

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☐ Female ☑ Male	21 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/22/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

I bought a bottle of Hylands Teething Tablets 2 weeks ago and was giving them to my son. The entire time he was taking them he was extremely fussy and sometimes beyond fussy. I thought this was because of him teething. Then on 10/22/2010 my son was screaming seeming to be in pain and unconsolable, he then broke out in a rash on his face and neck. After a little while the rash went away and he calmed down. This morning I saw that Hylands Teething Tablets had been recalled for inconstant amounts of belladonna. My son had many of the side effects listed on the recall page so I took him to the emergency room. A doctor confirmed that his behavior

More

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Tablets
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 10/12/2010 -- 10/22/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1 54973-7504-2	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-7504-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands

2. Common Device Name
Teething Tablets

OTC

3. Manufacturer Name, City and State
P&S Laboratories Los Angeles California 90061

4. Model #	Lot # 108269	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

and symptoms was due to the belladonna in the teething tablets.

DSS

OCT 27 2010

CaseID: 7665261

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

Individual Safety Report

7068249-X-00-01

The FDA Safety Information and Adverse Event Reporting Program

CDER

TARY reporting of product problems and ct use errors

Internet Submission - Page 1 of 3

FDA USE ONLY

Triage unit sequence # 433661

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 06 Months	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/25/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

I used the Hylands Teething Tablets for my son towards the end of August -the 25th is not an exact date- and he had problems with them. They instruction said to use 2-3 tablets 4 times per day. Well, he'd never had them before so I only gave him one tablet to start. He did go straight to sleep, but woke up SCREAMING! It wasn't a regular scream, it was like he was in terrible pain. I have a very relaxed and happy baby and for him to scream like that was very terrifying because that's not something he does - ever! I didn't associate the tablets with the screaming at first. So, a few days later, he had one more tablet. This time, about two

More

6. Relevant Tests/Laboratory Data, Including Dates

He had no tests.

More

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

He does have allergies.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

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D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hylands Teething Tablets — Not provided on label — Hylands Inc.

#2

2.	Dose or Amount	Frequency	Route
#1	2-3 Tablets	4 times daily	sl
#2			

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

#1 08/25/2010 -- 09/04/2010

#2 --

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

#1 Teething pain

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☑ Yes ☐ No ☐ Doesn't Apply

6. Event Reappeared After Reintroduction?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☑ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109352	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hylands

2. Common Device Name: Hylands Teething Tablets

3. Manufacturer Name, City and State: Hylands Inc. Los Angeles, CA.

OTC

4. Model #	Lot # 109352	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

Hylands Teething Tablets. These were used over a period of about 1-2 weeks on three separate occasions. The dates where around the last week of August

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

minutes after taking the tablet, he started vomiting. He threw up very hard and there was a large amount of vomit. He stomach stayed upset for a few hours after as well. Once again, I didn't really associate the tablets to the vomiting. So once again, a few days later, he one more tablet. Then, in less time than before, he started throwing up again and became very irritated. That's when I made the connection to the tablets. He only had three tablets total and on three different days, but every single time he had a reaction and became irritable and seemed to be in pain.

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F. Other (Concomitant) medical products continued

2010 and the first week of September 2010.

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OCT 27 2010

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CaseID: 7665361

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

Individual Safety Report

7068287-7-00-01

Adverse Event Reporting Program

LUNTARY reporting of
ents, product problems and
product use errors

omission - Page 1

FDA USE ONLY
Triage unit sequence # 433689

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	4 Months	☑ Female ☐ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/10/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

We used the recalled Hyland's Teething Tablets and our daughter has been constipated ever since.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

(b) (6) has reflux and is on Prevacid, which may also cause constipation.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets Hyland's
#2

2.	Dose or Amount	Frequency	Route
#1	2-3	every other day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/10/2010 -- 10/23/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108274?	#1
#2	#2

9. NDC # or Unique ID
108274?

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7665383

Individual Safety Report

7068666-8-00-01

CDER

UNTARY reporting of
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oduct use errors

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

FDA USE ONLY
Triage unit sequence # 433887

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☐ Male	28 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/22/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

My son was rushed to ER by EMS do to vomiting and passing out -possible seizure activity- It was found he was severly constapated. He has also been complaining of headaches over the past 3-4 weeks since he has been taking the teething tabs.

More

6. Relevant Tests/Laboratory Data, Including Dates

Abdominal X rays - (b) (6)

More

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

Egg allergy

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Hylands teething tabs

#2

2.	Dose or Amount	Frequency	Route
#1	2 tabs	BID	po
#2			

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

#1 10/01/2010 -- 10/22/2010

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Teething

#2

6. Lot #	7. Expiration Date
#1 109665	#1
#2	#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
3 54973 75041

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7068463-3-00-01

The FDA Safety Information and Adverse Event Reporting Program

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Internet Submission - Page 1

CaseID: 7665414

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

FDA USE ONLY
Triage unit sequence # 433642

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	17 Months	☑ Female ☐ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/08/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

While our daughter was teething, we were giving her the Hyland's Teething tablets. On (b) (6) she experienced a seizure lasting two to three minutes which she came out of on her own. She was transported to the ER and treated. She had a fever of approximately 101 degrees at the ER. While the fever was not high, the seizure has been attributed to the fever. She was seen the following week by a pediatric neurologist. The neurologist also attributed the seizure to fever.

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6. Relevant Tests/Laboratory Data, Including Dates

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

Blood work and x-rays
EEG

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1	Hyland's Teeting Tablets	none	Hyland's
#2	Hyland's Teeting Tablets	none	Hyland's

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	As needed	po
#2	2 to 3 tablets	As needed	po

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 As needed during teething
#2 As needed during teething

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

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2 Teething

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 105300	#1
#2 108713	#2

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

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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MedWatch

The FDA Safety Information and Adverse Event Reporting Program

Individual Safety Report

7067991-4-00-01

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Internet/Submission - Page 1

CaseID: 7665509

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

FDA USE ONLY
Triage unit sequence # 433638

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 9 Months	☑ Female ☐ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/24/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

My 9 month old daughter has been taking Hylands Tething Tablets in reccommended dosages as indicated on the bottle. She has been showing some of the symptoms that have been published. She was admitted into the hospital for a "cold" because the medicine that was prscribed to her was not being accepted by her body.. The symptoms that are showing is the breathing difficulties, excessive sweating, fatigue, and sleeping too much. She has been released from the hospital, but she still is haveing the symptoms. She is taking albuterol, and pulmacort through a nebulizer and liquid prednizone. The (b) (6) Poison Control Center has been

More

6. Relevant Tests/Laboratory Data, Including Dates

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Homeopathic n/a Hylands Inc.
#2

2.	Dose or Amount	Frequency	Route
#1	2	every 4 hours	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 04/01/2010 -- 10/23/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething baby
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 103565	#1
#2	#2

9. NDC # or Unique ID
54973-7504-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands Homeopathic Teething tablets
2. Common Device Name
Teething Tablets
3. Manufacturer Name, City and State
Hylands Inc. Los Angeles, Ca 90061

OTC

4. Model #	Lot # 103565	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

notified of the situation. The situation has been documented with them..

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

Individual Safety Report

7067996-3-00-01

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CaseID: 7665512

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

...LUNTARY reporting of
...nts, product problems and
...roduct use errors
...mission - Page 1

FDA USE ONLY
Triage unit sequence # 433037

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	10/24/2010

5. Describe Event, Problem or Product Use Error

My baby experienced severe agitation and was overly drowsy. I brought him to the ER and they discharged him as stable.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 --
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name Hyland's
2. Common Device Name Teething Tablets
3. Manufacturer Name, City and State

OTC

Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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Individual Safety Report

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Adverse Event Reporting Program

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Internet Submission - Page 1

CaseID: 7665552

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

FDA USE ONLY

Triage unit sequence # 433633

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Infant In confidence	(b) (6) 5 Months	☑ Female ☐ Male	12 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
05/30/2008	10/24/2010

5. Describe Event, Problem or Product Use Error

I gave my daughter 2 Hylands Teething Tablets. She started going limp, her eyes rolled back in her head and she became unresponsive. -No jerking as a seizure would indicate.- I called the doctor who instructed me to call 911. 911 called Poison Control and instructed me to take her to the closest hospital. She remained comatose & limp and barely breathing. The ER doctor did a few tests on her and my daughter started to come around. I told the ER doctor about the Tablets and he was unsure whether they would cause this. All information is documented in the ER report. We visited her normal pediatrician later that day. He took the bottle and

More

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) Hospital, (b) (6)
(b) (6) (b) (6)

More

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

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hylands Teething Tablets — 2 tablets every 3-4 hours as need — Standard Homeopathic Company
   #2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	once	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 one time only 05/30/2008 -- 05/30/2008
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething pain
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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OCT 27 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

said he was going to look into it and see if there had been any other cases. All information is documented in her medical records.

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CDER

CaseID: 7665603

Individual Safety Report

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

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FDA USE ONLY
Triage unit sequence # 433630

7068016-7-00-01
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	28.2 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/24/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

Just received news that Hyland's Teething Tablets have been recalled. After giving my son the suggested dosage by the manufacturer, I noticed he's somewhat "out of it" if the 3 tablets were given to him during the day, or he almots immediately goes to sleep afterwards. I am presently unaware of any long-term damage done to my son's body, as we have been using these since he was about 9 month old.

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6. Relevant Tests/Laboratory Data, Including Dates

Will be seeing pediatrician on 10/28. Will update form as needed.

More

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

Reflux from 4 weeks of age to 7 months.Possible dairy intolerance, allergic to apples.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets 125 tablets Hyland's
#2

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	4x/day	po
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/08/2010 -- 10/24/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Homeopathic remedy of symptoms of irritability while teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109515	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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 DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7665769

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

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Individual Safety Report

7068678-4-00-01

...NTARY reporting of ..., product problems and ...uct use errors

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The FDA Safety Information ...
Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 433481

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☑ Female ☐ Male	14 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/23/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

After using the teething tablets religiously for 3 days -every 2 hours when needed, not exceeding 12 tablets in 24 hours- on (b) (6) while playing with my daughter on the bed she suddenly lost all color in her face and her lips turned blue. She didn't choke, and showed no other signs of distress. She actually laughed through the whole thing. We rushed her into the ER where she was put through a battery of tests and an overnight stay they were unable to find anything wrong other then her O2 stats dropping at random, which resolved itself after a few hours. Durring the 20 hours we spent at (b) (6) I had to hold my baby girls arms above

More

6. Relevant Tests/Laboratory Data, Including Dates

EKG, Heart monitoring, x-rays, full blood and metobolic screening, 20 hours hospital observation.

More

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

From birth to about 16 weeks she had slight reflux issues.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Hyland's Teething Tablets — Not indicated on Hyland's Inc. bottle

#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	Every 2 hours	po
#2			

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

#1 10/15/2010 -- 10/23/2010

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Teething pain

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 NDC 54973-7504	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State — OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

her head while the strapped her into a tube used to prevent her from moving while they took x-rays, I had to hold her down while they tood blood and inserted an IV, and I had to hold her still while they did an EKG. Life flight was waiting to take her to (b) (6) if they found a heart defect. Through out all of these tests my sweet baby girl cried and screamed and the top of her lungs, looking at me holding her down letting these people hurt her. She spent the night hooked up to a telemetry monitor and an O2 monitor, there were 6 wires attached to my baby. The only test that wasn't done was a tox screen because they didn't believe it to be necessary. The only thing she had consumed in the 72 hours prior were breast milk and the teething tablets. My pediatrician believes the teething tablets are likely to be the cause of the hell we've went through the last 2 days.

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OCT 27 2010

Individual Safety Report

7068698-X-00-01

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CaseID: 7665775

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

FDA USE ONLY
Triage unit sequence # 433480

The FDA Safety Information and
Adverse Event Reporting Program

Internet Submission - Page 1 of 2

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 13 Months	☑ Female ☐ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/25/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

extreme sleepiness, difficulty and pain urinating, not wanting to walk, agitation, reduced balance and walking ability, oversleeps during regular and consistent nap and sleep times.

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6. Relevant Tests/Laboratory Data, Including Dates

been in contact with dr's about daughter's symptoms for past week, daughter was given Hyland teething tablets on and off since molars began breaking through two weeks ago. received FDA warning today and daughter's symptoms match most of symptoms listed according to Belladonna poisoning. very, very

More

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

none

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets n/a Hyland's Homeopathic
#2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	1-2 x day- on & off	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/08/2010 -- 10/25/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 13mo's old, molars breaking through with pain
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 106789	#1
#2	#2

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

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

DSS
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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B6. Relevant tests/laboratory data, including dates continued

concerned.

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CaseID: 7665784

Individual Safety Report

7068720-0-00-01

CDER

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # 433479

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☐ Female ☑ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/16/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

My baby was crying constantly and couldn't use the bathroom -poop-, he was straining and would cry, he would not take bottle or have anything to do with any type of food, was having problems urintaing and when he did it was really strong in odor. We took him to the emergancy room where he was diagnosed as being constipated, we just found out about this recall today and he had been taking these teething tablets since the middle of September. We just gave them to him again today and then my mom called about the recall of this product.

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More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland's Teething Tablets N/A Hyland's Inc.
   #2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	4 X day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 09/12/2010 -- 10/25/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 35497375041	#1
#2	#2

9. NDC # or Unique ID: N/A

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets
2. Common Device Name: Hyland's Teething Tablets
3. Manufacturer Name, City and State: Hyland's, INC. Los Angeles, Ca. 9[illegible]

OTC

4. Model #	Lot # 35497375041	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)* 01/01/2011	☐ Health Professional ☐ Lay User/Patient ☑ Other:
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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

started giving teething tablets to my baby around the middle of Sept. to 10/25/2010 Stopped giving them to him when I seen this recall.

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7665927

CDER

Individual Safety Report

7068593-6-00-01

Adverse Event Reporting Program

TARY reporting of product problems and t use errors

ion - Page 1

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

FDA USE ONLY
Triage unit sequence # 433611

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 7 Months	☑ Female ☐ Male	19.15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/22/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

Had given daughter teething tablets right before she cut her first tooth. On Sept 22 she had her first seizure. Since then she has had several major seizures with abot 50 small ones. She was hospitalized for having 3 major seizures on (b) (6) She was put on 1 ml of keppra was fine for a week, then she had 8 seizures within a 10 minute time span and put on a higher dose of keppra, 1.5 ml.

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6. Relevant Tests/Laboratory Data, Including Dates

on 9/22/2010 1st seizure had CT scan nd blood work- normal 9/28/2010 blood work - normal 10/08/2010 EEG- normal (b) (6) MR and blood work- normal

More

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

none

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething tablets hyland
   #2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	bid	sl
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
   #1 07/01/2010 -- 09/22/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 teething
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☑ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108790	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Homeopathic Teething Tablets
2. Common Device Name: Teething Tablets
3. Manufacturer Name, City and State: Hyland's Homeopathic Teething Tablets OTC

4. Model #	Lot # 108790	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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 DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7665929

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

[U.S. Department of Health and Human Services]

Individual Safety Report

7068605-X-00-01

Adverse Event Reporting Program

TARY reporting of product problems and ct use errors

ion - Page 1 CDER

FDA USE ONLY

Triage unit sequence # 433602

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
baby In confidence	(b) (6) 11 Months	☐ Female ☑ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/24/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

Baby has had rash, flushed cheeks, extremely agitated and fussy, Fever, drowsy,

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething TAbs unknown Hylands
   #2

2.	Dose or Amount	Frequency	Route
#1	2 tabs		po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 10/01/2009 -- 10/25/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1
   #2

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

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

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CaseID: 7665937

Individual Safety Report

7068608-5-00-01

Adverse Event Reporting Program

VOLUNTARY reporting of e events, product problems and product use errors

. Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 433601

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event, or Date of Birth: (b) (6) 4 Months
3. Sex: ☐ Female ☑ Male
4. Weight: 17.11 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event (mm/dd/yyyy): 10/18/2010
4. Date of this Report (mm/dd/yyyy): 10/25/2010

5. Describe Event, Problem or Product Use Error

Child became extremely constipated and was screaming trying to go to the restroom.

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6. Relevant Tests/Laboratory Data, Including Dates

N/A

More

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

N/A

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Teething Tablets Hyland
#2

2.	Dose or Amount	Frequency	Route
#1	1-2 tablets	every 6 hours	po
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 10/06/2010 -- 10/25/2010
#2 --

4. Diagnosis or Reason for Use (Indication)
#1 Irritability, restlessness, discomfort
#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 106206
#2

7. Expiration Date
#1
#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland
2. Common Device Name: Teething tablets
3. Manufacturer Name, City and State

OTC

4. Model #	Lot #	5. Operator of Device
106206	106206	☐ Health Professional
Catalog #	Expiration Date (mm/dd/yyyy)	☑ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone #
E-mail (b) (6)

2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

U.S. Department of Health and Human Services

CDER

CaseID: 7666052

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

Individual Safety Report

7068621-8-00-01

ITARY reporting of product problems and ict use errors

ion - Page 1

FDA USE ONLY
Triage unit sequence # 433594

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 16 Months	☐ Female ☑ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/16/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

(b) (6) was teething so we gave him HYLAND'S HOMOPATHIC TEETHING TABLETS. He has been hospitalized twice in a month for seizures. The doctors ran all kinds of tests including a spinal tap for menengitis, influenza, pnemonia...the works. His first seizure caused him to be hospitalized and quarentined for three days. His second seizure a month later, (b) (6) had him hospitalized for another three days and the neurologist ordered an EEG. We still have no answers to why he was having seizures...possibly the teething tablets...now that we kn

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6. Relevant Tests/Laboratory Data, Including Dates

Spinal tap for menegitis (b) (6) influenza test (b) (6) pneumonia test (b) (6) EEG (b) (6) Lots and lots of blood work (b) (6) and (b) (6)

More

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

(b) (6) had no previous illness, allergies, or anything leading up to these seizres. He was teething.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 TEETHING TABLETS HYLAND'S INC
#2

2.	Dose or Amount	Frequency	Route
#1	3 TABLETS	4 TIMES A DAY	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/01/2010 -- 10/14/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 TEETHING
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108134	#1
#2	#2

9. NDC # or Unique ID
108134

E. SUSPECT MEDICAL DEVICE

1. Brand Name
HYLAND'S HOMOPATHIC TEETHING TABLETS
2. Common Device Name
HYLAND'S HOMOPATHIC TEETHING TABLETS
3. Manufacturer Name, City and State
HYLAND'S INC. LOS ANGELES, CA 90061

4. Model #	Lot # 108134	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

OTC

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CDER

CaseID: 7666143

Individual Safety Report

7068626-7-00-01

Adverse Event Reporting Program

NTARY reporting of
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uct use errors

Internet Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 433582

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 3 Months	☑ Female ☐ Male	11 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/19/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

constipation for over 2 week period

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More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets Hyland™s
#2

2.	Dose or Amount	Frequency	Route
#1	2 or 3 tablets	every hr for 6 hr	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/07/2010 -- 10/15/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 104527	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland™s Teething Tablets

2. Common Device Name
Hyland™s Teething Tablets

OTC

3. Manufacturer Name, City and State
Los Angelos , CA

4. Model #	Lot # 104527	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

Individual Safety Report

7068642-5-00-01

CaseID: 7666176

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

CDER

...NTARY reporting of ...ts, product problems and ...oduct use errors

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1

FDA USE ONLY
Triage unit sequence # 5433556

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 05 Months	☐ Female ☑ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	10/25/2010

5. Describe Event, Problem or Product Use Error

My son has been using the hylands teething tablets and has been having irregular constipation and breathing a little more heavy.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland's Teething 125 Tablets Hyland's, INC.
   #2

2.	Dose or Amount	Frequency	Route
#1	2-3	ever 6 hrs as need	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 09/10/2010 -- 10/22/2010
   #2 --

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
   #1 teething
   #2

8. Event Reappeared After Reintroduction?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109519	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets
2. Common Device Name: Hemopathic
3. Manufacturer Name, City and State: Hyland's Inc Los Angeles, CA

OTC

4. Model #	Lot # 54973-7504-1	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7666215

Individual Safety Report

7068646-2-00-01

Adverse Event Reporting Program

CDER

NTARY reporting of
s, product problems and
duct use errors
ssion - Page 1/2

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

FDA USE ONLY
Triage unit sequence # 433555

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 13 Months	☑ Female ☐ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
07/06/2009	10/25/2010

5. Describe Event, Problem or Product Use Error

Hyland's Teething Tablets were used for the first time the evening of (b) (6) We used 2 tablets at 4pm, and 2 tablets at 9pm. Our 13 month old daughter did not wake up (b) (6) (b) (6) She was extremely lethargic. She was rushed to the emergency department. Her drug screen was negative. Her alcohol level was negative. Her ketones were 4+. Her blood sugar was 31. She had no underlying illnesses. She was transported to a PICU for 24 hours for observation. All of her tests came back negative. The only thing they could think of was that the levels of belladonna in the teething tablets caused extreme lethargy and sedation or

More

6. Relevant Tests/Laboratory Data, Including Dates

Ketones 4+ Blood Glucose 31 Her drug screen was negative. Her alcohol level was negative.

More

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

None

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Hyland's Teething Tablets
#2

2. Dose or Amount	Frequency	Route
#1 as needed		
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 07/05/2009 -- 07/05/2009
#2 --

4. Diagnosis or Reason for Use (Indication)
#1 teething pain
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

Individual Safety Report

7068646-2-00-02

WATCH

ofessionals of adverse events and product problems

Internet Submission - Page 2

B5. Describe event or problem continued

the levels of the other ingredients caused excessive dehydration and ketosis, causing her sugars to drop.

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CaseID: 7666246

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

Individual Safety Report

7071936-0-00-01

Adverse Event Reporting Program

CDER

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its, product problems and
oduct use errors
ission - Page 1

FDA USE ONLY
Triage unit sequence # 433684

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 5 Months	☐ Female ☑ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/15/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

After using this product we've noticed numerous of the side effects that were described. He has had breathing problems, skin flushing/rash, lathargy, agitation, and constipation. We have been trying to figure out what has been causing these issues but nothing has seemed to work. Until running across this recall we now realize that all the issues have been caused by the teething tablets. We will no longer be using this product and will not purchase this brand in the future!

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets 125 tablets Hyland's Homeopathic
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	Every 4 hours	
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/15/2010 -- 10/26/2010
#2 --

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(indication)*
#1 Cutting Teeth/Teething
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108713	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's
2. Common Device Name: Homeopathic Teething Tablets OTC
3. Manufacturer Name, City and State: Hyland's Inc. Los Angeles, CA 90067

4. Model #	Lot # 108713	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient
Serial #	Other # 54973-7504-1	☐ 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

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OCT 28 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7666248

U.S. Department of Health and Human Services

Individual Safety Report

7068648-6-00-01

CDER

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # 433996

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	24 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem (e.g., defects/malfunctions)
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
01/01/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

Recall of Hyland's Teething Tablets used from January 2010 to September 2010. Breathing irregularities.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Hyland's Teething Tablets	n/a	Standard Homeopathic Company
#2		

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	3-10 times per wk.	po
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
   #1 01/01/2010 -- 09/25/2010
   #2 --

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)
   #1 teething pain
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109178	#1	NDC 54973-750
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Homeopathic Teething Tablets
2. Common Device Name: Hyland's Homeopathic Teething Tablets
3. Manufacturer Name, City and State: Hyland's Inc. Los Angeles, CA 90061

4. Model #	Lot # 109178	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☑ Lay User/Patient
Serial #	Other #	☐ Other:

OTC

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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OCT 27 2010

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

Individual Safety Report

7072071-8-00-01

Adverse Event Reporting Program

CDER

JNTARY reporting of ts, product problems and duct use errors

Internet Submission - Page 1 of 2

CaseID: 7666261

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

FDA USE ONLY
Triage unit sequence # 433687

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☑ Female ☐ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/10/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

The infant was exhibiting symptoms of teething and Hyland's teething tablets were administered. The infant appeared relieved of symptoms, so the tablets were continued for several days. After a few days the infant began waking several times in the night, screaming inconsolably. After a few nights of the recurring episodes. The teething tablets were stopped. The episodes immediately stopped. This was discussed with the child's pediatrician. All other causes were ruled out. Additionally, the child became drowsy after tablets were administered but the manufacturer states that drowsiness is to be expected because the teething symptoms have been

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

The child is in good health.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets n/a Hyland's Homeopathic
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	once daily	sl
#2			

3. Dates of Use *(If unknown, give duration)* from/to *(or best estimate)*
#1 prn for 2 months
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Relief of teething symptoms in infant
#2

6. Lot #	7. Expiration Date
#1 107178	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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
DSS
OCT 28 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

relieved and the child can rest.

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

CaseID: 7666263

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

Individual Safety Report

7072105-0-00-01

CDER

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

Internet Submission - Page 1

Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 433688

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/23/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

Child experienced flushing of the skin and irritability after using the product.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething Tablets Hyland's
   #2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	2 times a day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 08/10/2010 -- 10/25/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 symptoms of teething
   #2

6. Lot #	7. Expiration Date
#1 107651	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
   54972-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's
2. Common Device Name: Teething Tablets
3. Manufacturer Name, City and State: Hyland's Inc. Los Angeles, CA [illegible]

OTC

4. Model #	Lot # 107651	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CDER

CaseID: 7666284

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

Individual Safety Report

7071071-1-00-01

Adverse Event Reporting Program

OLUNTARY reporting of
:vents, product problems and
product use errors

ubmission - Page 1

FDA USE ONLY

Triage unit sequence # 433453

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/16/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

Used 1 Hyland's Teething Tablet and patient had flushed cheeks the following day. Used Humphrey's Teething Tablets one week later and patient was lethargic and excessively tired.

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Humphrey's Teething Pellets — Humphreys Pharmacal Inc.
#2 Hyland's Teething Tablets

2.	Dose or Amount	Frequency	Route
#1	1-3 Pellets	2 hrs. up to 4x/da	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 10/13/2010 -- 10/25/2010	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 10/16/2010 -- 10/16/2010	#2 ☑ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 Teething	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 Teething	#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	0219-1103-00
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Humphrey's/Hyland
2. Common Device Name: Teething Pellet/Teething Tablets
3. Manufacturer Name, City and State: Humphreys Pharmacal, Inc. [illegible] CT

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
OCT 27 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

CDER

CaseID: 7666316

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

Individual Safety Report

7071097-8-00-01

NTARY reporting of
s, product problems and
duct use errors
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Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	433492

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 1 Years	☑ Female ☐ Male	30 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/04/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

My daughter ended up in the ER, because she collapsed at my parents house while I was st work. My parents said she was playing with a toy and all of a sudden she collapsed. My dad picked her up and screamed for my mom. When my mom took her, she said her eyes rooled to the back of her head and her lips were blue. They called 911 and when the paramedics came, they treated it as a seizure. No fever.. nothing. She was and is a healthy 22 month old now, but we had been giving her the hylands teething tablets, but never would have thhought this might have been the reason for this.

More

6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) ran a chemistry panel, hematology panel, urine sample.

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1	hyland's teething tablets	2 tablets	hyland's teething tablets
#2			

2.	Dose or Amount	Frequency	Route
#1	2 tablets every hour	2	sl
#2			

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

#1	09/01/2009	01/03/2010
#2		

5. Event Abated After Use Stopped or Dose Reduced?

#1	☑ Yes	☐ No	☐ Doesn't Apply
#2	☐ Yes	☐ No	☐ Doesn't Apply

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

#1	teething
#2	

8. Event Reappeared After Reintroduction?

#1	☐ Yes	☐ No	☑ Doesn't Apply
#2	☐ Yes	☐ No	☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 106560	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: hyland's teething tablets
2. Common Device Name: hyland's teething tablets
3. Manufacturer Name, City and State: hyland's homeopathic teething tablets los angeles, ca 90061

4. Model #	Lot # 106560	Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient
Serial #	Other #	☐ Other:

OTC

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7666359

U.S. Department of Health and Human Services

Individual Safety Report

7071099-1-00-01

JNTARY reporting of
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duct use errors
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Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 433490

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 6 Months	☐ Female ☑ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/18/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

My son has been very agitated and very sleepy since we started the new bottle of the teething tablets.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

He has a milk allergie

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland Teething Homeopathic Hylands tablets
   #2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	4 times a day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 Like 2 or 3 months
   #2

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething relief
   #2

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

6. Lot #
   #1 54973-7504-1
   #2

7. Expiration Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   Hylands Teething tablets
2. Common Device Name
   Teething tablets
3. Manufacturer Name, City and State
   Los Angeles, CA 90061

OTC

4. Model #	Lot #	5. Operator of Device
	109665	☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
Serial #	Other #	☑ Other: Parent

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

Individual Safety Report

7071142-X-00-01

The FDA Safety Information and Adverse Event Reporting Program

CDER

NTARY reporting of
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Internet Submission - Page 1

CaseID: 7666379

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

FDA USE ONLY
Triage unit sequence # 433629

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 1 Years	☑ Female ☐ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	10/24/2010

5. Describe Event, Problem or Product Use Error

Just want to report Hyland™s Teething Tablets make my daughter very sleepy. She goes from being very active to deep sleep within 5 minutes. I haven't put the date as she used the tablets on several occasions, last time about 2 weeks ago.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

none

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland™s Teething Tablets 2-3 pills Hyland's
#2

2.	Dose or Amount	Frequency	Route
#1	3 pills	1 per day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/01/2010 -- 10/01/2010
#2 --

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

4. Diagnosis or Reason for Use *(Indication)*
#1 teething pains
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108265	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's teething tablets
2. Common Device Name: Hyland's teething tablets OTC
3. Manufacturer Name, City and State: Hyland's, Inc. Los Angeles, CA 90061

4. Model #	Lot # 108265	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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OCT 27 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Other Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7667610

Individual Safety Report

7073654-1-00-01

Adverse Event Reporting Program

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product use errors

Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 433810

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	13 Months	☐ Female ☑ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/27/2010	10/27/2010

5. Describe Event, Problem or Product Use Error

Toddler is frequently falling after mastering walking. Horrible constipation and irritability that is not typical. Waking up from sleeping to screaming and hyperventalating for long periods of time before calming down. All started when taking hylands teething tablets. Just found out today it was recalled! That certainly explains it now!

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 hylands teething tablets
   #2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	per night	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 04/05/2010 -- 10/27/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 teething pain
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109099	#1
#2	#2

9. NDC # or Unique ID
   109099

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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OCT 28 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone #

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CDER

CaseID: 7667612

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

Individual Safety Report

7073688-7-00-01

NTARY reporting of
s, product problems and
duct use errors
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The FDA Safety ...
Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	433812

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	12 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/15/2010	10/27/2010

5. Describe Event, Problem or Product Use Error

I have been giving my daughter Hyland's Teething tablets and had to discontinue use due to GI issues. I gave her less than the recommended dose and the fussiness only got worse. She began arching her back and screaming in pain. I called the peditrician and they said to ride it out. I am infuriated with Hyland because on the bottle it states, "your baby may fall asleep after using this product because the pain has been relieved and your child can rest," and yes my child did fall asleep, I'm just glad she woke up!! How can they print on the bottle, "no side affects," when you look up belladonna there are many side affects????

More

6. Relevant Tests/Laboratory Data, Including Dates

N/a thankfully our side affect wasn't that serious.

More

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

NONE. Very healthy baby!

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething Tablets 3x Hyland's
   #2

2. Dose or Amount	Frequency	Route
#1 1 tablet	every hour	Buccal
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 08/13/2010 -- 10/17/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething pain
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108265	#1	NDC5497375041
#2	#2	

E. SUSPECT MEDICAL DEVICE

OTC

1. Brand Name: Hyland's Teething Tablets
2. Common Device Name: Homeopathic
3. Manufacturer Name, City and State: Hyland'sLos Angeles, CA

4. Model #	Lot # 108265	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☑ Other: mom
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
OCT 28 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7667724

7073984-3-00-01

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

CDER

MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1 / 2

FDA USE ONLY
Triage unit sequence # 433814

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 2 Years	☐ Female ☑ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☑ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/01/2010	10/27/2010

5. Describe Event, Problem or Product Use Error

NOTE that date of event is approximate. He found a bottle of Hyland's Teething Tablets, which do not have child-proof caps. I believe that the bottle originally contained 100 tablets; however, it could have been 50 tablets. My calculation at the time -when I called poison control- was that there were approximately 30-35 tablets remaining in the bottle. The two year old was able to remove the cap, and ate an unknown quantity, estimated to be about 20-25 tablets. At the time -before the recall-, poison control stated that since the amount belladonna in the tablets is controlled, even eating an entire bottle should not have affected

More

6. Relevant Tests/Laboratory Data, Including Dates

none. doctor not consulted.

More

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

none relevant.

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets — Standard Homeopathic Company
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 --
#2 --

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

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

OTC

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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 8, Enter Name and Address of Reprocessor

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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OCT 28 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

1 of 2

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

him -and we knew the bottle was partially empty-. We were advised to watch for certain symptoms, and call the doctor if we noticed them, but we did not. He had no adverse effects in the short term or the long term. I can recall at least one other incident where he was able to open the bottle, but luckily the second time I turned around and saw him climbing to get it and I made it across the room as he got the cap off, before he could eat any of the tablets. I was motivated to submit this report upon hearing of the recent recall of Hyland's tablets. I hope that this submission is considered along with the others, to motivate the FDA to require that ALL medical products, prescription, OTC, homeopathic, or otherwise -even vitamins- be REQUIRED to have child-proof caps.

DSS

OCT 2 8 2010

Individual Safety Report

7071232-1-00-01

CaseID: 7667738

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

LUNTARY reporting of
ents, product problems and
product use errors

bmission - Page 1

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 433801

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Daughter In confidence	(b) (6) 1 Years	☑ Female ☐ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/27/2010	10/27/2010

5. Describe Event, Problem or Product Use Error

daughter began having seizures and high temp while using Hyland Teething Tablets

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MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets unknown Hyland
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	4 times a day	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 10/27/2010 -- 10/27/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109352	#1
#2 109090	#2

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland

2. Common Device Name
Teething Tablets

OTC

3. Manufacturer Name, City and State
Hyland's Inc. Los Angeles, CA 900[illegible]

4. Model #	Lot #	5. Operator of Device
	109352	☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☑ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 28 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer
		☐ User Facility
		☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

CaseID: 7667743

Individual Safety Report

7071256-4-00-01

Adverse Event Reporting Program

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

...NTARY reporting of ...ts, product problems and ...duct use errors
...ission - Page 1

FDA USE ONLY
Triage unit sequence # 433804

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 16 Months	☐ Female ☑ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	10/27/2010

5. Describe Event, Problem or Product Use Error

after giving my son the hylands teething tablets i notice that he does become sleepy and some times aggitated.

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More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands teething tablets all natural hylands homeopathic
#2

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	3 times a day	po
#2		

OTC

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 aprox 1 year	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply
4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 teething	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108661	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hylands teething tablets
2. Common Device Name:
3. Manufacturer Name, City and State: p&s laboratories lose angeles,ca 90061

4. Model #	Lot # 108661	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

DSS
OCT 28 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CDER

CaseID: 7667750

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

Individual Safety Report

7071263-1-00-01

Adverse Event Reporting Program

)LUNTARY reporting of
'ents, product problems and
product use errors

bmission - Page 1

FDA USE ONLY

Triage unit sequence # 433807

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 2 Years	☑ Female ☐ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/06/2008	10/27/2010

5. Describe Event, Problem or Product Use Error

My child had 3 seizures, lethargthic, and very sleepy. We had to take her to the hospital 2 times before she was admitted. She did have and ear infection and RSV but the doctor was not sure why she had the seizures, so they said they were feviral seizures. I happen to be giving her the teething tablets. So now I am wondering if they may have been the cause.

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6. Relevant Tests/Laboratory Data, Including Dates

(b) (6) she has 3 seizures was admitted into the hosptal.

More

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

NA

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hyland's Teething Tablets — Hyland's

#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4 times a-day	
#2			

3. Dates of Use *(if unknown, give duration) from/to (or best estimate)*

#1 October 2007-March 2008 --

#2 --

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

#1 Teething

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 102581	#1
#2	#2

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name OTC

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

DSS
OCT 28 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7667922

Individual Safety Report

7070482-8-00-01

The FDA Safety Information and Adverse Event Reporting Program

JNTARY reporting of ts, product problems and oduct use errors

ission - Page 1

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

FDA USE ONLY

Triage unit sequence # 433606

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 2 Months	☑ Female ☐ Male	12 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	10/26/2010

5. Describe Event, Problem or Product Use Error

She has had some difficulty breathing and has also been constipated.

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More

6. Relevant Tests/Laboratory Data, Including Dates

N/A

More

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

N/A

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland's teething tablets
   #2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	once, twice daily	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 09/01/2010 -- 10/24/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

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

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☑ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	3 54973 75041
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets
2. Common Device Name
3. Manufacturer Name, City and State: Hyland's

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7668156

U.S. Department of Health and Human Services

Individual Safety Report

7070489-0-00-01

...TARY reporting of product problems and ...ict use errors

...sion - Page 1 / 2

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

FDA USE ONLY

Triage unit sequence # 433598

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 6 Months	☐ Female ☑ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)*
☑ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/30/1993	10/26/2010

5. Describe Event, Problem or Product Use Error

Hyland Teething pills. I thought they were taken off the market years ago. I just see that they are going to be taken off. My son was 6 1/2 months old. I had given him a teeting pill at 10 AM. We went out to the zoo and noticed pumps on the back of his neck . My 12:30 PM, he had a big rash all over his body- everywhere. I called the pediatrician. Brought him in at 1:30 Pm and the pediatrician screamed at me after he saw the Hylands bottle and saw that the ingredient was Bella Donna. He said my son could have gone into cardiac arrrest and died. Instead, he had a severe rash and was fine. I called the Hyland's company and spoke with a

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 HYLANDS TEETHING PILLS
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

#1 --
#2 --

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

#1
#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hylands teeting pills

OTC

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

person in the pharmacy dept who was a scientist and he said it is completely safe and nothing was wrong and they had never had a problem or a complaint. Since this was not regulated by the FDA, I couldn't notify the government at the time and I was buy working and had a 6 month old. I stopped using it and told everyone else.

DSS
OCT 27 2010

U.S. Department of Health and Human Services

CaseID: 7668251

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

Individual Safety Report

7070791-2-00-01

TARY reporting of product problems and ct use errors

ion - Page 1

FDA USE ONLY
Triage unit sequence # 433577

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	14 Months	☑ Female ☐ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/21/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

I gave my child hylands teething tablets after the doctor informed me that it would help her with the pain of teething. she was taking it every day for exactly one week when the symptoms occurred. she got a high fever and then started having a seizure we immediately took her to the emergency room. they ran no tests on her they said she had an ear infection and sent us home. the next day her regular doctor seen her and said she did not have any signs of an ear infection at all. she said it was probably a viral infection and to just keep giving her antibiotics. two days later her skin became red and rash like. i took her back to the doctor and

More

6. Relevant Tests/Laboratory Data, Including Dates

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MEDWATCH CTU

More

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

none

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 teething tablets hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	4 times per day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/21/2010 -- 10/25/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething fussiness runny nose mouth in pain
#2

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

6. Lot #
#1 109723
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-7504-2

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

she said it may be roseola or a reaction to medicine. that same night i learned of this recall just two hours after giving this medicine to my child. i feel that this medicine was what caused my child to be sick and have a seizure out of nowhere. she was fine until she started taking this medicine and the doctors didnt even really know what was going on with her they just kept guessing at what they thought might be wrong with her. she had the same symptoms as the ones listed as possible side effects to this drug -hyland's teething tablets-.

DSS
OCT 27 2010

Individual Safety Report

7070841-3-00-01

Adverse Event Reporting Program

CDER

OLUNTARY reporting of
vents, product problems and
product use errors

[illegible] Submission - Page 1

CaseID: 7668314

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

FDA USE ONLY

Triage unit sequence # 433575

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
baby boy In confidence	(b) (6) 1 Years	☐ Female ☑ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/08/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

Child used Hyland's Teething Tablets that were part of a recall. Excessive fussiness, and discomfort. Woke up screaming several times.

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MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland's Teething Tablets n/a Hyland's
   #2

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	4 times/day	po
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 09/23/2010 -- 10/20/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething pain
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108020	#1	54973-7504-2
#2	#2	

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑		☐ Distributor/Importer

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

Individual Safety Report

7070938-8-00-01

The FDA Safety Information and Adverse Event Reporting Program

CDER

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1/2

CaseID: 7668473

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

FDA USE ONLY
Triage unit sequence # 433587

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 9 Months	☑ Female ☐ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/20/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

Our family went on a vacation to (b) (6) our daughter was teething at the time. We gave her the hylands teething tablets to ease her discomfort. Later on, she was very sick. She wasn't even able to lift her head- she slept all day in my arms, that afternoon she had a temperature of 103.1 so we took her into the (b) (6) Childrens Hospital. They ran some tests and couldnt figure out why she was having such a high fever- it had spiked up again during her hospital stay. After all the testing was done, they never figured out what was wrong with her. We were told to help bring the fever down with motrin and went back home. She was very lethargic

More

6. Relevant Tests/Laboratory Data, Including Dates

The (b) (6) Childrens hospital ran the tests.

More

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

Otherwise healthy child. That was her only time of having a fever and being so sick.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Tablets n/a Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	twice a day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/04/2010 -- 01/20/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands

2. Common Device Name
Teething tablets

3. Manufacturer Name, City and State
Hyland's, inc. Los Angeles, OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other # NDC: 54973-7504-1	☑ Other: parents

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

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F. OTHER (CONCOMITANT MEDICAL PRODUCTS)

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

B5. Describe event or problem continued

and fussy for the next few days, wouldn't eat and couldn't lift her own head off my chest for a day or so.

DSS
OCT 27 2010

Individual Safety Report

7070842-5-00-01

CaseID: 7668607

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

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NTARY reporting of
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Internet Submission - Page 1 / 2

The FDA Safety Information and
Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 433573

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 9 Months	☐ Female ☑ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/24/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

I have been giving my baby who is 9 months old Hylands teething tablets. For about 2 days he was getting 2 tablets about 3 times a day. I noticed on October 23, 2010 he was breathing different, it sounded like he was having a hard time breathing. Also when i fed him he couldn't swollow the food he normally had no troubles eating. It was stage 3 gerber baby food. He would choke on it and throw up. It was like he had something stuck in his throat. He had also been very sleepy, I would describe it as "out of it" for the same 2 days. No signs of any illness, besides a runny nose. no coughing, no diarrhea, no throwing up.
(b) (6) (b) (6)

More

6. Relevant Tests/Laboratory Data, Including Dates

x-rays came back negative for anything stuck in his throat on (b) (6)

More

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

none

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething homeopathic Tablets Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	every 3 hours	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/20/2010 -- 10/26/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 107178	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's Teething Tablets
2. Common Device Name
Teething Tablets
3. Manufacturer Name, City and State
Hyland's INC Los Angeles, CA 9006

OTC

4. Model #	Lot # 107178	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

(b) (6) (b) (6) I knew i needed to get him to a hospital. When we got there they brought him back ahead of others since he was so little and having breathing problems. The doctors and nurses checked him completely out and did x-rays and saw nothing wrong with him. Today, two days later. I see the recall from the FDA about Hylands Teething Tablets and i see he had a lot of the same symptoms. I didn't even mention to the nurses he had been taking them because they are all natural and it didn't even cross my mind that they would make him sick. I do not have any proof these teethign tablets made my baby have these symptoms but it is very similar to the symptoms listed under the recall information.

DSS
OCT 27 2010

CaseID: 7668850

Individual Safety Report

7070636-0-00-01

The FDA Safety Information and Adverse Event Reporting Program

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VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

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

FDA USE ONLY
Triage unit sequence # 433533

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 2 Years	☑ Female ☐ Male	26.6 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/10/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

my daughter was taking teething tablets that are recalled now and was extremely sleepy and constipated to extent had to dig it out

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More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 highlands teething tablets — highlands
   #2

2.	Dose or Amount	Frequency	Route
#1	3	4 times day	Dental
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 10/01/2010 -- 10/25/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 teething
   #2

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

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7668887

Individual Safety Report

7070578-0-00-01

Adverse Event Reporting Program

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sion - Page 1

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

FDA USE ONLY
Triage unit sequence # 433553

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Baby boy In confidence	(b) (6) 9 Months	☐ Female ☑ Male	27 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/01/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

For the past month and a half, my son has had a strange rash all over his upper body and facial area. I've taken him to see his doctor a few times and we have not been able to come up with a conclusion as to why he has this rash. He has flushed cheeks, and seems agitated quite often. He has also been taking Hylands teething tablet for the past month and a half. I did some research on Belladonna and this can be an effect from it. I have immediately stopped using this product.

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MEDWATCH CTU

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6. Relevant Tests/Laboratory Data, Including Dates

Doctor prescribed steroid cream to help with this rash.

More

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

None

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands teething homeopathic hyland's tablets
#2

2.	Dose or Amount	Frequency	Route
#1	2 or 3 tablets	4 times a day	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 4-6 per day 08/10/2010 -- 10/23/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 108134
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
108314

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's

2. Common Device Name
teething tablets

OTC

3. Manufacturer Name, City and State
Hyland's, Los Angeles, Ca 90061

4. Model #	Lot # 108134	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

U.S. Department of Health and Human Services

CaseID: 7668927

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

Individual Safety Report

7070579-2-00-01

UNTARY reporting of
its, product problems and
oduct use errors
ission - Page 1 CDER

FDA USE ONLY
Triage unit sequence # 433550

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 15 Months	☐ Female ☑ Male	26 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/12/2010	10/24/2010

5. Describe Event, Problem or Product Use Error

My son is 15 months old now. He has been teething since he was 8 months old, and I have been giving him Hylands Teething tablets ever since he started teething. Starting on September 5th, My son began cutting 2 teeth, i gave him CONTNUOUS doses as recommended of the teething tablets to help with the pain. On (b) (6) my son woke up at 9:30pm with a fever over 105 degrees. I rushed him to the hospital. He was subjected to chest Xray, IV's, Blood draws, Catherization, and the worst, a spinal tap. They could not find the source of the fever. It caused his skin to be flushed, vomitting, lethargy, the high fever, shaking, irritability,

More

6. Relevant Tests/Laboratory Data, Including Dates

Chest Xray, bloodwork, spinal tap, urinealysis, all taken during hospital stay from (b) (6) thru (b) (6) No results were found, they did not do a toxicology including Belladonna.

More

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

He has NO pre existing conditions. No smoking, etc. He is 15 month old white male. No liver/kidney or any other health problems.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets 125 Tablets Hyland
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	every 8 hours	sl
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 03/01/2010 -- 10/23/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 1070 30	#1
#2 svrl bottles d	#2

9. NDC # or Unique ID
54973-7504

E. SUSPECT MEDICAL DEVICE

1. Brand Name Hyland
2. Common Device Name Teething Tablets
3. Manufacturer Name, City and State Hyland's, Inc Los Angeles CA

OTC

4. Model #	Lot # 1070 30	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

constipation etc. The doctor couldn't find any cause for the fever. He was released 3 days later with the diagnoses, FEVER WITH UNKNOWN ORIGIN. He cut 2 teeth. NOW, he is teething again...and last week I started using the tablets again. Starting on Wednesday, he was fussy, irritable, constipated, had a fever, and had NO appetite. I gave it until Friday, and took him to the Doctor who could not find anything wrong with him. Just instructed to give Tylenol. I continue to do that, off brand, of course, since Tylenol is recalled...but, until right now, I have continued to give him the teething tablets. He has ALL of the same symptoms that he did prior to his hospitalization, except for the extreme fever.

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OCT 27 2010

Individual Safety Report

7070580-9-00-01

CDER

CaseID: 7668946

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

NTARY reporting of
ts, product problems and
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The FDA Safety Information and Adverse Event Reporting Program

Incident Discussion - Page 1

FDA USE ONLY
Triage unit sequence # 433548

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 6 Months	☑ Female ☐ Male	14 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/29/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

I'VE NOTICE THAT WHEN I GAVE MY BABY THIS PRODUCT FOR THE FIRST TIME SHE SLEPT FOR HOURS AND I HAD TO WAKE HER UP! LAST NITE I EVEN GAVE HER SOME AND SHE SCREAMED HALF THE NITE AND DID'NT KNOW ABOUT THE RECALL OF THESE TABLETS.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

She is a premature baby and hope these tablets didnt harm her!

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 hylands teething tablets none hylands inc
   #2

2.	Dose or Amount	Frequency	Route
#1	2t	-	
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
   #1 --
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1
   #2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

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

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7070582-2-00-01

The FDA Safety Information and Adverse Event Reporting Program

CDER

r VOLUNTARY reporting of se events, product problems and product use errors

Internet Submission - Page 1

CaseID: 7668979

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

FDA USE ONLY

Triage unit sequence # 433547

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 8 Months	☐ Female ☑ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/25/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

My son has been taking these tablets for a couple of months and has had increasing agitation. I just happened to be watching CNN today and this item has been recalled due to one of the exact same effects.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething Tablets Homeopathic Hyland's
   #2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	as needed	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 08/17/2010 -- 10/24/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109178	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name Hyland's
2. Common Device Name Teething Tablets
3. Manufacturer Name, City and State Hylan's, Inc. Los Angeles, CA 90061

OTC

4. Model #	Lot # 109178	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Serial #	Other # 54973-7504-1	

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

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

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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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CaseID: 7669030

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

Individual Safety Report

7070701-8-00-01

Adverse Event Reporting Program

UNTARY reporting of
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FDA USE ONLY
Triage unit sequence # 433520

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
Baby In confidence	(b) (6) 11 Months	☐ Female ☑ Male	28 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/20/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

Very agitated and restless.
Constipation/diaheria

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More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland Teething Tablets
   #2

2.	Dose or Amount	Frequency	Route
#1	3 Tablets	4-6 hours	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 06/01/2010 -- 10/24/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☑ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland
2. Common Device Name: Teething tablets
3. Manufacturer Name, City and State: Hyland

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☑ Other: Parents

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

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OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone #	E-mail
(b) (6)	

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7070607-4-00-01

Adverse Event Reporting Program

CDER

JNTARY reporting of
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ission - Page 1

CaseID: 7669046

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

FDA USE ONLY

Triage unit sequence # 433535

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Female baby In confidence	(b) (6) 5 Months	☑ Female ☐ Male	14 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/24/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

She developed a terrible blister rash on her bottom and severe stomach pains.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hylands Teething Tablets 125 tablets Homeopathic

#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets dissolved in water	twice a day	po
#2			

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

#1 09/20/2010 -- 09/24/2010

#2 --

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

#1 teething pain

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets

2. Common Device Name: OTC

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7669964

Individual Safety Report

7070769-9-00-01

The FDA Safety Information and Adverse Event Reporting Program

CDER

LUNTARY reporting of
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omission - Page 1

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

FDA USE ONLY
Triage unit sequence # 433510

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/03/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

When given just 2 tablets, he would fall asleep within 5 minutes and sleep very hard. I never gave him more than 2 tablets at a time and never more than 2 doses a day because he would sleep so hard after having them. I wasn't too worried at the time because the bottle states that 'child may fall asleep due to the relief of discomfort'. But I felt I needed to be cautious with the product because it would change his normal sleep pattern.

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Hylands Teething Tablets — Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	1-2 times a day	po
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 09/01/2010 -- 10/15/2010
#2 --

4. Diagnosis or Reason for Use (Indication)
#1 discomfort with cutting teeth
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 108134
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

DSS
OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7669976

Individual Safety Report

7070789-4-00-01

Adverse Event Reporting Program

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

CDER

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

FDA USE ONLY

Triage unit sequence # 433509

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 4 Months	☐ Female ☑ Male	13.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/20/2010	10/25/2010

5. Describe Event, Problem or Product Use Error

After using two of the Hyland's teething tablets my son started throwing up. He threw up 4 or 5 times and had a hard time keeping anything down that night. The next day seemed to be fine.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hyland's Teething Tablets 1 tablet Hyland's

#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	every 6 hours	po
#2			

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

#1 10/20/2010 -- 10/21/2010

#2 --

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

#1 Teething

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109099	#1
#2	#2

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name OTC

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS

OCT 27 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

(b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CDER

CaseID: 7670100

Individual Safety Report

7071312-0-00-01

Adverse Event Reporting Program

TARY reporting of DQRS product problems and ct use errors

...ion - Page 1 / 2

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

FDA USE ONLY
Triage unit sequence # 433512

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 2 Years	☑ Female ☐ Male	26 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☑ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/22/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

Product Use Error - On Monday, September 6, 2010 I walked into my 23 month olds bedroom to find her with an open bottle of Hyland's Teething Tablets eating the pills. She had opened a dresser drawer, opened the non-child proofed bottle, and started eating tablets. Best guess is she ate b/w 10-15 at that time. She appeared to have no side effects after ingestion. Since that date she has probably only ingested 5-6 additional tablets. Out of our most recent bottle of 125 there are still 98 tablets. Possible Adverse Event - Two year old girl had a seizure on (b) (6) at approximately 10:00pm. After being rushed to the ER, and

Medication Error

More

6. Relevant Tests/Laboratory Data, Including Dates

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MEDWATCH CTU

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets — Hyland's
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	as needed	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 March/April-October 2010 --
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 108713
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

performing blood and urine analysis, CT Scan, EEG of Heart, and chest x-ray no cause for the seizure was found. In the past 2-3 months, she has probably ingested 27 Hyland Teething Tablets. Last two tablets were probably given to her two weeks ago. Probably since March-April 2010 she has ingested about 100 Hyland Teething Tablets. We did speak to a nurse at our Pediatrician's office and she did not think their was a correlation between the seizure and the tablets, but she suggested to contact you. We do have an appointment with a Pediatric Neurologist on Friday, October 29, 2010 to further evaluate our daughter after her seizure.

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DSS
OCT 27 2010

Individual Safety Report

7076918-0-00-01

Adverse Event Reporting Program

CDER

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1

CaseID: 7670493

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

FDA USE ONLY

Triage unit sequence # 433933

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 8 Months	☐ Female ☑ Male	16.12 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/25/2010	10/28/2010

5. Describe Event, Problem or Product Use Error

He has agitaion and rash.

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MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething Tablets symptomatic relief Hyland's
   #2

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	6 times a day	po
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 --
   #2 --

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

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109014	#1
#2	#2

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   Hyland's
2. Common Device Name
   Teething Tablets
3. Manufacturer Name, City and State
   Hyland's Inc. Los Angeles CA 90061

OTC

4. Model #	Lot # 109352	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of*

DSS

OCT 29 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

Individual Safety Report

7077323-3-00-01

The FDA Safety Information and Adverse Event Reporting Program

CDER

...UNTARY reporting of ...nts, product problems and ...roduct use errors

Internet Submission - Page 1/2

CaseID: 7670496

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

FDA USE ONLY
Triage unit sequence # 433959

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
hyland teething pil In confidence	(b) (6)	☐ Female ☑ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/14/2010	10/28/2010

5. Describe Event, Problem or Product Use Error

stasrting at 5 months old child was given up to 4 Hylands teething pills epr day but not every day, initial episode was sometime in Sept with what was labeled as a complex febrile seizure at another facility, between then and now child has had what sound like either breath holding or apneic episodes that never result in cyanosis and maybehas been up to 5-6 occurences, no other listed potential side effects were observed and child has continued to grow ,is his normal self , had no hx of problems at birth, except meconium aspiration which did not result in prolonged stay , the parents saw the voluntary recall and were wondering if the pills

More

6. Relevant Tests/Laboratory Data, Including Dates

head MRI and EEG, i believe about 10-14-2010 and were said to be normal

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 hyland's teething pills
#2

2. Dose or Amount	Frequency	Route
#1 up to 4 pills per day		po
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 05/01/2010 -- 10/26/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

6. Lot #	7. Expiration Date
#1	#1
#2	#2

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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 Used on a Patient?
☐ Yes ☐ No

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

MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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OCT 29 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7670496

433959

MedWatch

For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

might have something to do with the child's episodes, i saw him today and think not , but told them I would send this info in for your use

DSS
OCT 29 2010

Individual Safety Report

7077365-8-00-01

CDER

CaseID: 7670892

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

...UNTARY reporting of
...nts, product problems and
...roduct use errors
mission - Page 1

FDA USE ONLY
Triage unit sequence # 433998

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 9 Months	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☑ Product Use Error ☑ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/22/2010	10/28/2010

5. Describe Event, Problem or Product Use Error

I had given my daughter teething pills hylands homopathic pills. I had giver her six through the day and it made her very cranky n irritable n shaking her head!! I didn't know it had to do with the pills I thought she was comming down with a ear infection! She was up all day n night with sleeping maybe 15 mins at a time! the following day she was acting like her self again !! I didn't bother giving her any of the teething pills!!!!! She was constipated for 3 days !!!! I don;t know if that has to do with any of it !!!

More

6. Relevant Tests/Laboratory Data, Including Dates

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OCT 29 2010
MEDWATCH CTU

More

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

none

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 hylands teething tablets hyland's inc
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 pills	up to 4 times	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 morning n night 10/09/2010 -- 10/22/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109665	#1
#2	#2

9. NDC # or Unique ID
ndc5497375041

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
hylands
3. Manufacturer Name, City and State
hylands inc los angeles ca 90061

OTC

4. Model #	Lot # 109665	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☑ Other: mom

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of eve...*

DSS
OCT 29 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7673718

U.S. [illegible]

Individual Safety Report

7078408-8-00-01

CDER

RY reporting of duct problems and se errors

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

FDA USE ONLY
Triage unit sequence # 434056

The [illegible] Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1/2

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	4 Months	☑ Female ☐ Male	or 6.8 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: _____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/30/2010	10/31/2010

5. Describe Event, Problem or Product Use Error

4 mo old female who was BIBA after a 2nd episode of a 1-2 min all extremities "shaking" with white milk-appearing fluid coming out of the nares followed by a period of being less active than her normal state early this morning. She had no color change with the episode and has been without fever. The episode occurred approximately 1 hour after a feed. She has had no rhinorrhea, cough, vomiting, diarrhea or fussiness. One day prior to admission, mom states she had a similar episode again approx. 1 hour after a feed with the following additional features: eyes fluttering, increased drooling, lips and face turning purple, and she had gasping

More

6. Relevant Tests/Laboratory Data, Including Dates

Belladonna-Pending

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MEDWATCH CTU

More

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

None

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Hyland's Teething Tablets unknown Hyland

#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

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

#1 10/01/2010 -- 10/30/2010

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Teething

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109749	#1
#2	#2

9. NDC # or Unique ID

unknown

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
NOV 01 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

sounds. At that time EMS was called and she was seen at (b) (6) ED and discharged home with likely viral illness. Of note, infant drinks 6-1/2 ounces of slightly diluted formula every 3-4 hours. Mom also gives infant approx. 1 ounce of water a day. Also, infant received Hyland's teething tablets on the evenings prior to the morning episodes of "shaking."

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NOV 01 2010

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

CaseID: 7674000

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

Individual Safety Report

7078284-3-00-01

Adverse Event Reporting Program

NTARY reporting of
:s, product problems and
duct use errors
ession - Page 1

FDA USE ONLY
Triage unit sequence # 434116

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Baby Boy In confidence	(b) (6)	☐ Female ☑ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/16/2010	10/30/2010

5. Describe Event, Problem or Product Use Error

Constipation that led to the development of perianal fistula requiring surgical intervention. Second fistula developed -2 weeks before recall announced- & cleared with antibiotics & some invasive treatment, but non-surgical. No further fistulas developed when administration of Hylands teething tablets ceased. Last time Hylands teething tablets were administered was on Saturday, 10/23. 1 episode of severe constipation noted on Tuesday, 10/26. Since Tuesday, there have been no more episodes of severe constipation & Hylands Tablets have been completely discontinued with last dose administered on Saturday 10/23 as noted above.

More

6. Relevant Tests/Laboratory Data, Including Dates

Laboratory data will be conducted this Monday, November 1.

More

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

None. Healthy pregnancy. Baby born full term weighing 8.5 lbs.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets — 2-3 Tablets under tongue 4xs/day — Hyland's Inc
#2

2.	Dose or Amount	Frequency	Route
#1	2-4 Tablets	BID	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/01/2010 -- 10/01/2010 — Almost Daily
#2 --

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething Pain/Discomfort
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109024	#1	5497375041
#2	#2	

E. SUSPECT MEDICAL DEVICE

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

OTC

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4. Model # ____ Lot ____
Catalog # ____ Expiration Date *(mm/dd/yyyy)* ____
Serial # ____ Other # ____

5. Operator of Device
☐ Health Professional
☑ Lay User/Patient
☐ Other: ____

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
NOV 01 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Other Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7675902

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

Individual Safety Report

7078569-0-00-01

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

Internet Submission - Page 1

CDER

Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 434153

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 6 Months	☐ Female ☑ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/18/2010	10/29/2010

5. Describe Event, Problem or Product Use Error

severe constipation

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MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets 3X HPUS Hyland's
#2

2. Dose or Amount	Frequency	Route
#1 2 tablets	2-5/day	po
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/15/2010 -- 10/28/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething child
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109519	#1
#2	#2

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

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
NOV 01 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7078544-6-00-01

CDER

CaseID: 7676016

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

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The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1/2

FDA USE ONLY

Triage unit sequence # 434170

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	9 Months	☑ Female ☐ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - Initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/28/2010	10/29/2010

5. Describe Event, Problem or Product Use Error

I gave my child Hylands Teething Tablets: - 2 pills at 5:30pm on 10/27/2010 She woke up with a fever and was very agitated I gave her: - 3 pills at 7:30am on 10/28/2010 She was very drowsy and would not eat rice cereal. I took her to our pediatrician and she had a 100.1 temperature and a red throat. We thought she had a cold in addition to her teething. She woke up without a fever on 10/29/2010 and seems back to her normal self.

More

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

NO preexisting conditions. I did give her the Hylands Teething Tabs without incident on the following dates: 10/19/2010: 2 tabs 10/20/2010: 2

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Tablets Homeopathic Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	3 to 4/day	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 10/19/2010 -- 10/22/2010
#2 10/27/2010 -- 10/28/2010

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☑ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109834	#1
#2	#2

9. NDC # or Unique ID
109834

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

NOV 01 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

B7. Other relevant history, including preexisting medical conditions continued

tabs 2am, 2 tabs 6:30am, 2 tabs 12noon, 3 tabs 5:30pm 10/21/2010: 2 tabs 8:30am, 2 tabs 1pm, 2 tabs 6pm 10/22/2010: 2 tabs 9am, 2 tabs 2:30pm

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NOV 01 2010

CaseID: 7677527

Individual Safety Report

7078515-X-00-01

Adverse Event Reporting Program

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TARY reporting of
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DQRS

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

FDA USE ONLY
Triage unit sequence # 434073

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Daughter In confidence	(b) (6) 2 Years	☑ Female ☐ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/21/2009	10/30/2010

5. Describe Event, Problem or Product Use Error

I had using this product Hyland's Teething Tablets, 125 Tablets UPC# 3 54973 75041 on my daughter since she was 6 months when she first started teething. I thought it was a real good medicine a lot of people had recommended it so I decided to get it. It work real good but then my daughter started having seizures and we are still no able to find out the problem so I'm just wondering if maybe this medicine is what was causing her to have them. I had heard the recall Wednesday which was 10/27/10. The last time I had gave my daughter this medicine was two weeks ago around 10/12/10 thru 10/17/10 the last seizure she has had was 10/20/10. Since I

More

6. Relevant Tests/Laboratory Data, Including Dates

I can get records from her doctor if you need them. I even have her on video having a seizure.

More

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

Seizures

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C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland's Teething Tablets 125 Tablets — Hyland's Inc. Los Angeles, CA
   #2

2. Dose or Amount	Frequency	Route
#1 3 Tablets	2 times a day	
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 01/01/2009 -- 10/17/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 Walmart	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's
2. Common Device Name: Teething Tablets
3. Manufacturer Name, City and State: Hyland's Inc., Los Angeles, CA

OTC

4. Model #	Lot # Walmart	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

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

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

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

haven't gave her the medicine she hasn't had a seizure. I had called her doctor that she sees for her seizures and they told me that their not going to do anything until her next appt. but that is 3 months away from now. How are they going to find anything then if it is going to be out of her system by then. Is there are any that you can escalate this problem so I can figure out if this medicine was the cause of my baby's seizures. Please help asap. Thank you

DSS

NOV 01 2010

CDER

CaseID: 7679619

U.S. Department of Health and Human Services

Individual Safety Report

7083692-0-00-01

Adverse Event Reporting Program

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ission - Page 1

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

FDA USE ONLY
Triage unit sequence # 434465

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	1 Years	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
09/02/2010	11/02/2010

5. Describe Event, Problem or Product Use Error

Child was crying and uncomfortable and given then Hyland Teething Tablets as well as acetaminophen in the morning. She exhibited lethargy, rapid breathing and increased heart rate and was taking to the emergency room where she stayed for monitoring for several hours. She has several nebulizer treatments, chest X-ray, and other tests to rule out other difficulties. She had not exhibited difficulties prior to this event or had any difficulty breathing. She was using accessory muscles in her stomach to breathe and breathing seemed to take a lot of effort for her. Nebulizer treatments continued for several days after afterwards.

More

6. Relevant Tests/Laboratory Data, Including Dates

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NOV 08 2010
MEDWATCH CTU

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Hyland's Teething Tablets — Hyland's
#2

2. Dose or Amount	Frequency	Route
#1 3 tablets		po
#2		

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

4. Diagnosis or Reason for Use (Indication)
#1 teething pain
#2

6. Lot #	7. Expiration Date
#1 108018	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

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

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS

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More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Other Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

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Individual Safety Report

7091415-4-00-01

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CaseID: 7682004

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

The ... Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1 of 2

FDA USE ONLY
Triage unit sequence # 434777

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified	(b) (6)	☐ Female	21 lb
In confidence	5 Months	☑ Male	or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/10/2010	11/04/2010

5. Describe Event, Problem or Product Use Error

On (b) (6) my son of six months had 10 episodes in a total of five minutes. Each lasted from 3-5 seconds long. These episodes were determined to be some kind of seizures. Immediately after they happened, we took my son to the emergency room where they performed a cat scan, blood tests, and urine tests. The only abnormality they found was a slight increased level of an enzyme in the blood that is released when the muscles have become very tense. The doctors in the er couldn't figure out what caused the seizures so we meet with a pediatric neurologist and had 2 eegs done. The first came out very abnormal , but only when they flashed

More

6. Relevant Tests/Laboratory Data, Including Dates

He had his first EEG on the 13th of October. His second was on the 20th of October. The first showed abnormal spikes whenever the lights where flashed. There was a very distinct pattern. The second showed only a few abnormal spikes when the lights where flashed. There was no distinct pattern.

More

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

N/A

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NOV 05 2010

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Homeopathic N/A Hylands Teething Tablets

#2

2.	Dose or Amount	Frequency	Route
#1	2	every 4 hours	po
#2			

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

#1 08/23/2010 -- 10/04/2010

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Teething discomfort

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

7. Expiration Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands Homeopathic Teething Tablets

2. Common Device Name

3. Manufacturer Name, City and State
Hyland's, Inc. Los Angeles, CA 90061

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS
NOV 05 2010

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

B5. Describe event or problem continued

the lights. The second showed only a few abnormalties. We are scheduled for an mri because the tests where inconclusive, and we still haven't figured out what caused the seizures. We did recently hear of the Hylands teething tablets recall. Our bottle is on the recall list. My son first took these tablets on August 23, 2010. We gave them to him as needed until early October. Whenever we gave them to him, we gave him to tablets every four hours. We are not sure if the tablets are what caused the episodes, but we were told to report it anyways. We have not noticed any damage caused by the seizures, and he has not had the tablets since early October. I didn't mention the tablets to the doctor at the time because I was not aware of any adverse effects. The seizures were also a singular event, and we have not noticed anything related to them since that day. They can be described as a tightening of his whole body, with an arching of the back. His jaw clenched the right side and he seemed to be in a trance. After a couple seconds he would go back to normal, and then it would happen again. After it happened about ten times in a five minute time span, he just stared in the distance and would not respond to me. That lasted about thirty seconds. After all of this, he was acting the same as always.

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NOV 05 2010
MEDWATCH CTU

Individual Safety Report

7090121-X-00-01

CaseID: 7682299

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

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1 of 1

Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 434770

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 14 Months	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/01/2010	11/03/2010

5. Describe Event, Problem or Product Use Error

In (b) (6) my daughter had a seizure, lost consiousness & stopped breathing about 30 after I gave her 3 Hyland's Teething Tablets. She had to receive mouth-to-mouth CPR to resume breathing & was Brought to the hospital.

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NOV 05 2010
MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

Blood toxicology test.

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Teething Tablets Homeopathic Hyland's
   #2

2. Dose or Amount	Frequency	Route
#1 3 tablets	Every 6 Hours	po
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 05/01/2010 -- 09/30/2010
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 To relieve teething pains & calm baby.
   #2

6. Lot #	7. Expiration Date
#1 109178	#1 01/01/2012
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☑ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's
2. Common Device Name: Teething Tablets
3. Manufacturer Name, City and State: Hyland's, Inc. Los Angeles, 9[illegible]

OTC

4. Model #	Lot # 109178	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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NOV 05 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Other Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

U.S. Department of Health ... | CDER | CaseID: 7682451

Individual Safety Report

7091480-4-00-01

Adverse Event Reporting Program

CDER
UNTARY reporting of
nts, product problems and
oduct use errors

Internet Submission - Page 1/1

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

FDA USE ONLY
Triage unit sequence # 434810

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	____ lb or 8 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/04/2010	11/04/2010

5. Describe Event, Problem or Product Use Error

On 11-04-2010 my daughter suffered severe symptoms of seizures, lethargy,pale skin, cahnge in muscle tone and behavior. I was called by the school nurse and immediatley went to pick her up. I have been using Hyland's teething tablets and teething get over the last two months.

More

6. Relevant Tests/Laboratory Data, Including Dates

none yet

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MEDWATCH CTU

More

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

born with cerbal palsy

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1	Teething Gel	6x HPUS	Hyland's
#2	Teething tablets	3x HPUS	Hyland's

2.	Dose or Amount	Frequency	Route
#1	1 squeeze	3-4x a day	po
#2	4 tablets	3-4x a day	po

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

#1	10/29/2010	1week	11/04/2010
#2	08/28/2010	2 months	10/29/2010

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2 teething

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date
#1 n/a	#1
#2 n/a	#2

9. NDC # or Unique ID
54973-7521-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's
2. Common Device Name: Teething tablets/ gel
3. Manufacturer Name, City and State: Hyland's, INC Los Angelos, CA 90061 -800--624-9659

4. Model #	Lot #	5. Operator of Device
none present	none present	☐ Health Professional
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Lay User/Patient
none present		☑ Other: mother gave
Serial #	Other #	
none present	n/a	

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer
		☐ User Facility
		☐ Distributor/Importer

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

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

U.S. Department of Health and Human Services

Individual Safety Report

7090152-X-00-01

Adverse Event Reporting Program

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

Page 1 of 1

CaseID: 7684270

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

FDA USE ONLY
Triage unit sequence # 434733

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☒ Female ☐ Male	21 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)* ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/22/2010	10/26/2010

5. Describe Event, Problem or Product Use Error

My child had lethargy and excessive sleepiness due to taking the tablets

6. Relevant Tests/Laboratory Data, Including Dates

N/A

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

N/A

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MEDWATCH CTU

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☒ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

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

(1)

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	every 4hrs	047
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 8/2010
#2 10/24/2010

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain
#2

6. Lot #	7. Expiration Date
#1 108713.	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☒ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

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NOV 05 2010

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☒ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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Individual Safety Report

7094087-8-00-01

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Th... Adverse Event Reporting Program

...on - Page 1/1

CaseID: 7686705

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

FDA USE ONLY
Triage unit sequence # 43 49/8

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/07/2010	11/06/2010

5. Describe Event, Problem or Product Use Error

Fever, seizure, respirtory failure, and hospitalized for two days.

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More

6. Relevant Tests/Laboratory Data, Including Dates

many blood tests and x-rays

More

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

n/a

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething homeopathic Hyland Tablets
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	4 times a day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/15/2010 -- 11/05/2010
#2 --

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108867	#1	54973-7504-2
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland' teething tablets

2. Common Device Name
teething tablets

3. Manufacturer Name, City and State
P&S Laboratories Los Angeles, CA 90061

4. Model #	Lot # 108867	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of ...)*

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

U.S. Department of Health and Human Services

Individual Safety Report

7092689-6-00-01

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...n - Page 1/1

CaseID: 7686853

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

FDA USE ONLY
Triage unit sequence # 4348 91

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 6 Months	☐ Female ☑ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/04/2010	11/07/2010

5. Describe Event, Problem or Product Use Error

My son has used hylands teething tablets between the ages 3-6 months old. He has always been excessivley sleepy afterwards. He also has had spells of lethargy. I thought this to be normal because on the bottle it stated that the child may fall asleep afterward due to the relief of symptoms. However, since around 10/15/2010 he has had an increase in these symptoms. He also has had constipation and a significant decrease in urination since about 10/30/2010. I will be taking him to his pediatrition ASAP.

More

6. Relevant Tests/Laboratory Data, Including Dates

I will report these as soon as I recieve them.

More

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

CHILD HAD NO PRIOR CONDITIONS.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets — Hyland's Homeopathic
#2

2.	Dose or Amount	Frequency	Route
#1	2-3	few times daily	po
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 08/04/2010 -- 11/06/2010
#2 --

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☑ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething Symptoms
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☑ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 109665	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Homeopathic
2. Common Device Name: Teething Tablet's
3. Manufacturer Name, City and State: Los Angeles, CA

4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #

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MEDWATCH CTU

5. Operator of Device
☐ Health Professional
☐ Lay User/Patient
☑ Other: Mother

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

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NOV 08 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

U.S.

Individual Safety Report

7095154-5-00-01

The FDA Safety Information and Adverse Event Reporting Program

ARY reporting of oduct problems and use errors

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CaseID: 7688673

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

FDA USE ONLY
Triage unit sequence # 434934

Internet Submission - Page 1 of 2

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☑ Female ☐ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/27/2010	11/05/2010

5. Describe Event, Problem or Product Use Error

My daughter is 5 months old and teething. I gave her Hylands teething tablets starting on the 20th of October. The 23 she started having seizures. They would be every two minutes sometimes and she would become very out of it. She quit playing and giggling and rolling over. I took her to the doctor right away of course and stopped giving her any kind of meds. The teething tablets were recalled due to high amounts of belladonna. Belladonna causes seizures and my doctor and I both believe this is what was wrong with my daughter. As soon as I quit giving them to her they have stopped. She is back to being her happy self as far as i can tell. the

More

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

Only concern I have ever had with her were when I took her to the doctor for this on oct 27th.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets 145 tabs Hyland's
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tabs	once or twice a da	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/23/2010 10 to 15 seconds long 10/27/2010
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

Hyland's teething tablets

DSS
NOV 09 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7095154-5-00-02

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...professionals of adverse events and product problems

B5. Describe event or problem continued

NCD is 54973-7512-1

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

CaseID: 7691191

Individual Safety Report

7107418-7-00-01

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

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Adverse Event Reporting Program

Internet Submission - Page 1 /2

FDA USE ONLY
Triage unit sequence # 435287

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	3 Months	☑ Female ☐ Male	14 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)* ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	11/10/2010

5. Describe Event, Problem or Product Use Error

The Hyland's Teething Tablets were given to us as a baby shower gift in June 2010. We started using them on our 3 month old daughter about two weeks ago because we wanted to relieve her teething pain. We have only ever given her 1 tablet per 24 hours. After the first tablet, we noticed that she fell asleep immideately. The box containing the product says "Please note: If your baby has been crying or very upset, your baby may fall asleep after using this product because the pain has been relieved and your child can rest." So naturally I assumed she fell asleep because she was tired from the pain. After using the product for two weeks and

More

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6. Relevant Tests/Laboratory Data, Including Dates

More

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

My daughter has no known allregies or medical conditions.

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets unknown Hyland's Homeopathic
#2

2.	Dose or Amount	Frequency	Route
#1	1 Tablet	24 hrs	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/25/2010 -- 11/09/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Baby Teething Pain
#2

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

6. Lot #
#1 5497375041
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment...*

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NOV 12 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

noticing that she is lathargic and sleeps for an unusual length of time afterward, I started Googleing the product and discovered it was recalled. I have tried calling the 1800 number on the product box and have not been sucessful in contacting the company.The automated answering system ran me around in circles and I got nowhere.

DSS

NOV 12 2010

CaseID: 7698915

Individual Safety Report

7109653-0-00-01

NTARY reporting of s, product problems and duct use errors

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OTC

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

FDA USE ONLY

Triage unit sequence # 435392

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 7 Months	☐ Female ☑ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/05/2010	11/11/2010

5. Describe Event, Problem or Product Use Error

Due to the frequent use of you Hyland's teething tablets my child has started experiencing seizures, difficultly breathing,lethargy,excessive sleepiness, muscle weakness,and agiation. He has been hospitalized several times since the use of your product. He has to stay on an sleep apnea machine and be on two different medications twice a day. We did not know they were what was causing them so we continued to give them to him until they were recalled. Then we came to find out the reason for his medical status was due to the belladonna posioning.

More

6. Relevant Tests/Laboratory Data, Including Dates

Blood work (b) (6) Blood work (b) (6)
EEG (b) (6) Blood work (b) (6) X-ray
(b) (6) additional test information avaliable in charts.

More

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

none

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hyland's teething tablets — Hyland's

#2

2.	Dose or Amount	Frequency	Route
#1	3 tablets	4 times daily	
#2			

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

#1 07/26/2010 -- 10/28/2010

#2 --

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

#1 teething

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 104990	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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4. Model # Lot # 2010
Catalog # Expiration Date *(mm/dd/yyyy)*
Serial # Other #

MEDWATCH CTU

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

NOV 15 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Physician Assistant	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7110200-8-00-01

CaseID: 7699366

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

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FDA USE ONLY
Triage unit sequence # 435573

The FDA Safety Information ...
Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 2 Months	☑ Female ☐ Male	6 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/01/2010	11/12/2010

5. Describe Event, Problem or Product Use Error

Infant began using Hylands teething tablets a few months ago, and shortly after had constipation lasting 5-7 days. This is a healthy breastfed infant with no history of constipation prior to using teething tablets.

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MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Belladonna Hylands Tablets
#2

2.	Dose or Amount	Frequency	Route
#1	2-4	4 times day	sl
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/30/2010 -- 11/06/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 109665
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
NOV 16 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

7115576-3-00-01

Adverse Event Reporting Program

...NTARY reporting of ...s, product problems and ...duct use errors

Page 1 of 1

OTC

FDA USE ONLY

...iage unit ...equence # 435840

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☐ Female ☑ Male	20 lb or ___ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/30/2010	11/07/2010

5. Describe Event, Problem or Product Use Error

My son had a seizure, fell, and had a subdural hematoma. He had another seizure on arrival at the hospital. He was hospitalized for 4 days for observation and tests. We were using the teehting tablets at the time.

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MEDWATCH CTU

6. Relevant Tests/Laboratory Data, Including Dates

All labs were normal. MRI and CT showed right subdural hematoma.

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

No history. He is currently on anti-seizure medication and is followed by a neurologist.

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ___ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Hylands teething tablets
Strength: varies
Manufacturer: Hylands

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	every 4 hours	sublingual
#2		

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

#1 January 2010-July 2010

#2

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

#1 teethiing

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 54973-7504-1	#1	5497375041
#2 54973-7504-1	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

DSS

NOV 17 2010

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse Practitioner	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

PLEASE TYPE OR USE BLACK INK

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

CaseID: 7706830

OTC

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

Individual Safety Report

7117928-4-00-01

Adverse Event Reporting Program

...NTARY reporting of ..., product problems and ...luct use errors

...ssion - Page 1 / 1

FDA USE ONLY

Triage unit sequence # 435960

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6)	☑ Female ☐ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
	11/16/2010

5. Describe Event, Problem or Product Use Error

I have been giving my child Hyland's Homeopathic teething tablets since she was about 9 months old. She is now 23 months old. She has had problems with her stomach, mainly constipation, nearly the entire length of her short life. I believe that these so called homeopathic teething tablets were the cause of her numerous trips to the doctor's office and emergency room. Something should really be done about this. I mean they are administering a deadly chemical to BABIES and there's not a lawsuit or anything. Is the Company restricted from prodeucing more of the tablets? Why can I stil find these tablets at my local drug store?

More

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NOV 18 2010
MEDWATCH CTU

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hyland's Teething Homeopathic Tablets — Hyland's, Inc

#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4x daily -	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 09/01/2009 -- 10/24/2010	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 for relief from teething in children	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

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

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

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

DSS
NOV 18 2010

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Administrator	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

7118220-4-00-01

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

CDER

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

Internet Submission - Page 1 / 1

OTC

CaseID: 7707066

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

FDA USE ONLY

Triage unit sequence # 436071

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)* ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/17/2010	11/17/2010

5. Describe Event, Problem or Product Use Error

I have been using hylands teething tablets since my daughter started teething at 3 months. After her first 4 teeth came in I did not need to use it any more. She has had problems with constipation since she has been using them. I've had to give her suppositories on a regular basis. I did not make the connection until I needed to give them again. Her constipation immediately returned. When she is constipated she needs help passing a bowel movement due to the diameter of the stool. She also was having a lot of abdominal discomfort and was difficult to sooth because of this issue.

More

6. Relevant Tests/Laboratory Data, Including Dates

We have discussed constipation with our doctor at almost every well baby visit. We also had an additional visit just about constipation.

More

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

No other health problems.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hylands teething tablets — Hylands Inc

#2

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	4 times a day	po
#2		

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

#1 06/01/2010 -- 11/17/2010

#2 --

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

#1 Teething

#2

6. Lot #	7. Expiration Date
#1 109178	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

None

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

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4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7707821

Individual Safety Report

7117856-4-00-01

Adverse Event Reporting Program

UNTARY reporting of
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roduct use errors
mission - Page 1 of 1

OTC

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

FDA USE ONLY

Triage unit sequence # 435927

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
baby In confidence	(b) (6) 7 Months	☑ Female ☐ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/01/2010	11/16/2010

5. Describe Event, Problem or Product Use Error

Due to the Hyland's teething tablets, our little baby became severely constipated. We saw that it was recalled and stopped giving it to her. Since then, she is no longer constipated.

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MEDWATCH CTU

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

n/a

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 hyland's teething tablets
#2

2. Dose or Amount	Frequency	Route
#1 1 to 3	3x per day	Dental
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/01/2010 – 11/01/2010
#2 – –

4. Diagnosis or Reason for Use *(Indication)*
#1 teething pain
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
hyland's teething tablets

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7723951

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

Individual Safety Report

7125017-8-00-01

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...Submission - Page 1

Adverse Event Reporting Program

D4RS

FDA USE ONLY
Triage unit sequence # 436479

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/19/2010	11/22/2010

5. Describe Event, Problem or Product Use Error

(b) (6) was taking Teething Tablets made my Hyland for the last month and a half. She started taking them at the end of September. We continued to give them to her. She started acting really Funny, not her normal self, Started getting really agitated she didnt want nothing touching her. She started getting Dry skin around her face and started flushing of the skin. Then around (b) (6) she had a seizure. She has not yet been tested for sure, But they doctors think that is what she had. She Continued to take the tablets as needed. When her teeth would bother her. Well last week 11/17/2010 i found out there was a recall to the medication. I then

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

(b) (6) was diagnoised with septo -optic dysplasia when born (b) (6)

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets 00.00mg hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 Tablets	every hour	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/19/2010 -- 11/17/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 3 54973 75041	#1
#2	#2

9. NDC # or Unique ID
3 54973 75041

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands

2. Common Device Name
Teething Tablets

3. Manufacturer Name, City and State
Hylands, Los Angeles, CA

4. Model #	Lot # 5497375041	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

3 2010

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7723951

436479

B5. Describe event or problem continued

Stopped giving them to her all together Found out meds had belladonna in them. After, stopping tablets she then got a little cold. Well i told my husband to take her to the doctor today 11/25/2010 while i was at work. He called me and let me know she had to get blood work done because her liver was swollen. We are still waiting for the results of the blood test. But, I just wanted to warn everyone if this is the case. That her liver is swollen.

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NOV 23 2010

Individual Safety Report

7124959-7-00-01

Adverse Event Reporting Program

CBER-012 CaseID: 7733265

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

ITARY reporting of product problems and ict use errors

ission - Page 1 / 3

FDA USE ONLY
Triage unit sequence # 436577

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 7 Months	☑ Female ☐ Male	lb or 8.5 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/17/2010	11/22/2010

5. **Describe Event, Problem or Product Use Error**

On the morning of (b) (6) (b) (6) my seven-month old daughter (b) (6) -DOB (b) (6) was crying and fussy due to teething pains. My wife, (b) (6) gave (b) (6) two Hyland™s Teething Tablets. Thereafter, my wife laid (b) (6) on the bed, and (b) (6) stopped crying and became extremely calm. My wife noticed her eyes slowly tracking back and forth across the room and then rolling back into her head. Once her eyes rolled back into her head, (b) (6) began convulsing. At this point my wife picked up (b) (6) and she fell unconscious and stopped breathing. My wife

More

6. **Relevant Tests/Laboratory Data, Including Dates**

On (b) (6) (b) (6) we rushed (b) (6) to the Emergency Room at (b) (6) Children™s Hospital in (b) (6) The Children™s Hospital immediately began testing (b) (6) in an attempt to determine the cause of seizure. We spent two days (b) (6) and (b) (6) in the

More

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

(b) (6) has not preexisting medical conditions and is a perfectly healthy seven month old girl.

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*

#1 Hylands Teething Tablets | Hylands Teething Tablets | Hylands Teething Tablets

#2

2. Dose or Amount	Frequency	Route
#1 2 Tablets	when teething	po
#2		

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

#1 08/01/2010 -- 11/17/2010

#2 --

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

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

#1 Used for infant's teething pain

#2

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 UPC 54973-7504	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. **Brand Name** Hyland's Teething Tablets
2. **Common Device Name** Teething Tablets
3. **Manufacturer Name, City and State** Hyland Inc.

4. Model #	Lot #	5. Operator of Device
UPC 54973-7504-1	UPC 54973-7504-1	☐ Health Professional ☐ Lay User/Patient ☑ Other: Mother to
Catalog #	**Expiration Date** *(mm/dd/yyyy)*	
Serial #	**Other #**	

6. **If Implanted, Give Date** *(mm/dd/yyyy)*
7. **If Explanted, Give Date** *(mm/dd/yyyy)*
8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?** ☐ Yes ☐ No
9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

None

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NOV 23 2010

More

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

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

Phone # (b) (6) **E-mail** (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Lawyer	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

B5. Describe event or problem continued

assumed she was choking and performed infant choking rescue procedure on her, but she was still unconscious. (b) (6) was still not breathing at this point and her face had turned blue. My wife was unable to resuscitate her for a period of around two minutes, while on the phone with the 911 operators. About two minutes after the convulsion and seizure started, (b) (6) regained consciousness and started breathing again. The paramedics arrived shortly after (b) (6) regained consciousness. We rushed (b) (6) to the Emergency Room at (b) (6) Children™s Hospital in (b) (6) The Children™s Hospital immediately began testing (b) (6) in an attempt to determine the cause of seizure. We spent two days in the hospital and (b) (6) underwent a Computer Tomography Scan, an electroencephalography -EEG-, an electrocardiography -fiEKGfl-, and other tests to determine the cause of the seizure. All of the test results indicated that (b) (6) was perfectly healthy. Additionally, it was determined that (b) (6) did not have a high temperature or fever at the time of the episode. In the second day at the hospital my wife learned that the Hyland™s Teething Tablets had been recalled on October 25, 2010. The UPC code of the bottle from which (b) (6) received tablets, UPC 54973-7504-1, matched the UPC code list provided by the Hyland recall notice. We informed the pediatric physician for (b) (6) Dr. (b) (6) of the recall on the teething tablets on the second day in the hospital. Dr. (b) (6) stated that she was fairly confident teething tablets were the cause of (b) (6) episode and release (b) (6) from the hospital.

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NOV 23 2010

B6. Relevant tests/laboratory data, including dates continued

hospital and (b) (6) underwent a Computer Tomography Scan, an electroencephalography -EEG-, an electrocardiography -fiEKGfl-, and other tests to determine the cause of the seizure. All of the test results indicated that (b) (6) was perfectly healthy. Additionally, it was determined that (b) (6) did not have a high temperature or fever at the time of the episode.

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NOV 23 2010

(b) (6)

CaseID: 7733404

Individual Safety Report

Adverse Event Reporting Program

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

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

FDA USE ONLY

Triage unit sequence # 436975

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 6 Months	☑ Female ☐ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☑ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/26/2010	11/26/2010

5. Describe Event, Problem or Product Use Error

My daughter suffered a seizure while using this product. She was immediatly taken to the emergency room and many tests were conducted. All the testing showed no seizure disorder or any brain abnormalities. Since the discontinued use of this product she never had another seizure.

More

6. Relevant Tests/Laboratory Data, Including Dates

All tests were performed on (b) (6) x-ray, cat scan, blood work, physical exam, catherized urinalisis

More

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

none

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Hylands teething tablets none Hylands

#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4 times daily	po
#2			

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

#1 03/01/2010 -- 05/26/2010

#2 --

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

#1 teething

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

7. Expiration Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

108198

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
NOV 30 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

CaseID: 7739553

U.S. Department of Health and Human Services

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

Individual Safety Report

UNTARY reporting of
nts, product problems and
oduct use errors
ission - Page 1 of 2

FDA USE ONLY
Triage unit sequence # 436998

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/31/2010	11/29/2010

5. Describe Event, Problem or Product Use Error

On 8/25/10, I bought a new bottle of Hyland's teething tablets, that is part of the recent recall, Hyland™s Teething Tablets, 125 tablets, UPC # 3 54973 75041. I normally would only give my daughter 3 tablets in the evening before bed, but the week of 8/29/10-9/3/10, I gave her 3 tablets during the day and 3 at night. She was teething really badly that week. My daughter woke up with bruises she gave herself in the middle of the night the morning of 9/1/10 and the morning of 9/2/10, the morning of 9/3/10, I saw her sleep walking/running in her crib in a sleep state as she did not notice me come in the room. She stopped at the end of the

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets 125 ct UPC # 3 54973 75041
#2

2.	Dose or Amount	Frequency	Route
#1	6 tablets per day		
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 01/01/2010 -- 09/03/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

6. Lot #	7. Expiration Date
#1	#1
#2	#2

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets
2. Common Device Name: Teething tablets
3. Manufacturer Name, City and State: Hyland's Teething Tablets,

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other # UPC # 3 54973 75041	☐ Other:

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 779553

B5. Describe event or problem continued

crib and banged her slightly open mouth on the side of the crib before I could stop her. Her face was badly bruised from these nights. I have seen her have two petit mal seizures -On 11/4/10 and 11/20/10-, I am not aware if she had any from 9/3/10-11/4/10, but she is having an EEG test done on 12/2/10. I am very concerned about the inconsistant levels of belladonna in these bottles and I would like the FDA to test this bottle for it's specific level of belladonna.

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NOV 30 2010

CaseID: 7739701

Form Approved: OMB No. 09 10-029 1, Expires12/31/11
See OMB statement on reverse.

Individual Safety Report

7156366-5-00-01

FORM FDA 3500A (1/09)

by user-facilities,
outors and manufacturers
)ATORY reporting

Mfr Report # 2280705-2010-00016

UF/Importer Report #

OTC

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)
In confidence

2. Age at Time of Event: 19 Months
or
Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

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

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy)
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 11/15/10

4. Date of This Report (mm/dd/yyyy): 11/22/10

5. Describe Event or Problem

Consumer's pediatrician reported the following as conveyed by mother:
Within a few minutes of oral application by mother to the child's mouth, the child reportedly had a single seizure, lasting approximately two minutes. The child was taken to the hospital. Upon examination by hospital staff, no specific findings were evident; no therapy was administered. The pediatrician believes the adverse event was related to the use of a teething product; however she did not have the actual product that was used and referred to the product as "Baby Orajel".

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CDR

6. Relevant Tests/Laboratory Data, Including Dates

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

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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 Baby Orajel® Teething Pain Medicine oral pain
#2 (continued) reliever for teething

2. Dose, Frequency & Route Used
#1 Oral application
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 11/15/10
#2

4. Diagnosis for Use (Indication)
#1 UNK
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 UNK
#2

7. Exp. Date
#1 UNK
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
NDC# 10237-713-33

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

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Other #

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

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

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

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

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10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

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

DSS

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

NOV 30 2010

2. Health Professional? ☑ Yes ☐ No

3. Occupation: Physician

4. Also Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

CaseID: 7739701

Individual Safety Report

MED FORM 7156366-5-00-02

FDA USE ONLY

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

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual): Patient Code ___ - ___ - ___ ; Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

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

Jill D. Ferentz
Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

2. Phone Number: 609-497-7139

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

4. Date Received by Manufacturer (mm/dd/yyyy): 11/17/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

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

8. Adverse Event Term(s)

9. Manufacturer Report Number: 2280705-2010-00016

H. DEVICE MANUFACTURERS ONLY

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

Report made by third-party physician. Actual consumer unknown.

The consumer has not returned the unused portion of the product. Since the exact Baby ORAJEL® product has not been identified, this report was prepared using Baby Orajel® Teething Pain Medicine oral pain reliever for teething as the most likely used product under the brand family of products.

Baby Orajel® Teething Pain Medicine oral pain reliever for teething labels are attached.

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

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DEC 01 2010

NOV 30 2010

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 (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

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

CHERRY FLAVORED GEL

NEW & IMPROVED!

INSTANT TEETHING PAIN RELIEF

#1 Teething Brand Used By Pediatricians

Baby Orajel BENZOCAINE / 5

TEETHING PAIN MEDICINE

SAFETY SEALED TUBE TIP

Baby Orajel BENZOCAINE / 5

TEETHING PAIN MEDICINE

Baby Orajel TEETHING PAIN MEDICINE

ORAL PAIN RELIEVER FOR TEETHING

NET WT 0.33 OZ (9.4g) GEL

3 10310 03313 2

Church & Dwight Co., Inc.
Princeton, NJ 08543
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BOJFC-03313-02 7000782

NO INK NO VARNISH

NO INK NO VARNISH

Drug Facts

Active Ingredient — **Purpose**

Benzocaine 7.5% ..... Oral pain reliever

Use for the temporary relief of sore gums due to teething in infants and children 4 months of age and older

Warnings

Allergy alert: do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless told to do so by a dentist or doctor

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

Stop use and ask a dentist or doctor if ■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ use your fingertip or cotton applicator to apply a small pea-size amount of Baby Orajel ■ apply to the affected area up to four times daily or as directed by a dentist or doctor ■ for infants under 4 months of age, ask a dentist or doctor

Other information do not use if tube tip is cut prior to opening

Inactive Ingredients ammonium glycyrrhizate, FD&C red no. 40, flavor, glycerin, polyethylene glycol, purified water, sodium saccharin, sorbic acid, sorbitol

Questions or comments? call us at 1-800-852-5080 M-F 9am-5pm ET or visit our website at www.arahel.com

Baby Orajel

To clean your baby's new teeth, try BABY ORAJEL TOOTH & GUM CLEANSER

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30 2010

Individual Safety Report
7156366-5-00-03

CIRCUMFERENCE 1-63/64

OPEN END

1/4

NO PRINT AREA

1/4

EYE CLEARANCE

1/16" QUIET AREA

5/8" X 3-3/8"

1/32" QUIET AREA

Church & Dwight Co., Inc., Princeton, NJ 08543
© Church & Dwight Co., Inc.

OJTU-03313-01 7000615

IMMEDIATELY RELIEVES TEETHING PAIN

CHERRY FLAVORED

Baby Orajel TEETHING PAIN MEDICINE

Oral Pain Reliever For Teething

Benzocaine 7.5%

NET WT 0.33 OZ (9.4 g)

Active ingredient Benzocaine 7.5%

Use temporarily relieves sore gums due to teething in infants and children 4 months of age and older

Warnings **Allergy alert:** do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless told to do so by a dentist or doctor

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

Stop use and ask a dentist or doctor if ■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ use your fingertip or cotton applicator to apply a small pea-size amount of Baby Orajel ■ apply to the affected area up to four times daily or as directed by a dentist or doctor ■ for infants under 4 months of age, ask a dentist or doctor

Other information do not use if tube tip is cut prior to opening

1/32" QUIET AREA

PRINT HEIGHT 2-5/8

TUBE LENGTH 3-3/8

3/16

NO PRINT AREA

3/16

CAP END

FRONT PANEL C/L

BACK PANEL C/L

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DEC 01 2010

Individual Safety Report

7156366-5-00-04

NOV 30 2010

CaseID: 1743142

Individual Safety Report

7141282-5-00-01

Adverse Event Reporting Program

TARY reporting of product problems and ict use errors

ion - Page 1 of 4

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

FDA USE ONLY
Triage unit
sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 14 Months	☑ Female ☐ Male	18.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
02/15/2010	12/02/2010

5. Describe Event, Problem or Product Use Error

When my daughter first was given the Hyland's teething tablets, we were giving her 2-3 4 times a day, I have given them to her every time her teething has bothered her thinking everything would be okay. When we initially gave her these tablets, 2 days later she was having extreme dryness in her vaginal area and major trouble with urinating, she screamed every time she peed and gyrated that area all the time, major muscle weakness, very lethargic and weak. Some vision issues.She was having trouble trying to walk because her legs and arms would shake so bad, as well as never could crawl because her arms weren't strong enough. We stopped for

More

6. Relevant Tests/Laboratory Data, Including Dates

3 bladder infection tests for babies done since 2/15/2010, her last one was at her 6 month follow-up, so about March 2010, she as well has major agitation, as well as trouble urinating, which was for the need for the bladder tests, we thought maybe she had some type of bacterial issue as well. Also

More

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

She is an infant and only has acid reflux

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Hyland's Teething Tablets — Hyland's

#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4 times a day	po
#2			

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

#1 02/15/2010 -- 11/29/2010

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Teething

#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☑ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets

2. Common Device Name

3. Manufacturer Name, City and State: Hyland's Inc, Los Angeles, CA 90061

4. Model #	Lot # NDC 54973-7504-1	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient ☐ Other:

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

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

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

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

I do not remember the name, but the pediatrician said the effects she has had are not related to the acid reflux medicine. If you need the name you ca

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7141282-5-00-02

WATCH

rofessionals of adverse events and product problems
rnet Submission - Page 2

B5. Describe event or problem continued

awhile and all the symptoms went away, so I figured maybe it was just her being a baby, but recently in the last 3 months of reintroducing the teething tablets, it all came back and worse this time around. Since we have stopped the tablets from the recall, which I have reported all the events to my pediatrician and he said to stop it immediately and that there shouldn't be permanent side effects, she is now urinating wayyyyy more and normally, the dryness is subsiding and she is finally getting some moisture in the vaginal area, she isn't shaking anymore and her muscles are getting stronger. In 2 days of stopping the tablets, she is scooting way fast now and is now crawling, which she never could, she is getting up on her own and is almost walking by herself -steadily-! For her agitation, that is something that is going to take time the pediatrician said, but she isn't hitting and kicking me, acting out and snapping at everything as much as she was. She isn't really throwing anything now, just doing more normal baby dropping now thank goodness.

DSS

DEC 03 2010

B6. Relevant tests/laboratory data, including dates continued

was checked for lethargic issues and the weakness in her muscles, as she was having trouble trying to walk and crawl and scoot.

DSS

DEC 08 2010

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

F. Other (Concomitant) medical products continued

n call me and get it, I just don't have it handy right now. She has taken it since she was 8 months old.

DSS

DEC 03 2010

Individual Safety Report

7142309-7-00-01

CaseID: 7744127

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

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

FDA USE ONLY
Triage unit sequence # OTC 437531

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 4 Months	☐ Female ☑ Male	12 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/17/2010	12/02/2010

5. Describe Event, Problem or Product Use Error

we do not know for sure that the hyland teething tablets are the cause of my grandsons death i think it should be looked into! we have not recieved a cause of death yet.my daughter is 15.she does not know what to do about any of this he was given the tablets (b) (6) when she (b) (6) b) (6) (b) (6) he wasnt breathing; the local police the welfare-child abuse-have been involved because they investigate every childs death i have informed them and they have the tablets there was an autopsy i informed them about the recall!!!! we havent heard anything as of this time.

More

6. Relevant Tests/Laboratory Data, Including Dates

autopsy

More

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

he had a horseshoe shaped kidney and was born low birth weight 4.4lbs

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 hyland teething tablets
#2

2.	Dose or Amount	Frequency	Route
#1	1 or 2 tablets as needed		po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/13/2010 -- 10/16/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
hyland teething tablets

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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DEC 03 2010
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7750625

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

Individual Safety Report

7124602-7-00-01

Adverse Event Reporting Program

NTARY reporting of
s, product problems and
duct use errors
ssion - Page 1 /2

FDA USE ONLY
Triage unit sequence # 436400

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
9month infant In confidence	(b) (6) 9 Months	☑ Female ☐ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/18/2010	11/20/2010

5. Describe Event, Problem or Product Use Error

Was not aware of recall on the Hylands Teething Tablets -125 count- and had been giving to my 9 month old infant for approx. 3 days for teething symptoms. On the third day in the morning -after a good nights sleep- baby was lethargic and sleeping most of morning. Went online to see what could be causing this -thinking it was flu/or cold related- and came across the recall information. Called Poison Control who instructed me to take her to the pediatrician ASAP. Pediatrician confirmed Drug Toxicity. All symptoms included: eye dilation, decreased urinary output, lethargy, increased heart rate. Baby recovered from all symptoms withing

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablet -125 count bottle- Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets	4-6 hours	sl
#2			

3. Dates of Use *(If unknown, give duration)* from/to *(or best estimate)*
#1 11/15/2010 -- 11/18/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething Discomfort
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 All lot # reca
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
None

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

NOV 22 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

12 hours of last dose.

DSS

NOV 22 2010

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

CaseID: 7750696

Individual Safety Report

7152637-7-00-01

The FDA Safety Information and Adverse Event Reporting Program

LUNTARY reporting of ents, product problems and product use errors

bmission - Page 1 /1

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

FDA USE ONLY
Triage unit sequence # 437876

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 4 Months	☑ Female ☐ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/07/2010	12/07/2010

5. Describe Event, Problem or Product Use Error

I gave my daughter Hyland's teething tablets -less then the recommended dose- because she was starting to teeth. She had been crying for hours and I didn't want to give her any "real" medicine so I thought natural was best. Immediately after I gave them to her she started acting like she was drunk. After a few minutes of that, she just fell asleep. Just like that, just fell asleep. And FYI, she is one of those babies that must be rocked to sleep for at least 15 minutes before she will even try to go to sleep.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's teething tablets 100% natural Hyland
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	4 times a day	
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/07/2010 -- 12/07/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

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

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108134	#1
#2	#2

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's teething tablets

2. Common Device Name
teething tablets

3. Manufacturer Name, City and State
Hyland's Los Angeles, California

4. Model #	Lot # 108134	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
DEC 08 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

7167016-6-00-01

CaseID: 7754115

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Internet Submission - Page 1 of 2

FDA USE ONLY
Triage unit sequence # 438268

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	6 Months	☑ Female ☐ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
11/10/2010	12/11/2010

5. Describe Event, Problem or Product Use Error

My daughter started teething at 2 months old I began using Hylands homeopathic teething tablets when she turned 5 months old. She has suffered sever constipation, redness and flushing of her skin, constant agitation, and difficulty breathing since the start of the use of this product. I found out today December 11th 2010 that the FDA found these tablets dangerous and the company voluntarily recalled them. I have stopped use and will be taking my daughter to her Dr. to be evaluated. I also need to be sure that these symptoms have not caused permanent damage to her colon and that these symptoms will end with the discontinuation of the product.

More

6. Relevant Tests/Laboratory Data, Including Dates

I have not taken her to the DR. yet.

More

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

No preexisting conditions, healthy little girl before this product.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Highland's Homeopathic Tablets 3X of each TEETHING ingredient — P&S Laboratories
#2 — Highland's

2. Dose or Amount	Frequency	Route
#1 2-3 tablets	4 times per day	
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 11/08/2010 -- 12/11/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Pain and discomfort during teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109493	#1	54973-7504-2
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Highland's
2. Common Device Name: Homeopathic Teething Tablets
3. Manufacturer Name, City and State: P&S Laboratories Los Angeles, CA, 90061

4. Model #	Lot # 109493	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

Highland's Teething Tablets

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More

G. REPORTER *(See confidentiality section on back.)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

As a mother I am appalled by the companies lack of regulation of the use of Belladonna in this product. The syptoms my daughter has shown were linked by the FDA to the use of this product.

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DEC 13 2010

Individual Safety Report

7153530-6-00-01

CaseID: 7756415

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

...ARY reporting of ...roduct problems and ...t use errors ...on - Page 1/4

FDA USE ONLY
Triage unit sequence # 437977

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 6,7 Months	☐ Female ☑ Male	16 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/12/2010	12/08/2010

5. Describe Event, Problem or Product Use Error

we gave our son Hyland brand Teething Tablets for a period of 3 months starting early in october of 2010. Immediately we saw the negative side effects of unregulated amounts of 'Belladonna'. We were not aware of the cause at the time. I had to frequently watch my son sleep because he would breathe so shallowly and then stop for a few seconds, sometimes 10-12 seconds until I physicaly touched him or shook him slightly. He would then GASP for air and cry a second, and go back to sucking on his pacifier. He would breathe normally for 3-10 minutes, then slip back into the shallow breathing.. So Many nites were spent watching and not sleeping.

More

6. Relevant Tests/Laboratory Data, Including Dates

none done that i know of that were a direct result of the side effects - of course we were never aware of this issue until after the fact. There is a real possibility that there may be documented results/findings in some of the labs/tests that were done while our son was between 5-8 months at the

More

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

Our son was born with a heart defect, that was completely fixed on his 2nd day of life at (b) (6) Childrens Hospital. "Transposition of Great

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Teething Tablets Homeopathic - No Hyland's strength ind.
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tabs	4X per day	sl
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/01/2010 -- 12/08/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 pain from teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 109178
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

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

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

DEC 09 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)
(b) (6)
Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7756415

437977

B5. Describe event or problem continued

Also, at times when we would administer the tablets at different times of the day, he would many times fall asleep after we gave him 2 tablets.. We thought at that time - 'what a great product'. During one period of intense teething, he developed a weird rash or flushing of his neck and a little on his body and mouth area. We brought him to his pediatrician and they didn't really know what it was... and just said that it was normal from time to time, and could be caused by a number of things..

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DEC 09 2010

B6. Relevant tests/laboratory data, including dates continued

pediatricians office in (b) (6)

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DEC 09 2010

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

B7. Other relevant history, including preexisting medical conditions continued

Arteries".

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DEC 09 2010

CaseID: 7756528

U.S. Department of Health and Human Services

Individual Safety Report

7161246-5-00-01

NTARY reporting of
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Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 438155

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 14 Months	☐ Female ☑ Male	25 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☑ Death: (b) (6) (mm/dd/yyyy)
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
04/15/2010	12/09/2010

5. Describe Event, Problem or Product Use Error

We have yet to stop wondering what led to the early demise of our son, (b) (6) earlier this year (b) (6) The morning that he was sent to Children Hospital via care flight, it became apparent that he was neurologically impaired. Indeed, the certificate of death indicated cardiovascular collapse of unknown etiology. Recently, I read this FDA notification that a seemingly harmless supplement that our son had taken several times within 24 hours -and for a couple months prior- of his collapse was recalled due to dosage variations of the main ingredient, belladonna, AKA Deadly nightshade. He showed most of the symptoms listed

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Hyland's Teething Tablets 250 tablet — Hyland's / P&S Laboratories
#2

2.	Dose or Amount	Frequency	Route
#1	As directed, 2-3 tabs	every 4 hours	po
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 12/01/2009 -- 04/15/2010
#2 --

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)
#1 Teething discomfort
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 100610	#1	54973-7504-2
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Homeopathic Teething Tablets
2. Common Device Name: Hyland's teething tablets
3. Manufacturer Name, City and State: P&S Laboratories, Los Angeles, CA 90061

4. Model #	Lot # 100610	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Serial #	Other # NDC 54973-7504-2	

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

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DEC 10 2010
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of e

DSS
DEC 10 2010

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

on the FDA website including frequent seizures even while on life support. The very product that we used, Hylands belladonna for teething, was the one recalled for potentially toxic levels of belladonna. We have learned that belladonna is a potent neurotoxin and fear that is autonomic nervous system may have terminated following large does of this product. The Medical examiner said that the half life of various alkaloids in belladonna is so short that his 3 day hospital stay would have flushed it from his tissue long before being taken off of life support and the subsequent autopsy. I would like actual citation of other children harmed - even to the point of death - from this product. Please help us... Respectfully, (b) (6)

(b) (6)

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DEC 10 2010

CaseID: 7758002

U.S. Department of Health and Human Services

Individual Safety Report

7176546-7-09-01

...UNTARY reporting of ...nts, product problems and ...roduct use errors

...mission - Page 1 /1

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

FDA USE ONLY
Triage unit sequence # 438562

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 10 Months	☑ Female ☐ Male	30 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/01/2009	12/14/2010

5. Describe Event, Problem or Product Use Error

After using Hyland's teething tablets she had what appeared to be seizures with constipation. These symptoms lasted until we quit using the product.n

More

6. Relevant Tests/Laboratory Data, Including Dates

More

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

More

C. PRODUCT AVAILABILITY

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

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's TEETHING TABS
#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets		
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/01/2010 -- 10/15/2010
#2 --

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

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

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS
DEC 15 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # | E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

7178924-4-00-01

DQRS

CaseID: 7763555

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

LUNTARY reporting of
ents, product problems and
product use errors

Internet Submission - Page 1/2

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 438834

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 14 Months	☑ Female ☐ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/17/2010	12/16/2010

5. Describe Event, Problem or Product Use Error

My oldest Daughter died (b) (6) Her cause of death was undetermined but I believe that Hylands Teething tablets caused an adverse reaction and she died from it. I woke her up at 8:30 that morning and she was acting oddly lethargic. She just seemed like she needed more sleep. She didn't even want to finish breakfast. It was out of character for her not to want to eat or play but when she kept trying to fall asleep on the floor I put her back into her bed and allowed her to sleep. When I went back upstairs to wake her up because it had been a long time, I found her unresponsive and with no pulse. I called 911 and they couldn't resuscitate.

More

6. Relevant Tests/Laboratory Data, Including Dates

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More

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

My daughter had a blood disorder called Hereditary Spherocytosis which caused hemolytic anemia and a lower immune system.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Tablets not sure Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4 times a day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 05/31/2010 -- 06/17/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 108198	#1
#2	#2

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

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hylands

2. Common Device Name
Teething Tablets

3. Manufacturer Name, City and State
Hylands inc. Los Angeles, CA

4. Model #	Lot # i don't know don't	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other # 108198	☑ Other: parent

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

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

DSS

DEC 17 2010

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

The day she died I gave her one dose of the Hylands teething tablets because I thought she may be acting tired because of teething and I thought if I could help soothe her gums then maybe she would wake up. She had been taking the tablets for about two weeks on and off.

DSS

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7178809-3-00-01

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. . . OLUNTARY reporting of adverse events, product problems and product use errors

Internet Submission - Page 1

CaseID: 7764708

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

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence #

438796

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 7 Months	☐ Female ☑ Male	22 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

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

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/15/2010	12/16/2010

5. Describe Event, Problem or Product Use Error

Hello, I was giving my son the Hylands teething tablets back in march when he suddenly went into an episode of metahemaglobanemia. He was 7 months old. We rushed him to the ER and the doctor could not figure out what may have caused this to happen. Maybe the Teething tablets were the cause. I just though that maybe you wanted to know about this. Since that incident I have never given them to him again, and we have never had another episode. Thank you Sincerely, (b) (6) USAF military overseas.

More

6. Relevant Tests/Laboratory Data, Including Dates

they ran labs on (b) (6) and concluded with metahemaglobanemia

More

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

n/a

More

C. PRODUCT AVAILABILITY

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

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething homepathic Hylands, INC
Tablets
#2

2.	Dose or Amount	Frequency	Route
#1	3 tabs	4x a day -	sl
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 03/01/2010 -- 03/15/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Teething Tablets

2. Common Device Name

3. Manufacturer Name, City and State
Los Angeles, CA 90061

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☑ Other: Mother

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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

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More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

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

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

U.S. Department of Health and Human Services

CDER-OTC

CaseID: 7777563

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Individual Safety Report

LUNTARY reporting of
ents, product problems and
roduct use errors
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7206062-0-00-01

FDA USE ONLY	
Triage unit sequence #	439780

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	11 Months	☑ Female ☐ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☑ Life-threatening
☑ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/01/2010	12/28/2010

5. Describe Event, Problem or Product Use Error

At 3pm on (b) (6) I put my 11 1/2 month old daughter down for a nap in her crib. She seemed warm, despite not having any other symptoms, so I checked her temperature and saw that it was 100.1. I thought perhaps this was due to teething so thought nothing of it. Close to 6pm my husband went upstairs to get her out of her crib. She was lying unresponsive in her crib, wheezing rhythmically, and not making eye contact. Her crib sheets were soaked, either by sweat or urine. My husband picked her up and she laid limp in his arms. I tried to breastfeed her to see if she'd respond, and she still remained limp and unresponsive

More

6. Relevant Tests/Laboratory Data, Including Dates

X-rays, MRI, EEG, Lumbar puncture all performed during (b) (6) - (b) (6)

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

No pre-existing medical conditions.

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething Tablets
#2

2.	Dose or Amount	Frequency	Route
#1	2 - 3 tablets		po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 09/01/2009 -- 04/01/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething pain and restlessness
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Expiration Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☑ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

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DEC 29 2010

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report
7206062-0-00-02

MEDWATCH
essionals of adverse events and product problems
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B5. Describe event or problem continued

showing no reaction to anything. I called the pediatrician who told us to go the ER right away. We drove to the hospital within minutes and rushed her into the ER. 4 nurses and a Dr. tried for 30 minutes to get an IV in her, during which time the left side of her body was seizing and her eyes were not focusing on anything. They gave her doses of Ativan and Phenobarbital, after which her body stopped seizing. She was transported by ambulance to another hospital with a well-equipped pediatric ICU, where she was admitted for 2 days and had all sorts of tests performed on her. She was sleeping or lethargic during her entire hospital stay. (b) (6) morning, (b) (6) she was discharged because the Dr.'s were unable to find any cause for her symptoms and diagnosed it as a complex febrile seizure.

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DEC 29 2010

CaseID: 7786988

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
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U.S. Department of Health ...

Individual Safety Report

7215952-4-00-01

TI

Adverse Event Reporting Program

...ARY reporting of ...roduct problems and ...t use errors

...on - Page 1 COBR OTC

FDA USE ONLY

Triage unit sequence # 440117

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6)	(b) (6)	☑ Female ☐ Male	19 lb or ____ kg
In confidence	6 Months		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/30/2010	12/30/2010

5. Describe Event, Problem or Product Use Error

My six month old daughter was taking the Hylands Teething tablets and showed slight signs of reaction. I thought at first it was just symptoms of the teething issue itself, but then researched online and found out it could be more. She would become flushed and very sleepy after taking the teething tablets. No serious injurys, and I disposed of the remaining tablets. I just wanted to report that I am fairly sure she was having a slight reaction to this remedy

More

6. Relevant Tests/Laboratory Data, Including Dates

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7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands Teething tablets — Hylands
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 --
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

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JAN 04 2011

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

U.S. Department of Health and Human Services

CaseID: 7788941

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Individual Safety Report

7215922-6-00-01

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FDA USE ONLY	
Triage unit sequence #	440140

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6)	(b) (6)	☑ Female ☐ Male	14 lb or ____ kg
In confidence	5 Months		

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
12/03/2010	01/03/2011

5. Describe Event, Problem or Product Use Error

Our 5 month old Daughter started having seizures and difficulty breathing and what appeared to be vision problems shortly after we started using Hylands Teething Tablets. Her eyes would roll back in her head and head would jerk. for short periods she seemed to stop breathing or take take longer periods than normal without a breath which to us seemed unusual. she would squint her eyes and shake her head a lot at the same time and she seemed to spit up a lot also.

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6. Relevant Tests/Laboratory Data, Including Dates

We took her to (b) (6) Hospital where she had Blood work and a CAT scan. They transfered us to (b) (6) - all childrens - Hospital where she had an EEG and several other tests done.

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Infant tablets — Hyland's Inc
#2

2.	Dose or Amount	Frequency	Route
#1	two Tablets	twice Daily	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/15/2010 -- 12/01/2010
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID
3 54973 75041

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's Teething Tablets
2. Common Device Name
Hyland's Teething Tablets
3. Manufacturer Name, City and State
Hyland's Inc California

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

No treatment yet given

DSS
JAN 04 2011

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☑ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7794877

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Individual Safety Report

7225061-6-00-01

...NTARY reporting of
..., product problems and
...uct use errors

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1 /4

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 9 Months	☐ Female ☑ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
09/01/2010	01/06/2011

5. Describe Event, Problem or Product Use Error

Teething tablets used august 2010 to January 2011 Tablets weren™t given on a regular basis, but when they were no more than 3 times a day 1 to 3 tabs at a time. Morning, noon and evening doses were given as part of a routine when other meds were given. Fluoride, reflux meds Tylenol or ibuprofen etc. We started using the teething tablets in August because (b) (6) did not like the Orajel. A friend had recommended them to us, since she used them with her children 10 to 14 years ago and swore by them. I began using them. (b) (6) took these tablets very easily and with enthusiasm when I reached for the bottle, there was no hesitation and smiled

More

6. Relevant Tests/Laboratory Data, Including Dates

working on it with dr now

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

(b) (6) has not slept a whole night EVER. Its unexplained, the other children never had any issues with sleep. They had regular bed times and slept 10

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☑ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 homeopathic tething tablets hylands
#2 TEETHING

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tablets	up to 4 times dail	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/01/2010 – 10/01/2010
#2 09/01/2010 – 11/01/2010

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☑ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109822	#1	54973-7504-1
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hylands
2. Common Device Name: teething tablets
3. Manufacturer Name, City and State: los angeles california

4. Model #	Lot # 109822	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

RECEIVED
DSS JAN 07 2011
JAN 07 2011 MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

just found out about the recall January 4,2010 contacted company, then a lawyer. made an appt with pediatrician for January 7, 2011 to discuss history

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☑ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

excitedly while laughing as he stuck out his tuck waiting patiently for them. Issues Bely aches/pains, Irritability, pushing to poop, screaming then farts, unexplained rashes, attributed it to formula changed formula in August, seemed to have less reflux stopped the reflux meds, still continued to have hard stools very infrequent and tough to go. (b) (6) had periods where he was very irritable and cried a lot. Most of the crying was during the night. I can recall several times where I went over to the crib to get him, pick him up because he was whining and whimpering his eyes were closed he began crying which turned to a scream, he was not soothing by my touch or my voice-.I sat him straight up -sitting on my lap-this was LATE at night- and say his name VERY LOUDLY 3 to 5 times until he finally opened his eyes and looked at me, disoriented and glazed over in the eyes at this time he would just stare at me, finally about 3 to 5 min later he would smile at me, take a bottle and began to relax again and fall asleep. When he would awaken he would cry for long periods of time, he was very restless -I would have to walk him around the house- and other times provide massages to his abdomen to help release the excess gas, then he would fart and seem to calm and fall asleep, this was a major problem for him for several months. Although the soy formula helped (b) (6) pass bowels more, the issues were still present. Some times more than others, I think this had to with the irregular administration of the teething tablets. I did notice that his heart beat very very fast at times. I especially noticed it at bed times when we were relaxing to go to bed; he was very fidgety constantly moving very restless.

DSS

JAN 07 2011

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B7. Other relevant history, including preexisting medical conditions continued

to 12 hours every night. In (b) (6) sleep, he is moaning/groaning. born to term, had pyloric stenosis diagnosed and had surgery at 6 weeks. no smothing or alcohol use during pregnancy no other problems

DSS

JAN 07 2011

F. Other (Concomitant) medical products continued

of behavior over the months of august, september, october, november and december of 2010. very worried about long term effects if any and the fact that my son suffered from poisoning for 4+ months while using this product. The fact that there wasn't much attention paid to the recall, because i know that i bought the product after November of 2010 at a local pharmacy and target. i also recieve emails from several online parenting resources and never read anything about the recall as well as watching the nightly local and world news and again NEVER heard a thing. consumer protection warrants more to be done.

DSS
JAN 07 2011

Individual Safety Report

7239231-4-00-01

CaseID: 7803115

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

DQRS

FDA USE ONLY
Triage unit sequence # 441756

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 1 Years	☑ Female ☐ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☑ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
01/01/2011	01/14/2011

5. Describe Event, Problem or Product Use Error

Using Teething Tablets with daughter and she is experiencing some of the mild symptoms described under the belladona toxicity: Flushed cheecks and irritable. Even though the product was recalled in October 2010 and we have used the product since Spring of 2010 we just found out today the product was voluntarilly recalled when we went to our local grocery store. We will be dicontinuing the use of product and monitoring our toddler for continued symptoms.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)

#1 Teething Tablets Calcarea Phosphorica 3x Hyland

#2

2.	Dose or Amount	Frequency	Route
#1	2 tablets - when needed	3 times a day	po
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 03/01/2010 -- 01/11/2011

#2 --

4. Diagnosis or Reason for Use (Indication)

#1 Used for teething infant who then became teething toddler

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name
hyland Teething Tablets

2. Common Device Name
Teething Tablets

3. Manufacturer Name, City and State
Hyland Inc, Los Angeles, CA

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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JAN 19 2011
MEDWATCH CTU
DSS
JAN 19 2011

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone #	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7274900-1-00-01

CaseID: 7813863

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1 DQRS

FDA USE ONLY
Triage unit sequence # 442946

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 5 Months	☐ Female ☑ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/20/2010	02/01/2011

5. Describe Event, Problem or Product Use Error

We have been giving our child hylands teething tablets since he started teathing and recently he had to be taken to the emergency room due to high fever. I am not 100 percent sure the tablets were to blame al young kids run fevers all the time. Although we have gave our son over 200 tablets and are not sure the long term affect of these toxins can be. I am seeking.g compensation for the original purchase plus the funds to cover the emergency room visit.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 hylands homeopathic — hylands
#2

2.	Dose or Amount	Frequency	Route
#1	4 tablets	every other day	Dental
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 06/01/2010 – 01/29/2011
#2 – –

4. Diagnosis or Reason for Use *(Indication)*
#1 babys teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 109723	#1	109723
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: hylands teething tablets
2. Common Device Name: teething tablets
3. Manufacturer Name, City and State: Hands los Angeles ca

OTC

4. Model #	Lot # 109723	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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FEB 02 2011
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

DSS
FEB 02 2011

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

CaseID: 7837326

Individual Safety Report

7311977-9-00-01

...TARY reporting of
..., product problems and
...uct use errors

Page 1 of 2

FDA USE ONLY	
Triage unit sequence #	444531

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	10 months to 15 months	☑ Female ☐ Male	16 lb or 7.3 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: _____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☒ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
09/12/2010	01/29/2011

5. Describe Event, Problem or Product Use Error

Wheezing and hard time breathing, fatigue. Took my daughter to the ER and x-rays taken to make sure that she didn't choke on any food. X-rays showed to be normal. The ER doctor looking in the back of mouth thought that she could have swelling in the back of the mouth causing her to be wheezing. Prednisone was given to reduce the swelling.
On September 15 I had my daughter checked with an Ear, Nose and Throat Dr. He diagnosed her with Croup. I had a hard time believing that due to no coughing. On September 18, I took her to her Dr. He wasn't sure if she had asthma or croup and more prednisone was given for a back up on the wheezing.
The last couple of days I found out about the recall

6. Relevant Tests/Laboratory Data, Including Dates
(b) (6) Chest x-rays

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
Pulmonary Valve Stenosis

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FEB 15 2011
MEDWATCH CTU

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☑ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Name: Hylands teething Tablets
Strength: Homeopathic
Manufacturer: Hylands Inc.

#2 Name:
Strength:
Manufacturer:

2. Dose or Amount	Frequency	Route
#1 2 to 3 tablets	2 tablets Q1 hour	po
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 September - December 2010
#2 Jan 2011

4. Diagnosis or Reason for Use (Indication)
#1 Teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 106008	#1
#2	#2

9. NDC # or Unique ID
54973-7504-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hyland's Teething Tablets

2. Common Device Name
Teething Tablets

3. Manufacturer Name, City and State
Hylands Inc, Los Angeles, CA 90061

4. Model #	Lot # 106008	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☑ Other: Parent
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

SS
5 2011

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Nurse	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B.5. **Describe Event or Problem** *(continued)*

and since throwing away the bottle she has not had any symptoms. I worried over this with her heart condition. I just gave her 3 tablets this past week and after giving she started wheezing again. With the wheezing I had to give her prednisone so she can start breathing better.

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)*

F. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

DSS
FEB 15 2011

Individual Safety Report

7331394-5-00-01

CaseID:7859446

FORM 3500

CDER
DQRS

2-20-11

Dear FDA staff,

I read in the Feb 2011 newsletter of Worst Pills (www.worstpills.org), published by Public Citizen's Dr. S. Wolfe, that (1) Hyland's teething tablets were recalled. The first reason they should never have been allowed on the market is that they don't work, biologically speaking. Consumers pay $5.99 for 80 lactose. The second reason that you may not be aware of, is that they are a choking hazard. A few years ago, a mother told me that she put the tablet under her 7 month-old son's tongue, as per the instructions on the package. The pill dissolved, choked him, then he turned blue. Fortunately, he was finally able to cough it up. I think all teething pills should be banned, not just Hyland's. Thx.

(b) (6) MD

(b) (6)

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FEB 28 2011

MEDWATCH CTU

MEDWATCH
5600 FISHERS LANE
ROCKVILLE
MD 20852-9787

DSS

FEB 28 2011

CaseID: 7886606

U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

MedWatch — Individual Safety Report

The FDA Adverse Event Reporting ... 7371389-9-00-01

...Y reporting of ...ct problems and ...errors

- Page 1 /2

FDA USE ONLY
Triage unit sequence # 448148

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 13 Months	☑ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
08/05/2010	03/18/2011

5. Describe Event, Problem or Product Use Error

My 13 mo old grandaughter was in the care of my husband and I. I gave her 1 dose of Hyland's teething tablets and childrens motrin about 1 hr after breakfast, and another dose of teething tablets before her nap.She woke up from napping fussy. When I picked her up her eyes rolled back in her head and she was very nonresponsive. I rushed her to the hospital. After several tests the Dr. told my husband and I her urinalysis showed positive for cannabinoids. I was arrested for child felony endangerment, my grandaughter was detained,and hospitalized. My husband and I knew she did not ingest marijuana, we do not use marijuana. In researching we

More

6. Relevant Tests/Laboratory Data, Including Dates

IMMUNOASSAY URINALYSIS DRUG SCREEN BONE SURVEY ABDOMEN EXAM X-RAYS HEMATOLOGY TEST CHEMISTRY, SPECIAL CHEMISTRY TESTING

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething tablets — Hyland's Inc.
#2

2.	Dose or Amount	Frequency	Route
#1	2 to 3 tabs	4 times a day	po
#2	2 tabs	every hr for 5 dos	po

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 08/05/2010 — 08/05/2010
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108709	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

RECEIVED
MAR 21 2011
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
21 2011

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

found the type of urinalysis test used at the hospital was an Immunoassay drug screen which is not a confirmed test, a 2nd test called a Gas Chromatography/ Mass Spectrometry test must be ran for confirmation due to cross-reactivity problems with other over the counter drugs causing the first test to read a false positive. The second test was never done. Ibrophen can show as a false positive for marijuana in the test used. Then discovering the teething tablets had been recalled and the described symptoms of belladonna poisoning matched my grandaughters symptoms we are convinced the tablets are responsible for her condition that day. We still have the bottle of teething tablets in our possession and the upc# matches your recalled list We feel our grandaughter was misdiagnosed and the teething tablets that are labeled 100% natural, no side effects are to blame for my grandaughter being poisoned and taken from her family. She still remains in foster care as our family fights to get her returned.

DSS

MAR 21 2011

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 7899901

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

U.S. Department of Health and Human Services

Individual Safety Report

7381240-9-00-01

...r use by user-facilities, distributors and manufacturers MANDATORY reporting

Page 1 of 4

Mfr Report # 54973 MSB # 2011-02059

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 5 Months — or — Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - [ ] Death: ____ (mm/dd/yyyy)
   - [X] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - [ ] Disability or Permanent Damage
   - [ ] Congenital Anomaly/Birth Defect
   - [ ] Other Serious (Important Medical Events)
3. Date of Event (mm/dd/yyyy):
4. Date of This Report (mm/dd/yyyy): 02/23/2011
5. Describe Event or Problem:

5 MONTH OLD DAUGHTER STARTED HAVING SEIZURES AND DIFFICULTY BREATHING AND WHAT APPEARED TO BE VISION PROBLEMS SHORTLY AFTER THEY STARTED USING HYLAND'S TEETHING TABLETS. HER EYES WOULD ROLL BACK IN HER HEAD AND HER HEAD WOULD JERK. FOR SHORT PERIODS, SHE SEEMED TO STOP BREATHING OR TAKE LONGER PERIODS THEN NORMAL WITHOUT A BREATH. SHE WOULD SQUINT HER EYES AND SHAKE HER HEAD AT THE SAME TIME AND SEEMED TO SPIT UP A LOT.

6. Relevant Tests/Laboratory Data, Including Dates:

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
   #1 HYLAND'S TEETHING TABLETS
   #2
2. Dose, Frequency & Route Used
   #1
   #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1 TEETHING PAIN
   #2
5. Event Abated After Use Stopped or Dose Reduced?
   #1 [ ] Yes [ ] No [X] Doesn't Apply
   #2 [ ] Yes [ ] No [ ] Doesn't Apply
6. Lot #
   #1
   #2
7. Exp. Date
   #1
   #2
8. Event Reappeared After Reintroduction?
   #1 [ ] Yes [ ] No [X] Doesn't Apply
   #2 [ ] Yes [ ] No [ ] Doesn't Apply
9. NDC# or Unique ID: 54973-7504-1
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA)
    [ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
   Phone #: (b) (6)
2. Health Professional? [ ] Yes [X] No
3. Occupation
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [ ] Unk.

FDA DSS MAR 22 2011

MAR 21 2011

MAR 21 2011

...ividual Safety Report
7381240-9-00-02

FDA USE ONLY

F. FOR USE BY USER ...

1. **Check One**
☐ User Facility ☐ Importer

2. **Or...**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report**
☐ Initial
☐ Follow-up # ____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. **Report Sent to FDA?**
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. **Location Where Event Occurred**
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. **Report Sent to Manufacturer?**
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

VALERIE MAC LEAN
HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number**
310-768-0700

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
02/23/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**
SEIZURES AND BREATHING PROBLEMS

9. **Manufacturer Report Number**
54973 MSB#2011-02059

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?**
☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. **If Remedial Action Initiated, Check Type**
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
MAR 22 2011

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 - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

MAR 21 2011

STANDARD HOMEOPATHIC

CUSTOMER COMPLAINT RECORD

CaseID: 7899901

Individual Safety Report

7381240-9-00-03

COMPLAINT #: RVD022311VM001

DATE OF COMPLAINT: 02/23/2011

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS:

CITY:

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 5 MONTH OLD DAUGHTER STARTED HAVING SEIZURES AND DIFFICULTY BREATHING AND WHAT APPEARED TO BE VISION PROBLEMS SHORTLY AFTER THEY STARTED USING HYLAND'S TEETHING TABLETS. HER EYES WOULD ROLL BACK IN HER HEAD AND HER HEAD WOULD JERK. FOR SHORT PERIODS, SHE SEEMED TO STOP BREATHING OR TAKE LONGER PERIODS THAN NORMAL WITHOUT A BREATH, WHICH SEEMED UNUSUAL. SHE WOULD SQUINT HER EYES AND SHAKE HER HEAD A LOT AT THE SAME TIME AND SHE SEEMED TO SPIT UP A LOT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 02/24/2011

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: VALERIE MAC LEAN

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE022311VM001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 02/23/2011 BY: VALERIE MAC LEAN

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 03-09-11

DSS

MAR 22 2011

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

MAR 21 2011

STANDARD HOMEOPATHIC

Individual Safety Report

7381240-9-00-04

Hyland's 7899901

VERSE EVENT DATA FORM

AE #: RAE022311VM001

COMPLAINT #: RVD022311VM001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: UNKNOWN

ADDRESS: (b) (6)

CITY:

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Walth DATE: 03-10-11 DSS

BY: N/A DATE: MAR 22 2011

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

MAR 21 2011

7407756-4-00-01

DQRS

CaseID: 7906444

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

JNTARY reporting of
ts, product problems and
oduct use errors CDER

FDA USE ONLY
Triage unit sequence # 450164

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 8 Months	☐ Female ☑ Male	19.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
03/15/2011	04/07/2011

5. Describe Event, Problem or Product Use Error

We have been giving our son Humphrey's brand teething tablets and have noticed that he has been experiencing muscle weakness, mild seizures, and sleepiness, which from what I have read coincide with belladonna toxicity.

More

6. Relevant Tests/Laboratory Data, Including Dates

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MEDWATCH CTU

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

N/A

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1
#2

2. Dose or Amount	Frequency	Route
#1		po
#2		

3. Dates of Use *(If unknown, give duration)* from/to *(or best estimate)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 A505V	#1
#2	#2

9. NDC # or Unique ID

F. SUSPECT MEDICAL DEVICE

1. Brand Name: Humphrey's
2. Common Device Name: Teething Tablets
3. Manufacturer Name, City and State: Humphreys Pharmacal East Hampton CT 06424

OTC

4. Model #	Lot # A505V	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

Little Teethers - February - March Humphreys
Teething Pellets - March - April 2011

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS
APR 08 2011

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

7408066-1-00-01

CaseID: 7907505

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

JNTARY reporting of
ts, product problems and
oduct use errors

Internet Submission - Page 1/3

FDA USE ONLY
Triage unit sequence # 450247

The FDA Safety Information and Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 20 Months	☐ Female ☑ Male	20 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
02/15/2011	04/07/2011

5. Describe Event, Problem or Product Use Error

After the use of Hyland's teething tablets prior to going to bed our son woke us up crying at about 2:00 AM. By about 3:30 AM he had a severe rash with hives over his entire body, including the soles of his feet. There was pronounced swelling of his knees, lips, arms, and cheeks. His ears were a flaming red color and he had a low grade fever. We have him a very small dose of benaydryl -- 1/4 teaspoon- and a cool bath. This suppressed the fever somewhat, but did not relieve the other symptoms. We took him to the E.R. where he was given a 1 teaspoon dose of benadryl and a steroid shot. The E.R. doctor advised 1 tsp doses of benadryl

More

6. Relevant Tests/Laboratory Data, Including Dates

We finally received the allergy test results on April 5, 2011. Our son tested positive on only a handfull of items. On the 0-5 scale used, most reactions were at a level of 2 for common air born allergens such as pollen, pet dander, house dust, etc. Oak pollen tested as a level 3, which

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

none

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland's Teething Tablets 3x HSUS ??? Hyland's
#2 Hyland's Teething Tablets 3x HSUS ???? Hyland's

2.	Dose or Amount	Frequency	Route
#1	1-2 tablets	as needed	po
#2	1-2 tablets	as needed	po

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 02/15/2011 12 months or more 02/15/2011	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 02/15/2011 12 months or more 02/15/2011	#2 ☑ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*	8. Event Reappeared After Reintroduction?
#1 teething pain	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 teething pain	#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 108134	#1	N/A
#2 109515	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Hyland's Teething Tablets
2. Common Device Name: Hyland's Teething Tablets
3. Manufacturer Name, City and State: Hyland's unknown address

OTC

4. Model #	Lot # 108134 and 109515	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

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APR 08 2011

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Administrator	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

every 6 hrs for a few days, with a followup visit to his pediatrician if the symptoms got worse, or did not go away. Instead of waiting we went ahead and took him to see his pediatrician who prescribed the epi pen in case of emergency, and a 5 day prescription for oral steroid medication. He also referred us to a local MD for allergy testing. At this point we had no idea what could have caused the allergic reaction, and knew nothing of the recall of the Hyland's teething tablets. The steroid shot in E.R. significantly reduced the symptoms immediately. The severe hives and swelling subsided over a period of a few hours. But the red rash on his cheeks did not totally go away for several days. When we went to the allergy M.D. we opted for the full scope of blood based allergy testing for both airborn and food related allergies.

DSS
APR 08 2011

B6. Relevant tests/laboratory data, including dates continued

correlates with our observations of previous minor irritation after physical contact with pollen. The localized skin rash which occurs is eliminated with a small dose of benadryl. He had a single item which tested as a 4, which was egg whites. He tested negative for egg yolk. We had previously had an experience with minor facial rash due to eating scrambled eggs. Nothing in the allergy testing correlated with the degree of reaction observed on Feb 15, 2011. Also, he was not exposed during that evening to any of the items he tested positive for. Since that evening we have learned of the recall of the Hyland's teething tablets last October. We immediately stopped using the product. We did give him these tablets prior to bed time, and we have notice that since then the intermittent minor skin rash on his cheeks which we have observed for several months has gone away. We suspect that the minor skin rash, and more importantly the severe reaction, may have been due to the teething tablets. We have two bottles of this product which were purchased prior to the recall. One is from Hyland's lot number 109515. The other is from lot 108134. We think he was given tablets from lot 108134 on the evening of the severe reaction. If it is possible, we would like to send you the remaining product for testing. If the FDA cannot accept these samples for analysis, please recommend a laboratory. We would like to confirm whether or not we should be concerned about some other source of life threatening allergic reaction. We are not interested in making any claim against Hyland's. But we will not use their products again.

DSS

APR 08 2011

CaseID: 7915981

7412152-X-00-01

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

FORM FDA 3500A (10/05)

Page 1 of 4

Mfr Report # 54973 RAE#031011EF001

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 8 Months — or — Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: 20 lbs — or — kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: _____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☒ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 08/01/2010

4. Date of This Report (mm/dd/yyyy): 03/18/2011

5. Describe Event or Problem

STARTED GIVING JULY 2010 AND GAVE A TOTAL OF 5-6 TABS IN JULY. BEGINNING OF (b) (6) CHILD STARTED HAVING SEIZURES (SPACE OUT, STRAIGHTEN ARMS, SHAKE FOR A COUPLE SECONDS AT A TIME). HAPPENED A COUPLE OF WEEKS AFTER SHE GAVE THE 5-6 TABS. HAD A TOTAL OF 7 TO 8 MILD SEIZURES OVER A PERIOD OF 4 WEEKS; HAS NOT USED TEET SINCE. CHILD WAS HOSPITALIZED FOR 8 DAYS IN (b) (6) FOR EEG AND MRI TESTING. EEG CAUGHT 1 SEIZURE;MRI WAS NORMAL. DR. DIDN'T KNOW WHAT CAUSED SEIZURES. TOLD MOTHER TO "WAIT AND SEE" HOWEVER, RECOMMENDED SHE STOP USING PRODUCT BECAUSE THIS WAS SOMETHING NEW THAT WAS INTRODUCED.

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APR 05 2011
CDR

6. Relevant Tests/Laboratory Data, Including Dates
(b) (6) - EEC AND MRI

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABS X3 DAYS
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 RELIEF FOR TEETHING CHILDREN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 87535
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-8

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Other #
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS
APR 06 2011

2. Health Professional? ☐ Yes ☒ No
3. Occupation: N/A
4. Initial Reporter Also Sent Report to FDA? ☐ Yes ☒ No ☐ Unk.

APR 05 2011

CaseID: 7915981

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ (Specify)

13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

EDYTA FRACKIEWICZ
204 W. 131ST
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
03/10/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973 RAE#031011EF001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 06 2011

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 - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 05 2011

HOMEOPATHIC
MADE IN THE USA SINCE 1903

SECTION I: **COMPLAINT**

COMPLAINT #: RVD031011EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 03/10/11-EMAIL / 03/17/11-PHONE

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABS

LOT NO.: 87535

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY:

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: STARTED GIVING JULY 2010, AND GAVE A TOTAL OF 5-6 TABS TOTAL IN JULY. BEGINNING OF (b) (6) CHILD STARTED HAVING SEIZURES; (SPACE OUT, STRAIGHTEN ARMS, SHAKE FOR A COUPLE SECONDS AT A TIME). THIS HAPPENED A COUPLE WEEKS AFTER SHE GAVE THE 5-6 TABS. HAD A TOTAL OF 7 TO 8 MILD SEIZURES OVER A PERIOD OF 4 WEEKS. HAS NOT USED TEET TABS SINCE THE 5-6 TABS SHE GAVE; CHILD WAS HOSPITALIZED FOR INVESTIGATION OF THE SEIZURES FOR 8 DAYS IN (b) (6) (DISCHARGED (b) (6)). DID 48 HOUR EEG (CAUGHT ONE SEIZURE ON THE EEG). PUT HIM TO SLEEP TO DO AN MRI WHICH WAS NORMAL. DOCTOR DIDN'T KNOW WHAT CAUSED SEIZURES. TOLD MOTHER TO WAIT AND SEE, BUT RECOMMENDED SHE STOP USING TEET SINCE THIS WAS SOMETHING NEW THAT WAS INTRODUCED. MOTHER WILL NOT SEEK ADDITIONAL MEDICAL EVAL SINCE CHILD HAS NOT HAD SEIZURE SINCE (b) (6)

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

Individual Safety Report

7412152-X-00-03

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 03/10/2011 & 03/17/2011

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE031011EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 03/10/2011 & 03/17/2011

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWatt

DATE: 03-28-11 DSS

BY:
QA / QC DIRECTOR

DATE: APR 06 2011

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 05 2011

HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

7915981

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE031011EF001 **COMPLAINT #:** RVD031011EF001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Safety Report
7412152-X-00-04

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 03-28-11 DSS

BY: DATE: APR 06 2011
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 05 2011

Individual Safety Report

7442353-6-00-01

CDER

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1

CaseID: 7933934

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 451723

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
baby girl In confidence	8 Months	☑ Female ☐ Male	17 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/24/2011	04/24/2011

5. Describe Event, Problem or Product Use Error

Parent gave baby girl Hyland's teething tablets for 2 days. Parent did not know of recall. Tablets had been given to parent at baby shower. Within 20 minutes of taking the product, baby girl would fall asleep and be very groggy. Baby girl also became constipated and would not drink as many bottles. However...baby girl also has a cold and the constipation and decrease in appetite could be from that.

More

6. Relevant Tests/Laboratory Data, Including Dates

DSS

APR 25 2011

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland Teething Tablets 125 tablets Hylands
#2

2. Dose or Amount	Frequency	Route
#1 2 tablets	3 times a day	
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 04/21/2011 -- 04/24/2011
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1 Irritablity while teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 I don't know	#1 --	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name Hylands Teething Tablets
2. Common Device Name Hylands
3. Manufacturer Name, City and State

OTC

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

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APR 25 2011
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report

7450105-6-00-01

...by user facilities, ...butors and manufacturers ...DATORY reporting

Form Approved: OMB No. 0910-0291 Expires: 12/31/11
See OMB Statement on reverse.

CaseID 7942346

Mfr Report #	2280705-2011-00017
UF/Importer Report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	or	☐ Female ☑ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: (mm/dd/yyyy)
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
3/29/11	04/20/2011

5. Describe Event or Problem

Consumer reported she "used this [the cherry flavor] twice on my son, yesterday, and last week.. And he stopped breathing both times, he was gasping trying to get air and couldn't get anything in. The first time we thought maybe he burped up something he ate and choked on it. When it happened the 2nd time. We knew that wasn't the case. It's within 30 seconds of putting it in his mouth."

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APR 21 2011
CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 Baby Orajel® oral pain reliever for teething

#2 (continued) Benzocaine 7.5%

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 Oral application	#1 03/29/11
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1 Teething Pain Relief	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

NDC# 10237-713-33

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	

OSS
APR 22 2011

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ● Unk.

APR 21 2011

PLEASE TYPE OR USE BLACK INK

CaseID: 7942346

Individual Safety Report

7450105-6-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ☐☐☐ - ☐☐☐ - ☐☐☐
Device Code ☐☐☐ - ☐☐☐ - ☐☐☐

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

Jill D. Ferentz
Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

2. Phone Number
609-497-7139

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
03/30/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
Stopped breathing

9. Manufacturer Report Number
2280705-2011-00017

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ☐☐☐ - ☐☐☐ - ☐☐☐ - ☐☐☐
Results ☐☐☐ - ☐☐☐ - ☐☐☐ - ☐☐☐
Conclusions ☐☐☐ - ☐☐☐ - ☐☐☐ - ☐☐☐

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☑ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

Baby Orajel® oral pain reliever for teething carton and tube label are attached.

This report and the information submitted under this report does not constitute an admission that the drug or Church & Dwight Co., Inc. or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight actually occurred.

DSS

APR 22 2011

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 (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

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APR 21 2011

Individual Safety Report
7450105-6-00-03

IFERENCE 1-63/64 →

OPEN END

1/4 NO PRINT AREA 1/4

EYE CLEARANCE

1/16" QUIET AREA

5/8" X 3-3/8"

1/32" QUIET AREA

Church & Dwight Co., Inc., Princeton, NJ 08543
© Church & Dwight Co., Inc.
OJTU-03313-01 7000615

IMMEDIATELY RELIEVES TEETHING PAIN

CHERRY FLAVORED

Baby Orajel®

TEETHING PAIN MEDICINE

Benzocaine 7.5%

NET WT 0.33 OZ (9.4 g)

Oral Pain Reliever
For Teething

Active ingredient Benzocaine 7.5%

Use temporarily relieves sore gums due to teething in infants and children 4 months of age and older

Warnings **Allergy alert:** do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless told to do so by a dentist or doctor

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

Stop use and ask a dentist or doctor if ■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ use your fingertip or cotton applicator to apply a small pea-size amount of Baby Orajel ■ apply to the affected area up to four times daily or as directed by a dentist or doctor ■ for infants under 4 months of age, ask a dentist or doctor

Other information do not use if tube tip is cut prior to opening

1/32" QUIET AREA

PRINT HEIGHT 2-5/8

TUBE LENGTH 3-3/8

3/16 NO PRINT AREA 3/16

CAP END

DSS
APR 22 2011

FRONT PANEL C/L

BACK PANEL C/L

APR 21 2011

Individual Safety Report

7450105-6-00-04

CHERRY

INSTANT TEETHING PAIN RELIEF

#1 Teething Brand Used By Pediatricians

Baby Orajel®

BENZOCAINE 7.5%

TEETHING PAIN MEDICINE

SAFETY SEALED TUBE TIP

Baby Orajel®

BENZOCAINE 7.5%

TEETHING PAIN MEDICINE

Baby Orajel® TEETHING PAIN MEDICINE

ORAL PAIN RELIEVER FOR TEETHING

NET WT 0.33 OZ (9.4g) GEL

3 10310 03313 2

Church & Dwight Co., Inc.
Princeton, NJ 08543
© 2007 Church & Dwight Co., Inc.
BOJFC-03313-02 7000782

NO INK NO VARNISH

NO INK NO VARNISH

Drug Facts

Active Ingredient	Purpose
Benzocaine 7.5%	Oral pain reliever

Use for the temporary relief of sore gums due to teething in infants and children 4 months of age and older

Warnings

Allergy alert: do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless told to do so by a dentist or doctor

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

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Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ use your fingertip or cotton applicator to apply a small pea-size amount of Baby Orajel ■ apply to the affected area up to four times daily or as directed by a dentist or doctor ■ for infants under 4 months of age, ask a dentist or doctor

Other information do not use if tube tip is cut prior to opening

Inactive ingredients ammonium glycyrrhizate, FD&C red no. 40, flavor, glycerin, polyethylene glycol, purified water, sodium saccharin, sorbic acid, sorbitol

Questions or comments? call us at 1-800-962-5080 M-F 9am-5pm ET or visit our website at www.orajel.com

To clean your baby's new teeth, try BABY ORAJEL® TOOTH & GUM CLEANSER

Baby Orajel®

DSS

APR 22 2011

APR 21 2011

7490497-5-00-01

For use by user facilities, importers, distributors and manufacturers
MANDATORY reporting

See OMB statement on reverse.

CaseID: 7966799

Mfr Report #

UF/Importer Report # 0000000000-2011-000001

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	7 1/2 Months	☐ Female	23 lbs
In confidence	or Date of Birth:	☑ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
4/18/11	5/10/11

5. Describe Event or Problem

On April 18, 2011 at 11:00AM I received a telephone call from a pharmacist who stated that an employee of the hospital purchased a bottle of Humphreys Very Cherry Teething Relief Pellets, administered them to her son who later experienced a reaction. I asked to have the employee contact me directly for more information regarding this incident. At 5:00PM on April 18, 2011 I received a telephone call from the mother who informed me that on April 6, 2011 upon the recommendation of several other mothers who encouraged her to try Humphreys Very Cherry Teething Relief Pellets, she purchased a bottle of said pellets, Lot# A470C. On April 9, 2011 she administered one pellet to her son and then on April 10, 2011 another 2 pellets. The mother reported further that on April 11, 12 and 13 the child went to day care but was experiencing jerky motions. The mother reported further that on (b) (6) at 8:00PM the child had a seizure which spiked between (b) (6) and (b) (6) On (b) (6) (b) (6) the mother took her son to the emergency room at the local hospital. Blood tests were conducted. The child had no fever.

6. Relevant Tests/Laboratory Data, Including Dates

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7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 Humphreys Very Cherry Teething Relief Pellets

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 1 pellet oral	#1 4//09/11
#2 2 pellets oral	#2 4/10/11

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 Teething Relief	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A470C	#1 N/A	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 0219-1103-00

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS
MAY 13 2011

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ● No ☐ Unk.

MAY 12 2011

PLEASE TYPE OR USE BLACK INK

7490497-5-00-02

FDA USE ONLY

CaseID: 1366733

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - ☐ Death
   - ☐ Serious Injury
   - ☐ Malfunction
   - ☐ Other:

2. **If Follow-up, What Type?**
   - ☐ Correction
   - ☐ Additional Information
   - ☐ Response to FDA Request
   - ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
   - ☐ Not Returned to Manufacturer
   - ☐ Yes ☐ Evaluation Summary Attached
   - ☐ No *(Attach page to explain why not)* or provide code:

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?** ☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*

Method				
Results				
Conclusions				

7. **If Remedial Action Initiated, Check Type**
   - ☐ Recall
   - ☐ Repair
   - ☐ Replace
   - ☐ Relabeling
   - ☐ Notification
   - ☐ Inspection
   - ☐ Patient Monitoring
   - ☐ Modification/ Adjustment
   - ☐ Other:

8. **Usage of Device**
   - ☐ Initial Use of Device
   - ☐ Reuse
   - ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

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MAY 18 2011

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

Humphreys Pharmacal Inc.
31 East High Street
East Hampton, CT 06424

2. **Phone Number**
(860) 267-8710

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☐ Study
   - ☐ Literature
   - ☑ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
4/18/11

5. (A)NDA # ____ IND # ____ STN # ____ PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☐ Initial
   - ☑ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**
seizure

9. **Manufacturer Report Number**
0000000000-2011-000001

1. Check One / 2. UF/Importer Report Number

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person / 5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* / 7. Type of Report / 8. Date of This Report *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # ____

9. Approximate Age of Device / 10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?

☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred

- ☐ Hospital
- ☐ Home
- ☐ Nursing Home
- ☐ Outpatient Treatment Facility
- ☐ Outpatient Diagnostic Facility
- ☐ Ambulatory Surgical Facility
- ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?

☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

MAY 12 2011

B.5. **Describe Event or Problem** *(continued)*

On (b) (6) the child was scheduled for an EEG to be conducted on Friday, April 15, 2011. There were no negative results found from either the blood tests or the EEG. The mother told me that at this point the child seemed to be getting better. The mother did not indicate to me that further intervention was needed or conducted. During this conversation I asked the mother that she have her physician contact me for further discussion. The mother did not give me the doctor's name or contact information. I advised the mother that we would send a mailing envelope to her and asked that she return the product in the envelope to my attention for our laboratory to analyze. Lot# A470C was manufactured from April 2, 2009 to May 14, 2009 yielding (b) (4) units (bottles) of product. No other complaints have been made on this Lot#. On April 19, 2011 a mailing envelope was sent to the mother to return the unused portion of the product. We received the product on April 26, 2011 and brought it to the laboratory for analysis. Finished product testing was conducted showing no signs of adulteration, contamination or deterioration. Micro testing was conducted demonstrating that the product was free from any microbial contamination. I attempted to contact the mother at 9:15AM, April 23,2011(left message), at 11:00AM, April 24,2011(left message) and again at 10:45AM, April 29, 2011 (left message). On May 2, 2011 at 10:50AM the mother called me to tell me that for over two weeks her son did not have any further incidents and has returned to normal. The EEGs were conducted by her pediatric neurologist who found no further problems. I asked that she have her doctor contact me for further discussion. I have not received any correspondence from her doctor as of this date, however we are reporting this incident as a matter of record.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS

MAY 13 2011

MAY 12 2011

7518414-X-00-01

CDER

CaseID: 7988073

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1 of 2

The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY
Triage unit sequence # 455293

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 6 Months	☐ Female ☑ Male	19 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
05/24/2011	05/26/2011

5. Describe Event, Problem or Product Use Error

On 5-23-2011 my wife purchased Humphreys Teething Tablets over the counter at Walgreens Pharmacy located at (b) (6) (b) (6) On the evening of 5-23-2011 my child was given the product as prescibed on the bottle to help with teething pain. On Monday 5-24-2011 at approximately 4pm we received a call from our childs day care that he had broken out in a severe deep hive like rash, and was having respatory problems. My wife picked him up and immediately took him to his pediatrician in (b) (6) The pediatricians office was unable to determine the cause of the rash. On the evening of 5-24-2011 our child was broken out

6. Relevant Tests/Laboratory Data, Including Dates

Doctor visits on 5-24-2011 and 5-25-2011 which they were ubale to determine the cause of the allergic reaction.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Coarctation of the Aorta, Surgery perfomed on (b) (6)

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 Humphreys Teething Pellets Not listed ndc0219-110300
#2

2. Dose or Amount	Frequency	Route
#1 3 pellets	2-4 hours	po
#2		

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 05/24/2011 -- 05/25/2011
#2

4. Diagnosis or Reason for Use (Indication)
#1 Teething Pain
#2

6. Lot #	7. Expiration Date
#1 ndc0219-110300	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
0219-110300

E. SUSPECT MEDICAL DEVICE

1. Brand Name: Humphreys Teething Pellets
2. Common Device Name: Teething Pellets
3. Manufacturer Name, City and State: Humphreys Pharmacal Inc East Hampton CT

4. Model #	Lot # 0219110300	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☑ Lay User/Patient ☐ Other:
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:

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

DS
JUN 01 2011

Phone # (b) (6)
E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☑ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

all over his body with a hive like rash, and was unable to sleep. On the morning of 5-25-2011 we again took him to see his pediatrician, who was not able to determine the cause of the sever rash and breathing problem. On the evening of 5-25-2011 my wife was about to give him the teething tablets again, I immediately stopped her and realized it was the only thing he had been given different in the recent days. I did a quick google search and noticed that a similiar product containing Belladonna had been banned by the FDA. I feel this product is what caused the sever allergic reaction to my child, and request an immediate investigation into Humphreys teething tablets.

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7545318-9-00-01

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/OLUNTARY reporting of events, product problems and product use errors

CaseID: 7998999

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 456286

Internet Submission - Page 1/2

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event, or Date of Birth: (b) (6) 13 Months	3. Sex ☑ Female ☐ Male	4. Weight 20.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
06/09/2011	06/09/2011

5. Describe Event, Problem or Product Use Error

I gave my daughter 3 Hyland teething tablets last night before bed in her bottle. She slept fine but woke this morning with a cough and minor upper respiratory wheezing. She drank a bottle, sounded better and went back to sleep. My husband said that she was super sleepy this morning and difficult to wake. She did go to daycare and was fine all day. When I picked her up this afternoon, her cheeks were really red. She doesn't seem to be getting sick this evening so the coughing seems really odd. This is the second or third time that I've noticed her have a cough after taking these tablets. I started evaluating what an allergy would look

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hyland Teething Tablets NDC 54973-7501-1
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 pills	every 2 hours	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 10/01/2010 04/08/2011
#2

4. Diagnosis or Reason for Use *(Indication)*
#1 teething
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 105476	#1
#2 109515	#2

9. NDC # or Unique ID
54973-7501-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

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 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

like and found the product recall today. I really wish that I had known.

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DSS
JUN 13 2011

7550989-7-00-01

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

OTC

Form Approved: OMB No. 09 10-0291 Expires 12/31/11
See OMB statement on reverse.

CaseID: 8007694

Mfr Report #

UF/Importer Report # 0000000000-2011-000002

FDA Use Only

FORM FDA 3500A (6/10) Page 1 of 3

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 4 1/2 Months or ____ Date of Birth:
3. Sex: [x] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [x] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [ ] Hospitalization - initial or prolonged
- [ ] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 5/12/11

4. Date of This Report (mm/dd/yyyy): 6/3/11

5. Describe Event or Problem

On May 12, 2011, at 5:06 PM EST we received an email through our company website from a customer who purchased a carton of Humphreys Teething Relief Pellets. The report from the respondent indicated that her granddaughter had apparent seizures after taking two of the teething pellets. She called a pediatrician and pharmacy and was told (in error) that there was a warning issued for the product. After receiving the email, I placed a call to the respondent at 11:45 AM on 5/13/11 to inform her that she was confusing our product with another brand that was, in fact, voluntarily recalled. I was sent to her voicemail and could not leave a message as her mailbox was full. I then proceeded to send an email to her stating that there had been no limit for use or removal of our product from the market, that we would do all that was necessary to resolve the issue and would like to discuss it further. I included both the company phone number and cell phone number and sent the email at 12:03 PM. I called again at 3:04 PM that same day and tried to establish a conversation with the respondent, however she hung up on me. I immediately called back, but there was no answer. On 5/13/11 at 7:20 PM I received an email from the

6. Relevant Tests/Laboratory Data, Including Dates

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7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 Humphreys Teething Relief Pellets
#2

2. Dose, Frequency & Route Used
#1 2 pellets oral 1 time
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 5/12/11
#2

4. Diagnosis for Use (Indication)
#1 Teething Relief
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [x] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 unknown
#2

7. Exp. Date
#1 N/A
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [x] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

SS
JUN 10 2011
JUN 09 2011

2. Health Professional? [ ] Yes [x] No
3. Occupation
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [ ] Unk.

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FDA USE ONLY

Ony)

1. Check One
☐ User Facility ☐ Importer

2. ...mber

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

Humphreys Pharmacal Inc.
31 East High Street
East Hampton, CT 06424

2. Phone Number
860-267-8710

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
5/12/11

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
seizure

9. Manufacturer Report Number
0000000000-2-11-000002

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
JUN 10 2011

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

JUN 09 2011

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

B.5. **Describe Event or Problem** *(continued)*

respondent who stated that she would contact me when she had a moment. I responded on 5/16/11 at 9:18 AM, stating that we believe that, like many people, she had confused our product with another brand of similar name which was voluntarily recalled. I also stated that Humphreys Pharmacal did not have any issues and was not the subject of a recall. On 5/16/11 at 11:37 AM she responded via email, stating that the pediatrician told her of a warning on our teething pellets and that the active ingredient belladonna is toxic. On 5/16/11 at 1:23 PM I responded via e-mail, again indicating that our products were not those in question and provided two links which detailed the recall of Hyland's teething products: http://www.fda.gov/safety/recalls/ucm230769.htm and http://www.hydlandsteething.com/recall/teething-tablet-recall-faq/html. In addition, I also provided information on the safety and efficacy of belladonna, referencing the governing compendium, The Homeopathic Pharmacopoeia of the United States (HPUS) and discussed the long history of safety of our product. Lastly I requested the lot number of the product from her and asked that she return the product to us for testing. On 5/16/11 at 6:01 PM via email, the respondent thanked us and provided a link as well: http://fda.gov/ForConsumers/ConsumerUpdates/ucm230762.htm. My last correspondence was on 5/17/11 at 3:14 PM in which I thanked her for the link and pointed out its mention of the long history of medicinal use and safety of the ingredient and asked her to contact us at her earliest convenience for further discussion. Also, I again encouraged her to provide us with the lot number of the product and any other information. To date, we have received no further correspondence from the respondent regarding this or any other issue. We are, however, reporting this incident as a matter of record.

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS

JUN 10 2011

JUN 09 2011

Individual Safety Report

7459691-3-00-01

CaseID: 8008866

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Submission - Page 1 CDER

Adverse Event Reporting Program

FDA USE ONLY

Triage unit sequence # 452541

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
BABY BOY In confidence	(b) (6) 8 Months	☐ Female ☑ Male	22.6 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/13/2010	05/03/2011

5. Describe Event, Problem or Product Use Error

BABY BOY AFTER Using Humphry's teething tablets showed seizure like behavior as indicated by ER doctor report on (b) (6) (b) (6) and then again on (b) (6) Child was given EEG and refered to pediactric neurologist on 4/28. All test normal no known illness. Childs seizures have stopped no longer taking teething tablets. Reported to manufacturer and sent back product to (b) (6) at Humphry's He has verbally reported that there were no abnormalities in testing and that they have never had any side effects from this product.

More

6. Relevant Tests/Laboratory Data, Including Dates

EEG Normal Lab test for product were done by humphry's (b) (6)

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

none, infant in good health

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☑ Returned to Manufacturer on: 04/22/2011 *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Humphy's teething tablets 3 humphy's

#2

2.	Dose or Amount	Frequency	Route
#1	6 tablets total	over 5 day period	Other
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*

#1 as needed for teething 04/09/2011 -- 04/13/2011

#2 --

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*

#1 seizure like behavior

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1 a470c	#1	a470c
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: teething tablets

2. Common Device Name: very cherry

3. Manufacturer Name, City and State: Humphy's Richard Harper 31 East High street PO Box 149 east hampton CT06424

4. Model #	Lot # a470c	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/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

RECEIVED
MAY 04 2011
MEDWATCH CTU

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

DSS
MAY 04 2011

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6) Email (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Other Health	☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 8047188

Individual Safety Report

7611477-2-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

For use by user-facilities, ~~ters, distributors~~ and manufacturers for MANDATORY reporting

Page 1 of 3

Mfr Report #

UF/Importer Report # 0000000000-2011-000003

FDA Use Only

FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	15 Months or Date of Birth:	☑ Female ☐ Male	40 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/03/2011	06/21/2011

5. Describe Event or Problem

On Tuesday, June 7, 2011 we received an email through our company website from an initial reporter (mother) who stated that upon administration of Humphreys Teething Relief Swift Strips her daughter experienced an alleged adverse reaction. After receiving the inquiry, I placed a call to the initial reporter that same day and left a message asking her to contact me. The following day on 6/8 at 6:00PM I received a phone call from the initial reporter. During the call she stated that after administering said product, her daughter experienced apparent seizures that later subsided. She subsequently took her daughter to the hospital for an EEG examination. I asked if she could return the product to us for our evaluation, however, she stated she no longer had it. I then set up a time to call her the next day on Thursday, 6/9 at 3:00 PM. During this call the reporter stated that at this time her daughter was fine and not experiencing any further adverse conditions. She also said that her daughter's EEG turned out to be normal showing she was not at risk for seizures. The reporter then said that she would also be taking her to a pediatric neurologist just to be sure everything was fine.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

RECEIVED
JUN 28 2011
L#513830
CBER/DCC

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 Humphreys Teething Relief Swift Strips

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate)*
#1 1 strip, 2X daily 047	#1 5/20/2011 - 6/2/2011
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 Teething Relief	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 unknown	#1 n/a	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 0219-4103-00

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name DSS

3. Manufacturer Name, City and State

JUL 08 2011

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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)*

JUN 28 2011

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	

CBER DCC
100044004

US

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No	NA	☐ Yes ☐ No ● Unk.

Individual Safety Report

7611477-2-00-02

CaseID: 8047188

FDA USE ONLY

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

Humphreys Pharmacal Inc.
31 East High Street
East Hampton, CT 06424

2. Phone Number: 860-267-8710

3. Report Source *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 6/3/2011

5. (A)NDA # / IND # / STN # / PMA/510(k) #

Combination Product: [ ] Yes
Pre-1938: [ ] Yes
OTC Product: [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- [ ] 5-day
- [ ] 30-day
- [ ] 7-day
- [ ] Periodic
- [ ] 10-day
- [x] Initial
- [x] 15-day
- [ ] Follow-up # ____

8. Adverse Event Term(s): seizure

9. Manufacturer Report Number: 0000000000-2011-000003

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Request
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- [ ] Yes [ ] No

6. Evaluation Codes *(Refer to coding manual)*

Method: ____ - ____ - ____ - ____
Results: ____ - ____ - ____ - ____
Conclusions: ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

DSS
JUL 08 2011

JUN 28 2011

Patient Information

1. Check One
- [ ] User Facility
- [ ] Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code: ____ - ____ - ____
Device Code: ____ - ____ - ____

11. Report Sent to FDA?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Outpatient Diagnostic Facility
- [ ] Home
- [ ] Ambulatory Surgical Facility
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

14. Manufacturer Name/Address

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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Individual Safety Report

7611477-2-00-03

(CONTINUATION PAGE)
For use by user-facilities,
s, distributors, and manufacturers
r MANDATORY reporting

FORM FDA 3500A (6/10) *(continued)*

B.5. Describe Event or Problem *(continued)*

When questioned about frequency of use, the initial reporter stated that she had been giving her daughter the product every day for two weeks, twice a day, one strip in the morning and one at night. Although there was no definitive correlation between said product and the alleged event, the reporter was concerned because of the recent recall of a similar product. We assured her that Humphreys did not have any issues with our products and we were not the subject of a recall. The voluntary recall that she had heard of was exclusive to the other company' s products. I concluded the discussion by stating we are willing to help in any way possible and offered to talk to her physician. She said not at this time, but would offer that suggestion during her next visit to her physician. No further communication has taken place since 6/9/2011. We are submitting this report as a matter of record.

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)*

DSS

JUL 08 2011

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

JUN 28 2011

Other Remarks

CaseID: 8060254

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Individual Safety Report

7631125-5-00-01

TC
user-facilities,
ors and manufacturers
TORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 2280705-2011-00018

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 19 Months or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*: 06/23/2011

4. Date of This Report *(mm/dd/yyyy)*: 07/14/2011

5. Describe Event or Problem

Consumer reported she applied the product for (b) (6) days before her child displayed any symptoms. On the (b) (6) day the child had a bluish skin color, swollen lips and was lethargic - basically unresponsive.

Child was given oxygen and transported to the hospital. He was given methylene blue and diagnosed with methemoglobinemia due to benzocaine in the product.

Child was reported to be better at the time the incident was reported.

Consumer did not return product for evaluation. A lot report was generated and no other similar complaints were reported for this lot code for this product. Review of batch records revealed no non-conformance.

6. Relevant Tests/Laboratory Data, Including Dates

CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 Baby Orajel® Daytime/Nighttime Twin Pack oral pain
#2 (continued) reliever for teething Benzocaine 7.5%

2. Dose, Frequency & Route Used
#1 Oral application 3X/day
#2

3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 6/17/2011-6/23/2011
#2

4. Diagnosis for Use *(Indication)*
#1 Teething Pain Relief
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 LL0228A
#2

7. Exp. Date
#1 8/2012
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
NDC# 10237-716-36

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

JUL 15 2011

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS

JUL 18 2011

2. Health Professional? ☐ Yes ☑ No
3. Occupation: NA
4. Initial Reporter Also Sent Report to FDA: ☐ Yes ☐ No ◉ Unk.

Individual Safety Report

7631125-5-00-02

FDA USE ONLY

IMPORTER (Devices Only)

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
Jill D. Ferentz
Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543
2. **Phone Number** 609-497-7139
3. **Report Source** *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 06/27/2011
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)** Methemoglobinemia
9. **Manufacturer Report Number** 2280705-2011-00018

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☑ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

Baby Orajel® Daytime/Nighttime Twin Pack oral pain reliever for teething labels are attached. The adverse event was associated with the Daytime Regular Formula.

This report and the information submitted under this report does not constitute an admission that the drug or Church & Dwight Co., Inc. or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight actually occurred.

DSS

JUL 15 2011 JUL 18 2011

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 (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 8060254

ntent & Color Break
0 pm, Dec 28, 2009

OLOR

Individual Safety Report
7631125-5-00-03

1.36 in
35.16 mm

1.35 in
34.37 mm

1.47 in
37.31 mm

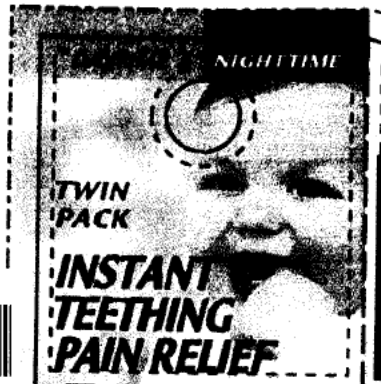
0.75 in
19.05 mm

189.71 mm

0.75 in
19.05 mm

NO INK
NO VARNISH

NO INK
NO VARNISH



#1 Teething Brand Used By Pediatricians

Baby Orajel

CONTAINS 2 TUBES
SAFETY SEALED TUBE TIPS

NEW & IMPROVED!

Baby Orajel

ORAL PAIN RELIEVER FOR TEETHING

DAYTIME REGULAR FORMULA

NIGHTTIME FORMULA

BENZOCAINE 7.5% / BENZOCAINE 10%

2 TUBES NET WT 0.18 OZ (5.1 g) EACH

Church & Dwight Co., Inc. Princeton, NJ 08543
© 2007 Church & Dwight Co., Inc.
BOJFC-31955-03V 1871025

3 10310 31955 7

Other information do not use if tube tip is cut prior to opening

Inactive ingredients ammonium glycyrrhizate, flavor, glycerin, polyethylene glycol, purified water, red 40, sodium saccharin, sorbic acid, sorbitol

NIGHTTIME Formula

Drug Facts

Active ingredient — **Purpose**
Benzocaine 10%..... Oral pain reliever

Use temporarily relieves sore gums due to teething in infants and children 4 months of age and older

Warnings

Allergy alert: do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use
- more than directed
- for more than 7 days unless told to do so by a dentist or doctor

When using this product
- fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

NIGHTTIME Formula

Drug Facts (continued)

Stop use and ask a dentist or doctor if
- sore mouth symptoms do not get better in 7 days
- irritation, pain or redness does not go away
- swelling, rash or fever develops

Keep out of reach of children.
In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions
- wash hands
- cut open tip of tube on score mark
- use your fingertip or cotton applicator to apply a small pea-size amount of Baby Orajel
- apply to the affected area up to four times daily or as directed by a dentist or doctor
- for infants under 4 months of age, ask a dentist or doctor

Other information do not use if tube tip is cut prior to opening

Inactive ingredients ammonium glycyrrhizate, flavor, glycerin, polyethylene glycol, purified water, red 40, sodium saccharin, sorbic acid, sorbitol

Questions or comments? call us at 1-888-852-8888 M-F 9am-5pm ET or visit our website at www.orajel.com

DAYTIME Regular Formula

Drug Facts (continued)

Directions
- wash hands
- cut open tip of tube on score mark
- use your fingertip or cotton applicator to apply a small pea-size amount of Baby Orajel
- apply to the affected area up to four times daily or as directed by a dentist or doctor
- for infants under 4 months of age, ask a dentist or doctor

DAYTIME Regular Formula

Drug Facts

Active ingredient — **Purpose**
Benzocaine 7.5%..... Oral pain reliever

Use temporarily relieves sore gums due to teething in infants and children 4 months of age and older

Warnings

Allergy alert: do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use
- more than directed
- for more than 7 days unless told to do so by a dentist or doctor

When using this product
- fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your dentist or doctor.

Stop use and ask a dentist or doctor if
- sore mouth symptoms do not get better in 7 days
- irritation, pain or redness does not go away
- swelling, rash or fever develops

Keep out of reach of children.
In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

DSS

JUL 18 2011

1.63 in
41.28 mm

1.38 in

1.63 in

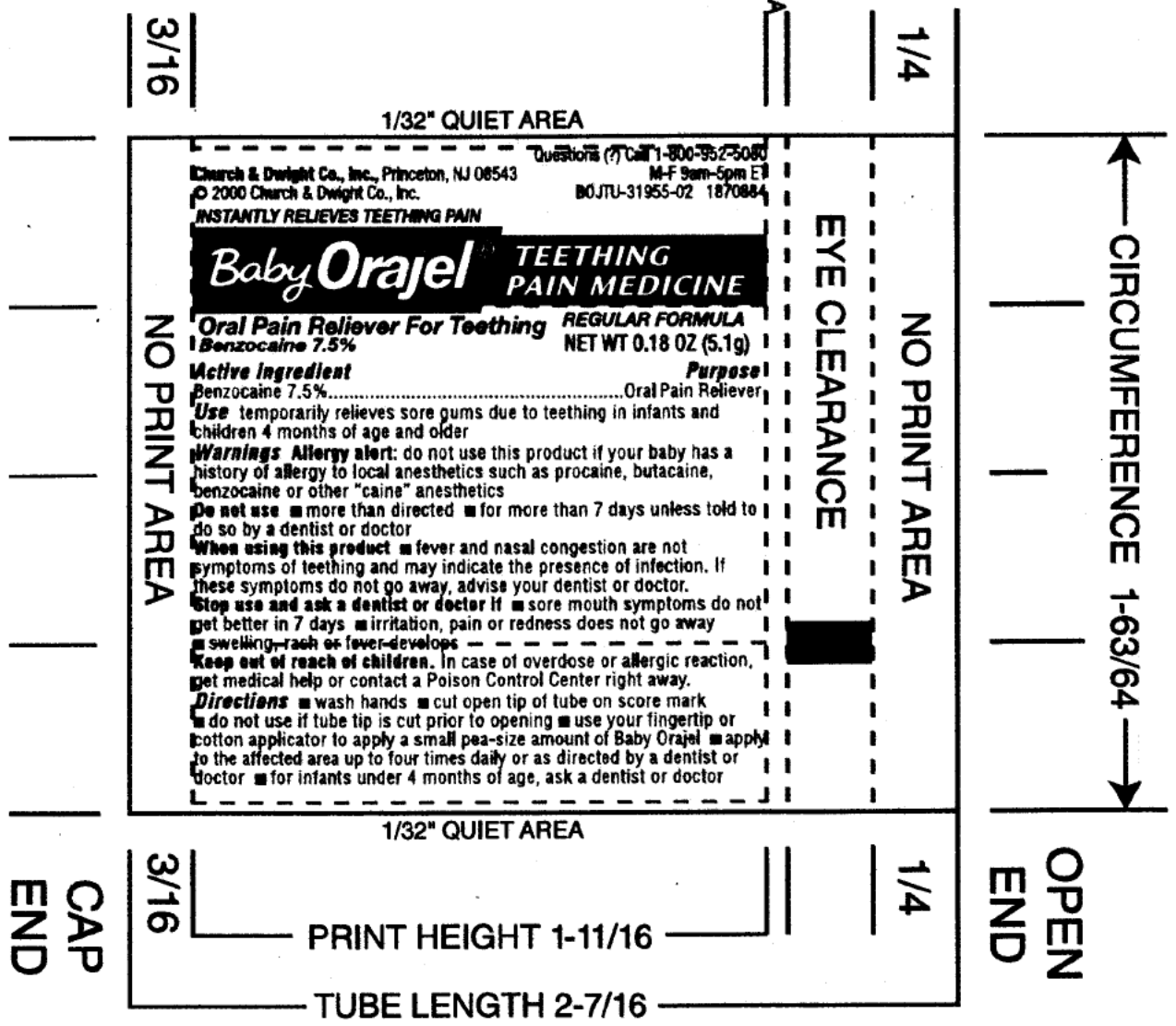
1.34 in

JUL 15 2011

DEL LABS.

5/8" X 2-7/16"

NOT FOR



(b) (4) (b) (4)

IGHT	JOB: Baby Orajel Teething Pain Medicine 5.1g			DSS	DATE:
).# 47-09-05559	CIRC: 1-63/64	SIZE: 5/8 x 2-7/16		SUB: WHITE	
(b) (4) K 1	(b) (4) DECK 2	BLACK DECK 3			JUL 18 2011

Any ink deck location can change provided the color order is maintai

75 50 25 5 1 PAPER 100 90 75 50 25

JUL 15 2011

CaseID: 8148601

Individual Safety Report

7755732-4-00-01

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

CDER

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only H Pad

Triage unit sequence # 462749

Page 1 of 23

A. Patient information

1. Patient identifier: see Attached — In confidence
2. Age at time of event: or Date of birth: (b) (6)
3. Sex: ☑ female ☐ male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☑ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ____
3. Date of event (mo/day/yr): 9/3/2011
4. Date of this report (mo/day/yr): 9/4/2011
5. Describe event or problem

See Attached Note from Pediatrician

RECEIVED
SEP 15 2011
MEDWATCH CTU

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

None

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Hyland's Baby Teething Tablets
   #2
2. Dose, frequency & route used
   #1 PRN 1 tablet
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 9/3/2011
   #2
4. Diagnosis for use (indication)
   #1 Teething
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
   #1 112759
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
   54973-3127-01
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ____
5. Expiration date (mo/day/yr)
6. model # DSS
   catalog #
   serial # SEP 15 2011
   lot #
   other #
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   (b) (6)
   (b) (6)
2. Health professional? ☑ yes ☐ no
3. Occupation: Physician
4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

9-1-11 462749

(b) (6)

Individual Safety Report

7755732-4-00-02

(b) (6)

(b) (6)

I had a patient admitted over the weekend, who had a very alarming reaction to a product.
This so called "teething tablet" was purchased in Walmart, (b) (6) at the baby section.
Produced by a company called Hyland's. This is a Homeopathic product, not regulated by the FDA. When you see in the ingredients listed, one of them is Belladonna alkaloid. The list does not include the mg being in a pill. So who can tell how much or so. The family gave me this bottle, with the pills in it.
This child touched a shrimp, did not ingest it, later went unresponsive for ~ 45 min also mother tells me her pupils were pinpoint.
No other symptoms noted. I am sure this was not an allergic reaction, but a toxic effect of Belladonna
I would like you to report it, find contact at the FDA, so we can start an investigation and pull this dangerous, unregulated product from the shelves.
Thank you so much (b) (6)

DSS
SEP 25/2011

CaseID: 8148601

Individual Safety Report

7755732-4-00-03

DSS

SEP 16 2015

CaseID: 8247199

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Individual Safety Report

7913562-4-00-01

OTC

...is by user facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	5 Months	☑ Female	14 lbs
In confidence	or Date of Birth:	☐ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/16/2011	10/28/2011

5. Describe Event or Problem

MOTHER STARTED BABY TEETHING TABLETS FOR THE FIRST TIME ON 10/15/11 AND GAVE 1 TABLET AT A TIME EVERY HOUR FOR 3 DOSES (SO 3 TABLETS TOTAL ON 10/15/11). NO OTHER DOSES OF BABY TEETHING TABLETS GIVEN. LATE (b) (6) (b) (6) EYES STARTED SHAKING (NYSTAGMUS), UPPER BODY TREMORS(HEAD, NECK, ARMS). WENT TO THE ER (b) (6) AT NOON, NOT ADMITTED TO HOSPITAL. IN THE HOSPITAL, NEUROLOGY ASSESSED CHILD. MOTHER WAS TOLD TO OBSERVE THE CHILD AND SENT HOME. THE MORNING OF (b) (6) SEIZURES WORSENED AND MOTHER AND CHILD WENT BACK TO THE ER. PERFORMED CT SCAN WHICH WAS NORMAL. TOLD TO CONTINUE TO MONITOR SYMPTOMS AND SEE A NEUROLOGIST IN 2 WEEKS. MOTHER ALSO REPORTED THAT CHILD HAD A LOW GRADE FEVER OFF AND ON FROM 10/11 TO 10/13 (UP TO 101.6F). WENT TO SEE PMD ON 10/13 AND BLOOD WORK SHOWED "SLIGHTLY ELEVATED WBC" PER MOTHER. CHILD GIVEN AN INJECTION OF ROCEPHIN ON 10/14. NO ANTI-SEIZURE MEDS HAVE BEEN PRESCRIBED AT THIS TIME.

RECEIVED

NOV 10 2011

CDR

6. Relevant Tests/Laboratory Data, Including Dates

10/13/11: BLOOD TESTS (SHOWED SLIGHTLY ELEVATED WHITE BLOOD CELL COUNT)

(b) (6) CT SCAN (RESULTS NORMAL)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO KNOWN ALLERGIES.
TAKING LACTULOSE FOR CHRONIC CONSTIPATION.
GIVEN AN INJECTION OF ROCEPHIN ON 10/14/11.
VENTRICULAR SEPTAL DEFECT.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2 ROCEPHIN

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TABLET X 3 DOSES	#1 EVERY HOUR 10/15/2011
#2 INJECTION UNKNOWN DOSE	#2 10/14/2011

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 IRRITABILITY / TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ANTIBIOTIC	#2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 112799	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☑ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS

NOV 14 2011

NOV 10 2011

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No		☐ Yes ☐ No ◉ Unk.

Individual Safety Report

7913562-4-00-02

CaseID: 8247199

FDA USE ONLY

1. **Check One** ☐ User Facility ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report** ☐ Initial ☐ Follow-up # ____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. **Location Where Event Occurred**
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number**
310-768-0700

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
10/17/2011

5. (A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**
SEIZURES

9. **Manufacturer Report Number**
54973 AE # 616

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. **If Follow-up, What Type?**
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?** ☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. **If Remedial Action Initiated, Check Type**
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. **Usage of Device**
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
NOV 10 2011 NOV 14 2011

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
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Please DO NOT RETURN this form to this address.

NOV 10 2011

Individual Safety Report

7913562-4-00-03

CaseID: 8247199

ER COMPLAINT RECORD

COMPLAINT #: 1067

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/17/2011

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: 135 TABLETS

LOT NO.: 112799

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: STARTED USING SATURDAY NIGHT 10/15 BECAUSE CHILD WAS IRRITABLE WITH SPOT ON GUM. FIRST TIME SHE USED. GAVE 1 TABLET AT A TIME EVERY HOUR UP TO 3 TABLETS. LATE (b) (6) EYES STARTED SHAKING (NYSTAGMUS), UPPER BODY TREMORS (HEAD, NECK, ARMS). WENT TO ER (b) (6) AT NOON, NOT ADMITTED. IN THE HOSPITAL NEUROLOGY ASSESSED HER AND THEY THOUGHT BELLADONNA IN THE TEETHING TABLETS COULD HAVE CAUSED IT. THIS MORNING SEIZURES WORSENED AND WENT BACK TO THE ER. DID CT SCAN (NORMAL). RECOMMENDATION TO CONTINUE TO MONITOR AND SEE NEUROLOGIST IN 2 WEEKS. ALSO REPORTED THAT THE CHILD HAD A FEVER ON AND OFF FROM TUES. 10/11/11- THURS. 10/13/11(LOW GRADE 101.8). DID BLOOD WORK AT PMD ON 10/13 SHOWED SLIGHTLY ELEVATED WBC. GAVE A SHOT OF ANTIBIOTICS (SOUNDED LIKE ROCEPHIN) ON 10/14, BUT EPILEPSY NEUROLOGIST SAID THAT ROCEPHIN WOULD NOT LIKELY BE THE CAUSE OF SEIZURE. NO ANTISEIZURE MEDICINE PRESCRIBED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

10/17/11- GAVE ADDRESS TO SEND BACK.

PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) N

DATE REQUESTED PRODUCT BE RETURNED: 10/17/2011

UPS CALL TAG ISSUED: Y (CIRCLE ONE) N

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: ORGANOLEPTIC TESTS WERE DONE ON THE FOLLOWING LOT NUMBERS: 112783,112799, AND 112825 AND EVERYTHING LOOKED FINE. PRIOR TO RELEASE, BELLADONNA ALKALOIDS ASSAY AND MICRO TEST WERE PERFORMED, AND THEY WERE ALL WITHIN SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/17/2011

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 616

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/17/2011 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: R Wall

DATE: 10-26-11

DSS

NOV 14 2011

BY: Regineen Darlene
QA / QC DIRECTOR

DATE: 10-26-11

cc: QA / QC
Packaging
Production
Shipping / Receiving

NOV 10 2011

Form # VD1

NOV 10 2011

Individual Safety Report

7913562-4-00-04

CaseID: 8247199

Hyland's

DVERSE EVENT DATA FORM

AE #: 616 COMPLAINT #: 1067

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

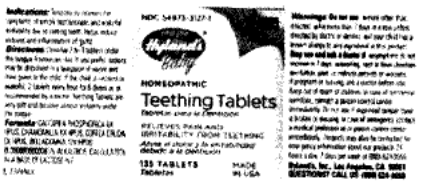
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

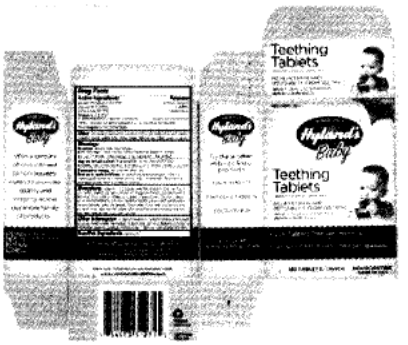
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Walter DATE: 10-26-NOV 14 2011

DSS

BY: Regina Paulin DATE: 10-26-11

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

NOV 10 2011

CaseID: 8267907

Individual Safety Report

7929632-0-00-01

OTC

For use by user facilities, rs, distributors and manufacturers r MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	3 Months or Date of Birth:	☑ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/13/2011	10/26/2011

5. Describe Event or Problem

ON 10/13/11, MOTHER GAVE CHILD ONE HYLAND'S TEETHING TABLET. NEXT DAY, 10/14/11, CHILD HAD SYMPTOMS OF SWEATING, CONSTIPATION AND CRANKINESS. ON (b) (6) THESE SYMPTOMS WORSENED; MOTHER TOOK THE CHILD TO SEE PHYSICIAN AND IN THE OFFICE THE CHILD HAD AN ELEVATED HEART RATE. THE HEART RATE WAS UP TO 280 - 300 BPM WITH SVT (SUPRAVENTRICULAR TACHYCARDIA). CHILD WAS HOSPITALIZED (b) (6) FOR THE SVT AND RELEASED ON (b) (6)

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 1 TABLET ON 10/13/11	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 113051	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

[redacted] 2011

NOV 16 2011

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Pharmacist	☐ Yes ◉ No ☐ Unk.

Individual Safety Report

7929632-0-00-02

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- ☐ Death
- ☐ Serious Injury
- ☐ Malfunction
- ☐ Other:

2. If Follow-up, What Type?
- ☐ Correction
- ☐ Additional Information
- ☐ Response to FDA Request
- ☐ Device Evaluation

3. Device Evaluated by Manufacturer?
- ☐ Not Returned to Manufacturer
- ☐ Yes ☐ Evaluation Summary Attached
- ☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*

Method				
Results				
Conclusions				

7. If Remedial Action Initiated, Check Type
- ☐ Recall
- ☐ Repair
- ☐ Replace
- ☐ Relabeling
- ☐ Notification
- ☐ Inspection
- ☐ Patient Monitoring
- ☐ Modification/ Adjustment
- ☐ Other:

8. Usage of Device
- ☐ Initial Use of Device
- ☐ Reuse
- ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

NOV 16 2011

DSS
NOV 17 2011

☐ User Facility ☐ Importer

2. [illegible] Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- ☐ Initial
- ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code			
Device Code			

11. Report Sent to FDA?
- ☐ Yes _____ *(mm/dd/yyyy)*
- ☐ No

12. Location Where Event Occurred
- ☐ Hospital
- ☐ Home
- ☐ Nursing Home
- ☐ Outpatient Treatment Facility
- ☐ Outpatient Diagnostic Facility
- ☐ Ambulatory Surgical Facility
- ☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
- ☐ Yes _____ *(mm/dd/yyyy)*
- ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
- ☐ Foreign
- ☐ Study
- ☐ Literature
- ☑ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

5.
- (A)NDA # _____
- IND # _____
- STN # _____
- PMA/ 510(k) # _____
- Combination Product ☐ Yes
- Pre-1938 ☐ Yes
- OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☑ Initial
- ☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number

54973 AE # 622

8. Adverse Event Term(s)

INCREASED HEART RATE (SVT)

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

CaseID: 8267907

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: 1085

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/21/11

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: 135 TABLETS

LOT NO.: 113051

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WALGREEN'S PHARMACIST REPORTED THAT MOTHER CALLED AND STATED SHE HAS PURCHASED BABY TEETHING TABLETS. ON THURSDAY, 10/13/11, GAVE CHILD 1 TAB. ON FRIDAY, 10/14/11, CHILD HAD SYMPTOMS OF SWEATING, CONSTIPATION, AND CRANKINESS. ON (b) (6) SYMPTOMS WORSENED AND CHILD TALEN TO M.D. WHERE SHE HAD HIGH HEART RATE @ THE DOCTOR'S OFFICE AND WAS SUBSEQUENTLY HOSPITALIZED THAT SAME DAY WITH HEART RATE OF 280 – 300 BPM WITH SVT. RELEASED ON (b) (6) MOTHER CALLED WALGREEN'S BECAUSE SHE SAW ON THE INTERNET REGARDING THE RECALL. I INFORMED PHARMACIST THAT THIS PARTICULAR BOTTLE IS NOT PART OF THE RECALL. I ASKED PHARMACIST TO TELL MOTHER TO CALL US.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

10/24/11: I FOLLOWED UP WITH PHARMACIST AND ASKED HER TO CALL MOTHER TO TELL HER THAT IT'S IMPORTANT THAT SHE CALL US. PHARMACIST (b) (6) SAID SHE WOULD CALL MOTHER.

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

NOV 16 2011

DATE PRODUCT RECEIVED:

CDR

SECTION II: INVESTIGATION

INVESTIGATION: PERFORMED ORGANOLEPTIC TESTS ON 3 RETAINED SAMPLES. RESULTS OF TESTED BATCHES MATCH PRODUCT SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/21/11

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 622

ADVERSE EVENT SERIOUS: Y / N

ADVERSE EVENT REPORTED ON: 10/21/11

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 10-31-11

BY:
QA / QC DIRECTOR

DATE: 10-31-11

cc: QA / QC
Packaging
Production
Shipping / Receiving

NOV 16 2011

Individual Safety Report

7929632-0-00-03

Individual Safety Report

7929632-0-00-04

CaseID: 8267907

Hyland's

S ADVERSE EVENT DATA FORM

AE #: 622 **COMPLAINT #:** 1085

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: UNKNOWN FEMALE CHILD

ADDRESS:

CITY: STATE: (b) (6)

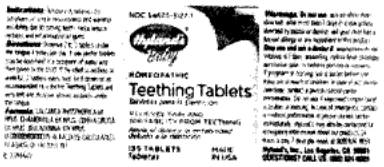
COUNTRY: USA ZIP CODE:

PHONE #:

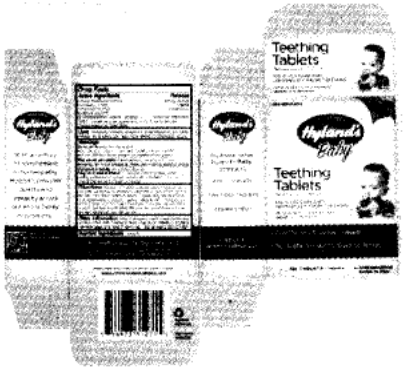
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-31-11

BY: QA / QC DIRECTOR DATE: 10-31-11

DSS NOV 17 2011

DISTRIBUTION: FDA ADVERSE EVENT FILE NOV 16 2011 FORM SAE01

CaseID: 8275969

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Individual Safety Report

7949125-4-00-01

for use by user-facilities, distributors and manufacturers MANDATORY reporting

Page 1 of 4

OTC

Mfr Report # 54973

Mfr/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 14 Months — or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 11/01/2011

4. Date of This Report (mm/dd/yyyy): 11/03/2011

5. Describe Event or Problem

GRANDMOTHER GAVE HER GRANDSON 2 BABY TEETHING TABLETS AT 11:30 THIS MORNING AND A HALF HOUR LATER HE HAD "A PETIT MAL SEIZURE". HE WAS STRETCHED OUT ON THE FLOOR UNDER THE TABLE AND WAS "TENSE". SHE GAVE HIM A "CHEST RUB" AND HE "CAME TO" WITH GLOSSY EYES, LETHARGIC AND DROOPY.

A DOCTOR WAS CALLED AND HE SAID TO BRING IN THE CHILD ONLY IF HE HAD ANOTHER EPISODE. CHILD HAD IBUPROFEN YESTERDAY FOR "MOUTH ULCERS". HE WAS ALSO VACCINATED IN SEPTEMBER 2011. CHILD ALSO HAD BREASTMILK.

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NOV 23 2011
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6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HISTORY OF GRAND MAL SEIZURE ON MOTHER'S SIDE (CHILD'S MATERNAL AUNT).

EAR INFECTION 2 WEEKS PRIOR TO EVENT.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2TABLETS X 6HRS X 3DAYS
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
TYLENOL AND IBUPROFEN

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Other #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

DSS
NOV 28 2011

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

NOV 23 2011

2. Health Professional? ☑ Yes ☐ No

3. Occupation: Other Healthcare Professional

4. Initial Reporter Also Sent Report to FDA: ☐ Yes ◉ No ☐ Unk.

Individual Safety Report

7949125-4-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

TUTTI GOULD
HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
11/01/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 AE # 635

8. Adverse Event Term(s)
PETIT MAL SEIZURE

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

RECEIVED
NOV 23 2011
CDR

DSS
NOV 28 2011

NOV 23 2011

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 8275969

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: 1106

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 11/01/11

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE:

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE GRANDSON 2 BABY TEETHING TABLETS AT 11:30 THIS MORNING AND A HALF HOUR LATER HE HAD "A PETIT MAL SEIZURE". HE WAS STRETCHED OUT ON THE FLOOR UNDER THE TABLET AND WAS "TENSE". SHE GAVE HIM A "CHEST RUB" AND HE "CAME TO" WITH GLOSSY EYES, LETHARGIC AND DROOPY. A DOCTOR WAS CALLED AND HE SAID TO BRING IN THE CHILD ONLY IF HE HAD ANOTHER EPISODE. THE CHILD HAD IBUPROFEN YESTERDAY FOR "MOUTH ULCERS". HE WAS ALSO VACCINATED IN SEPTEMBER 2011. THERE IS A HISTORY OF GRAND MAL SEIZURES (CHILD'S MATERNAL AUNT). CHILD HAD AN EAR INFECTION 2 WEEKS PRIOR AND WAS TREATED WITH TYLENOL AND IBUPROFEN. URGED GRANDMOTHER TO TAKE CHILD TO BE ASSESSED BY A DOCTOR.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

Individual Safety Report
7949125-4-00-03

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: PERFORMED ORGANOLEPTIC TESTING ON LOT NUMBERS 113079, 113114, AND 113207. RESULTS WERE WITHIN STANDARD SPECIFICATIONS. CHECKED MICRO AND ASSAY RESULTS WHICH PASSED SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/01/11

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

DSS
NOV 28 2011

SECTION IV: ADVERSE EVENT REPORTS

AE #: 635

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/01/11

BY: TUTTI GOULD

NOV 23 2011

SECTION V:

REVIEWED BY MANAGEMENT BY: R Walt

DATE: 11-11-11

BY: Dyanna Dahlen
QA / QC DIRECTOR

DATE: 11-10-11

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

CaseID: 8275969

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 635 **COMPLAINT #:** 1106

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

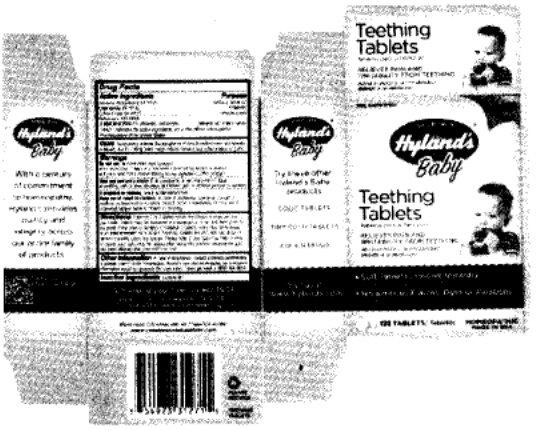
E-MAIL:

Individual Safety Report
7949125-4-00-04

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY: DATE: NOV 28 2011

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 11-11-11 NOV 23 2011

BY: QA / QC DIRECTOR DATE: 11-10-11

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

mld 4.25.11. Article# Case ID: 8285750 10048625 9365

Individual Safety Report

7967839-7-00-01

MEDWATCH

FORM FDA 3500A (6/10)

OTC

For use by user-facilities, orters, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Page 1 of 4

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	2 Years	☑ Female ☐ Male	27 lbs
In confidence	or Date of Birth:		or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
04/05/2011	04/20/2011

5. Describe Event or Problem

CHILD HAD DOSE OF TEETHING GEL PLACED ON GUMS IN THE AM. SEVERAL HOURS LATER, CHILD DEVELOPED A FEVER AND WAS GIVEN UNKNOWN DOSE OF ACETAMINOPHEN THEN ANOTHER DOSE OF TEETHING GEL. ABOUT 1 HOUR LATER, CHILD BECAME LETHARGIC, VOMITING, DELIRIOUS, AND STARTED TO TALK TO THINGS AND PEOPLE THAT WERE NOT THERE.

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CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO KNOWN ALLERGIES; NO PRE-EXISTING CONDITIONS; NO CONCOMITANT MEDICINES

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING GEL

#2 ACETAMINOPHEN

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 AS DIRECTED X 2 DOSES	#1
#2 UNKNOWN DOSE X 1	#2

4. Diagnosis for Use *(indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 100821P	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7521-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

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DEC 08 2011

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No	NA	☐ Yes ☐ No ◉ Unk.

DEC 07 2011

Individual Safety Report

7967839-7-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)* Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
204 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number** 310-768-0700
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 04/05/2011
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)** FEVER, VOMITING, LETHARGIC, DELIRIUM
9. **Manufacturer Report Number** 54973 AE # 424

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)* Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

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The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

DEC 07 2011

CaseID: 8285750

Individual Safety Report

7967839-7-00-03

TOMER COMPLAINT RECORD

COMPLAINT #: 779

DATE OF COMPLAINT: 04/05/2011

PRODUCT: TEETHING GEL

ITEM CODE: TGEL

SIZE:

LOT NO.: 1008P1

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE DOSE OF TEETHING GEL TO CHILD THIS MORNING AND IS THE FIRST TIME USING THE PRODUCT. LATER CHILD DEVELOPED A FEVER. GAVE THE CHILD ACETAMINOPHEN THEN TEETHING GEL AGAIN SHORTLY AFTER BECAUSE SHE THOUGHT SYMPTOMS WERE DUE TO TEETHING. AFTER 2ND USE OF TEETHING GEL, CHILD WAS LETHARGIC, THREW-UP AND "TALKING TO NOTHING". LIKE HALLUCINATING. CUSTOMER USED TEETHING TABS IN THE PAST AND HAD NO REACTION. FEVER AT THE TIME OF PHONE CALL WAS ABOUT 100° GRANDMOTHER ATTRIBUTED THE FEVER TO CHILD CUTTING MOLARS. TOLD GRANDMOTHER TO CONTACT A PHYSICIAN REGARDING SYMPTOMS CHILD IS EXPERIENCING. THE CHILD FEELS BETTER AFTER VOMTING.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: REVIEWED THE C OF A FOR LOT# 100821P AND ALL TEST RESULTS ARE WITHIN SPECIFICATIONS (SEE ATTACHED).

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 04/05/2011

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 424

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 04/05/2011 BY: EDYTA FRACKIEWICZ

SECTION V:

DSS

REVIEWED BY MANAGEMENT BY:

DATE: 04-22-11 DEC 08 2011

BY:

QA / QC DIRECTOR

DATE: 04/22/11

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

DEC 07 2011

Individual Safety Report

7967839-7-00-04

CaseID: 8285750

Hyland's

US ADVERSE EVENT DATA FORM

AE #: 424 COMPLAINT #: 779

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

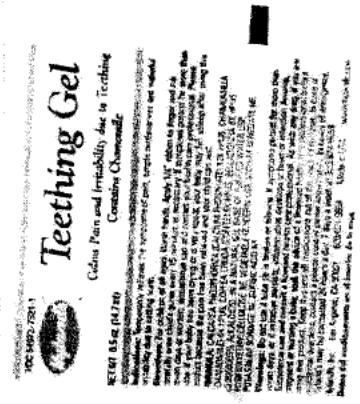
COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Walt DATE: 04-22-11 DSS

BY: QA / QC DIRECTOR DATE: 04/22 DEC 08 2011

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SR01

DEC 07 2011

CaseID: 8315407

Individual Safety Report

8001476-3-00-01

FDA Facsimile Approval 07/13/2006(Oracle)

Mfr report # 2011AP002941

UF/Importer Report #

"+" indicates item continued

FDA Use Only

FORM FDA 3500A (10/05)

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence

2. Age at Time of Event: 33 YEARS or Date of Birth: (b) (6)

3. Sex: [ ] Female [X] Male

4. Weight: 300 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g. defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death (mm/dd/yyyy)
- [ ] Life-threatening
- [X] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [X] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [X] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 01/04/2007

4. Date of This Report (mm/dd/yyyy): 12/13/2011

5. Describe Event or Problem

Reference number 2011AP002941 is a spontaneous case report received on 02-Dec-2011 from an attorney pertaining to a 33-year-old male who experienced plantar fasciitis, foot pain, fall, thoracolumbar strain, pharyngitis, myalgia, fatty liver infiltration, diabetes mellitus, gastritis, light headedness, nausea, thyroid nodule, urinary tract infection (UTI), navicular fracture, unspecified viral infection, fatigue, bodyaches, chest pain, sleep apnea, snoring, back injury, back pain, cellulitis of foot, rash to his leg foot and elbow and drug reaction while using lisininopril, hydrochlorothiazide (strength and manufacturer unknown), hydroxycut carb control capsules, hydroxycut hardcore drink packets (ignition stix) , hydroxycut hardcore ready to drink, hydroxycut max liquid caps, hydroxycut natural caplets, hydroxycut regular rapid release caplets and vicodin.

Patient had a medical history of pharyngitis, fractured lumbar spine, bulging cervical discs, hypertension, motor vehicle accident (lower back pain, band and shoulder pain), insomnia, possible aseptic meningitis (required hospitalization in (b) (6) cultures were negative), ulnar styloid fractures, work accident/hit by forklift (2003, lower back strain and shoulder instability), headaches, earaches, hypertriglyceridemia, hypercholesterolemia, dorsal +

6. Relevant Tests/Laboratory Data, Including Dates

06-FEB-2006: ALT 165 (10-50), AST 80 (13-40)
15-JUN-2007: abdominal ultrasound-possible fatty infiltration of liver
21-JUN-2007: AST 138 (13-40), ALT 226 (10-50)
09-AUG-2007: MRI-thyroid nodule, TSR WNL
11-OCT-2007: wrist x-ray-possible subtle fracture along the neck of the navicular bone
26-NOV-2007: TSR WNL, triglycerides 288 (30-200), +

7. Other Relevant History,Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PHARYNGITIS
LUMBAR VERTEBRAL FRACTURE
SLIPPED CERVICAL DISC
buldging servical disc
MOTOR VEHICLE ACCIDENT
Motor vehicle accident caused lower back pain,hand pain and shoulder pain.
INSOMNIA
ASEPTIC MENINGITIS +

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 LISINOPRIL TABLETS
#2 HYDROCHLOROTHIAZIDE

2. Dose, Frequency & Route Used
#1
#2 25 MG;QD;PO

3. Therapy Dates (If unknown, give duration)
#1 - 06/10/2008
#2 08/22/2003 - 06/10/2008

4. Diagnosis for Use (Indication)
#1 HYPERTENSION
#2 HYPERTENSION

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [ ] doesn't apply
#2 [ ] Yes [ ] No [ ] doesn't apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] doesn't apply
#2 [ ] Yes [ ] No [X] doesn't apply

9. NDC# or Unique ID: N/A

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

CLONIDINE	-
VALSARTAN	-
ATORVASTATIN CALCIUM	- 06/--/2007
FELODIPINE	-
ATENOLOL	-
CHLORTALIDONE	-

+

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9
CANADA

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2. Phone Number: 416-749-9300

3. Report Source (Check all that apply)
[ ] Foreign
[ ] Study
[ ] Literature
[ ] Consumer
[ ] Health Professional
[ ] User Facility
[ ] Company Representative
[ ] Distributor
[X] Other: LAWYER

4. Date Received by Manufacturer (mm/dd/yyyy): 12/02/2011

5. NDA # ANDA 076102
IND #
STN #
PMA/510(k) #
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [ ] Yes

DSS

6. If IND, Give Protocol #: N/A

7. Type of Report (Check all that apply)
[ ] 5-day [ ] 30-day
[ ] 7-day [ ] Periodic
[ ] 10-day [X] Initial
[X] 15-day [ ] Follow-up #

8. Adverse Event Term(s)
Plantar fasciitis
Pain in extremity
Fall
Muscle strain
Pharyngitis
Myalgia
Hepatic steatosis +

DEC 21 2011

9. Manufacturer Report Number: 2011AP002941

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone # (b) (6)
UNITED STATES

DEC 19 2011

2. Health Professional? [ ] Yes [X] No

3. Occupation: CON

4. Initial Reporter Also Sent Report to FDA? [ ] Yes [ ] No [X] Unk

FDA
3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report

8001476-3-00-02

FDA Facsimile Approval 07/13/2006(Oracle)

Mfr report #	2011AP002941
UF/Importer Report #	
	FDA Use Only

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler, if known)*

#3 HYDROXYCUT

#4 VICODIN

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#3 See cont page	#3 See cont page
#4	#4

4. Diagnosis for Use *(Indication)*

#3 DRUG USE FOR UNKNOWN INDICATION

#4 BACK PAIN

6. Lot #	7. Exp. Date
#3 See cont page	#3 See cont page
#4	#4

5. Event Abated After Use Stopped or Dose Reduced?

#3 ☐ Yes ☐ No ☐ doesn't apply

#4 ☐ Yes ☐ No ☐ doesn't apply

8. Event Reappeared After Reintroduction?

#3 ☐ Yes ☒ No ☐ doesn't apply

#4 ☐ Yes ☐ No ☐ doesn't apply

DSS

DEC 21 2011

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Apotex Inc. - Mfr. report # 2011AP002941

B2. Other Outcome - Continued

Med Significant - MEDICALLY SIGNIFICANT

B5. Describe Event or Problem - Continued

calcaneal spur, smoked 1/2 to 1 pack (for 10-20 years, chewing tobaco use), alcohol use (weekly to twice monthly), subconjunctival hemorrhage, mild hepatomegaly, abdominal pain, upper respiratory infection, increased aspartate aminotransferase (AST) and alanine aminotransferase (ALT), tinea pedis, eczema, dyspepsia, hand laceration, GERD, achilles tendon avulsion (subsequent mild spurring), recurrent UTIs, renal calculi and plantar fasciitis. Patient's concomitant medications included clonidine, Diovan (valsartan), Lipitor (atorvastatin calcium) (drug discontinued in Jun-2007), Plendil (felodipine), Tenoretic (atenolol and chlortalidone) and Atarax (hydroxyzine).

On an unknown date, the consumer started using lisinopril (dose and frequency unknown) for hypertension and vicodin (dose and frequency unknown) for back pain. On 22-Aug-2003, the patient started treatment with hydrochlorothiazide for hypertension. On an unspecified date in 2007, the patient started using hydroxycut carb control capsules, hydroxycut natural caplets and hydroxycut regular rapid release caplets. In Nov-2007, patient started Hydroxycut max liquid caps. In Feb-2009, he started with hydroxycut hardcore drink packets (ignition stix). In Apr-2009, hydroxycut hardcore ready to drink was started. It should be noted that hydroxycut hardcore drink packets (ignition stix), hydroxycut hardcore ready to drink and hydroxycut max liquid caps were not available until Feb-2009, Apr-2009, and Nov-2007 respectively. On 04-Jan-2007, after starting the product, the patient experienced recurrent plantar fasciitis (PLANTAR FASCIITIS) and foot pain (FOOT PAIN) which was treated with an injection of lidocaine, marcaine and celestone Soluspan (betamethasone injectable suspension). On an unspecified date in Feb-2007, the consumer fell (FALL) and injured his back (BACK INJURY). He was diagnosed with thoracolumbar strain (LUMBAR STRAIN) and treated with Flexeril (cyclobenzaprine hydrochloride) and another undecipherable medication. On 05-Feb-2007, he developed an unspecified viral infection (VIRAL INFECTION) with symptoms of fatigue (FATIGUE) and body aches (ACHE). On 08-Feb-2007, he was diagnosed with pharyngitis (PHARYNGITIS) after developing a headache, coughing and a sore throat. Treatment included amoxicillin. On an unspecified date in Jun-2007, the consumer experienced myalgia (MYALGIA) (resolved on an unknown date). On 15-Jun-2007, an abdominal ultrasound revealed possible fatty infiltration of the liver (FATTY LIVER INFILTRATION). On 21-Jun-2007, the consumer's ALT was 226 (10-50) and his AST was 138 (13-40). On 27-JUN-2007, the consumer was evaluated for burning stomach pain and diagnosed with gastritis (GASTRITIS). Treatment included omeprazole 20 mg. On 28-JUN-2007, a gastroenterologist confirmed the consumer's fatty liver disease and recommended weight loss, decreasing alcohol intake, and rechecking the liver function tests in 3 months. On 27-Jul-2007, the consumer became light headed (LIGHT HEADEDNESS) and nauseous (NAUSEA) after taking vicodin. The lightheadedness and nausea resolved the same day, and vicodin use continued. On 09-Aug-2007, magnetic resonance imaging (MRI) revealed a thyroid nodule (THYROID NODULE). Thyroid-stimulating hormone (TSH) was within normal limits (WNL), and it was ultimately determined that that thyroid nodule was of no consequence. On 02-OCT-2007, he was diagnosed with an UTI (UTI). On 11-OCT-2007, the consumer fell, injured his wrist, and was in pain. An x-ray revealed a possible subtle fracture along the neck of the navicular bone (NAVICULAR FRACTURE), and the wrist was splinted. The information regarding resolution and other treatment could not be deciphered. On 26-NOV-2007, lab work was repeated and revealed TSH WNL, triglycerides 288 (30-200), cholesterol 238 (less than 200), glucose 165 (65-115), AST 45 (13-40), and ALT 105 (10-50). On 09-Jan-2008, his A1C was 6.2 (4.8-6.0). On 14-Jan-2008, the consumer's medical records note controlled diabetes mellitus (DIABETES MELLITUS). On 12-Mar-2008, the consumer experienced chest pain (CHEST PAIN). Troponins, cardiac markers, electrocardiogram (EKG) and a chest x-ray were within normal limits. He was treated with Aspirin (acetylsalicylic acid) 325 mg. Medical records from 02-Jun-2008 note sleep apnea (SLEEP APNEA), snoring (SNORING), and continued back pain (BACK PAIN) from previous falls. He was advised to schedule a sleep study to further evaluate the sleep apnea, but the consumer refused. On 03-Jun-2008, he was diagnosed with cellulitis of the right foot (CELLULITIS OF FOOT) and treated with Augmentin (amoxicillin and clavulanate). On 10-Jun-2008, the consumer was re-evaluated as a rash had spread to his legs, foot, and elbows (RASH) and was diagnosed with a drug reaction (DRUG ALLERGY), and treatment with lisinopril, hydroxycut carb control capsules, hydroxycut hardcore drink packets (ignition stix), hydroxycut hardcore ready to drink, hydroxycut max liquid caps, hydroxycut natural caplets, hydroxycut regular rapid release caplets and HCTZ were discontinued.

The manufacturer of lisinopril and hydrochlorothiazide was not identified however, Apotex product cannot be ruled out from consideration.

DSS

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Apotex Inc. - **Mfr. report #** 2011AP002941

B6. Relevant Tests/Laboratory Data - Continued

cholesterol 238 (less than 200), glucose 165 (65-115), AST 45 (13-40), ALT 105 (10-50)
09-JAN-2008: A1C 6.2 (4.8-6.0)
12-MAR-2008: troponins, cardiac markers, EKG, chest x-ray WNL
20-OCT-2008: EKG WNL, glucose 151 (65-115), AST 56 (13-40), ALT 135 (10-50), A1C 8.2 (4.8-6.0), cholesterol 245 (less than 200), triglycerides 201 (30-200), LDL 152 (less than 100)
27-JAN-2009: toe and wrist x-rays-WNL; thoracic spine x-ray-mild compression fracture deformity of T12
28-JAN-2009: CT thoracic spine- mild DJD T9-T10, T10-T11, compression fracture deformity of T12 which appears chronic in nature, no acute findings
13-JUL-2009: glucose 231 (65-115), AST 63 (13-40), ALT 99 (10-50), A1C 8.7 (4.8-6.0), triglycerides 250 (30-200),
HDL 28 (greater than 40),
JUL-2009: head CT negative
16-JUL-2009: UA-glucose 1000, ketones 5 (negative)
17-SEP-2009: sleep study-moderate obstructive sleep apnea
23-SEP-2009: thoracic spine stable
23-SEP-2009: MRI thoracic spine-chronic compression fracture unchanged
01-NOV-2009: ankle x-ray - no fracture

B7. Other Relevant History - Continued

POSSIBLE ASEPTIC MENINGITIS WHICH REQUIRED HOSPITALISATION IN (b) (6) AND CULTURES WERE NEGATIVE.
FRACTURED ULNAR STYLOID PROCESS
ACCIDENT AT WORK
IN 2003, WAS HIT BY FORKLIFT WHICH CAUSED LOWER BACK STRAIN AND SHOULDER INSTABILITY.
HEADACHE
EARACHE
HYPERTRIGLYCERIDEMIA
HYPERCHOLESTEROLEMIA
CALCANEAL SPUR

SMOKER
HALF TO ONE PACK FOR 10 TO 20 YEARS, CHEWING TOBACCO USE
ALCOHOL USE
WEEKLY TO TWICE MONTHLY
SUBCONJUNCTIVAL HEMORRHAGE
HEPATOMEGALY
mild
ABDOMINAL PAIN
UPPER RESPIRATORY INFECTION
ASPARTATE AMINOTRANSFERASE INCREASED
TINEA PEDIS
ECZEMA
DYSPEPSIA
LACERATION OF HAND
GERD
ACHILLES TENDON ELONGATION
SUBSEQUENT MILD SPURRING
RECURRENT UTI
RENAL CALCULI
PLANTAR FASCIITIS
ALANINE AMINOTRANSFERASE INCREASE

DSS
DEC 21 2011

C2. Dose, frequency and route used And C3. Therapy dates - Continued

#3 HYDROXYCUT
--/--/2007 -
11/--/2007 -
02/--/2009 -
04/--/2009 -

DEC 19 2011

Apotex Inc. - Mfr. report # 2011AP002941

C6 and C7. Lot # and Exp. Date - Continued

#3 HYDROXYCUT
Lot No., Exp Date: Lot , Exp date .
Lot No., Exp Date: Lot , Exp date .
Lot No., Exp Date: Lot , Exp date .
Lot No., Exp Date: Lot , Exp date .

C10. Concomitant medical products - Continued

HYDROXYZINE

G8. Adverse event term(s) - Continued

Gastritis
Dizziness
Nausea
Thyroid neoplasm
Urinary tract infection
Wrist fracture
Sleep apnoea syndrome
Snoring
Back injury
Cellulitis
Rash
Drug hypersensitivity
Chest pain
Viral infection
Fatigue
Back pain
Diabetes mellitus

DSS

DEC 21 2011

DEC 19 2011

CaseID: 8325043

Individual Safety Report

8017549-5-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

use by user-facilities,
listributors and manufacturers
ANDATORY reporting

Page 1 of 5 12/21/12

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	1 Years	☐ Female	lbs
In confidence	or Date of Birth:	☑ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
XX/XX/2011	12/19/2011

5. Describe Event or Problem

1 YEAR OLD WENT TO ER TWICE WITH SEIZURES. ALSO EXPERIENCING SOME PATCHY BALDNESS.

RECEIVED
DEC 28 2011
CDR

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 UNKNOWN	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS

DEC 28 2011

DEC 29 2011

USA

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		◉ Yes ☐ No ☐ Unk.

CaseID: 8325043

Individual Safety Report

8017549-5-00-02

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Request
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- [ ] Yes [ ] No

6. Evaluation Codes *(Refer to coding manual)*

Method ____ - ____ - ____ - ____

Results ____ - ____ - ____ - ____

Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/ Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

1. Check One
- [ ] User Facility
- [ ] Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Home
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Outpatient Diagnostic Facility
- [ ] Ambulatory Surgical Facility
- [ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
12/15/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/ 510(k) # ____
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- [ ] 5-day
- [ ] 30-day
- [ ] 7-day
- [ ] Periodic
- [ ] 10-day
- [x] Initial
- [x] 15-day
- [ ] Follow-up # ____

8. Adverse Event Term(s)
SEIZURES, APOLECIA

9. Manufacturer Report Number
54973 RAE121511EF001

RECEIVED
DEC 28 2011
CDR

DSS
DEC 29 2011

DEC 28 2011

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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Individual Safety Report

8017549-5-00-03

(CONTINUATION PAGE)
For use by user-facilities,
s, distributors, and manufacturers
r MANDATORY reporting

FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

DSS

DEC 29 2011

Other Remarks

DEC 28 2011

CaseID: 8325043

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Individual Safety Report

8017549-5-00-04

Hyland's

SECTION I: **COMPLAINT**

RVD121511EF001

TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 12/15/11

PRODUCT: TEETHING TABLETS ITEM CODE: TEET

SIZE: UNKNOWN LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WENT TO EMERGENCY TWICE BECAUSE OF FULL SEIZURE. BABY IS 1 YEAR OLD. CONTINUES TO HAVE PROBLEMS INCLUDING PATCHY BALDNESS. GREAT-GRANDMOTHER CALLED TO REPORT AND SHE WOULD NOT PROVIDE MORE DETAILS AND WAS NOT CERTAIN WHICH PRODUCT IT WAS BECAUSE SHE DOES NOT LIVE IN THE SAME CITY AS THE CHILD. SHE WILL BE SEEING FAMILY OVER CHRISTMAS AND MAY OBTAIN MORE INFORMATION AT THAT TIME. OUR PHARMACIST STRESSED IMPORTANCE OF HAVING PARENTS CALL US TO PROVIDE MORE INFORMATION AND SHE STARTED THAT THEY ALREADY REPORTED IT, POSSIBLY TO FDA.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON:** 12/15/11

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY:** EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: RAE121511EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/15/11 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: R Watts DATE: 12-20-11

DSS
DEC 29 2011

BY: N/A DATE:

QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

DEC 28 2011

Individual Safety Report

8017549-5-00-05

CaseID: 8325043

JS ADVERSE EVENT DATA FORM

AE #: RAE121511EF001 COMPLAINT #: RVD121511EF001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: GREAT GRANDSON

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

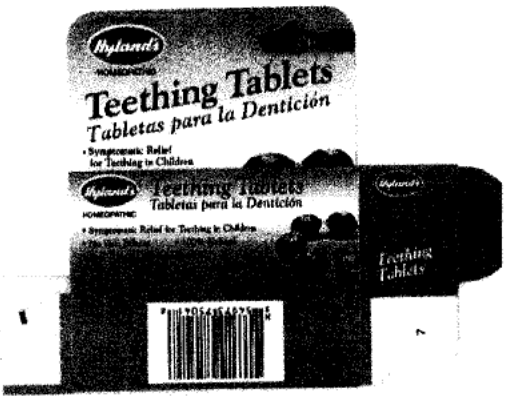
PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Walt DATE: 12-20-11

BY: N/A DATE: DEC 29 2011
QA / QC DIRECTOR

DSS

1

DISTRIBUTION: FDA ADVERSE EVENT FILE

DEC 28 2011

CaseID: 8400982

Form Approved: OMB No. 0910-0291, Expires 12/31/11
See OMB statement on reverse.

U.S. Food ... ME... FOR ...

Individual Safety Report

8115259-7-00-01

...ser-facilities, ...tors and manufacturers ...TORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. P...

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	or _____ Date of Birth:	☑ Female ☐ Male	_____ lbs or _____ kgs
In confidence			

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
00/00/2010	01/12/2012

5. Describe Event or Problem

CHILD HAD SEIZURES WHILE USING TEETHING TABLETS. NO OTHER INFORMATION PROVIDED. SEIZURES STOPPED WHEN TEETHING TABLETS DISCONTINUED.

RECEIVED

JAN 31 2012

CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 RELIEF OF TEETHING PAIN	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	

USA

FEB 01 2012 FEB 02 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

PLEASE TYPE OR USE BLACK INK

MI FO F.

Individual Safety Report

8115259-7-00-02

FDA USE ONLY

1.

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
01/08/2012

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURE

9. Manufacturer Report Number
54973E RAE010812EF001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360I(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
FEB 02 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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FEB 01 2012

Individual Safety Report

8115259-7-00-03

ONTINUATION PAGE)
use by user-facilities,
tributors, and manufacturers
NDATORY reporting

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
FEB 02 2012

FEB 0 1 2012

CaseID: 8400982

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: RVD010812EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 01/08/12

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: NOT PROVIDED

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL: UNKNOWN

NATURE OF COMPLAINT: POSTED ON (b) (6) THAT DAUGHTER HAD SEIZURES WHILE USING TEETHING TABLETS AND SEIZURES STOPPED WHEN TABLETS DISCONTINUED. SEE ATTACHED (b) (6) POST.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)
NOT SUCCESSFUL IN ATTEMPT TO CONTACT THIS CUSTOMER FOR MORE INFORMATION.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/08/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE010812EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/08/12

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt

DATE: 01-16-12

DSS

BY: N/A
QA / QC DIRECTOR

DATE:

FEB 02 2012

Individual Safety Report

8115259-7-00-04

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

FEB 0 1 2012

CaseID: 8400982

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1

Individual Safety Report

8115259-7-00-05

Hyland's

AE #: RAE010812EF001 COMPLAINT #: RVD010812EF001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

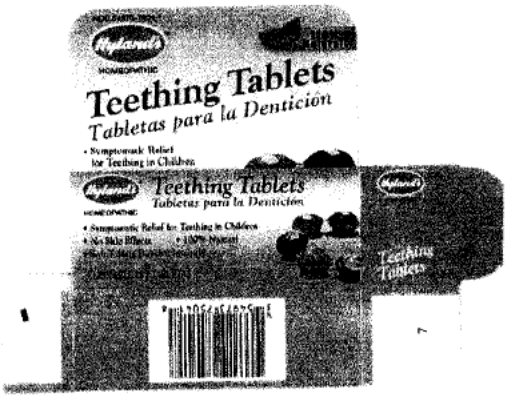
PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

BY: N/A DATE:

QA / QC DIRECTOR

DSS
FEB 02 2012

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

FEB 0 1 2012

Individual Safety Report

8224423-8-00-01

CaseID: 8455449

Form Approved: OMB No. 09-10-0291, Expires 12/31/11
See OMB statement on reverse.

For use by user-facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 7 Months or Date of Birth:	3. Sex	4. Weight
		☐ Female ☑ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/11/2012	02/21/2012

5. Describe Event or Problem

MOTHER GAVE UNKNOWN DOSE TO 7 MONTH OLD SON AND 30 MINUTES LATER CHILD HAD A SEIZURE AND WENT TO ER.

RECEIVED
MAR 19 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

WE HAVE NO INFORMATION AS TO PRESENCE OR ABSENCE OF FEVER, BUT ALSO WE HAVE NO ADDITIONAL CLINICAL INFORMATION ON THE CHILD.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 RELIEVES TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	

DSS
MAR 19 2012
USA
MAR 20 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

CaseID: 8455449

Individual Safety Report

8224423-8-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ☐ – ☐ – ☐
Device Code ☐ – ☐ – ☐

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 AE # 773

8. Adverse Event Term(s)
SEIZURE

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ☐ – ☐ – ☐ – ☐
Results ☐ – ☐ – ☐ – ☐
Conclusions ☐ – ☐ – ☐ – ☐

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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MAR 19 2012 MAR 20 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

Individual Safety Report

8224423-8-00-03

(CONTINUATION PAGE)
›r use by user-facilities,
listributors, and manufacturers
IANDATORY reporting

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
MAR 20 2012

MAR 19 2012

CaseID: 8455449

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: 1294

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 02/12/12

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: NOT PROVIDED

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: ON (b) (6) GAVE TO 7 MONTH OLD CHILD AND 30 MINUTES LATER HAS A SEIZURE AND WENT TO ER PER (b) (6) POSTING (SEE ATTACHED). CUSTOMER DID NOT RESPOND TO ATTEMPTS FOR CONTACT.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Safety Report

8224423-8-00-04

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PERFORMED ORGANELEPTIC TESTS ON 3 LOTS AND ALL TESTED LOTS MATCHED PRODUCT SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 02/12/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 773

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 02/12/12

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: R Wolf

DATE: 03-08-12

BY: QA / QC DIRECTOR

DATE: 02-23-12

DSS
MAR 20 2012

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form
MAR 19 2012

CaseID: 8455449

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 773 COMPLAINT #: 1294

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

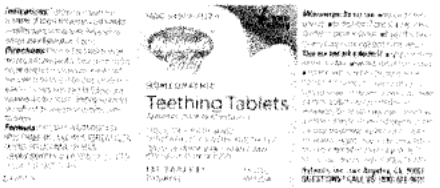
COUNTRY: USA ZIP CODE:

PHONE #:

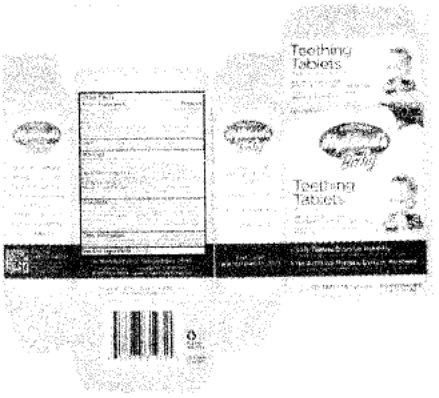
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Safety Report
8224423-8-00-05

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalf DATE: 03-08-12

BY: QA / QC DIRECTOR DATE: 02-23-12

DSS
MAR 20 2012

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

MAR 19 2012

Edyta Frackiewicz

From: Thao Le [tle@hylands.com]
Sent: Monday, February 13, 2012 9:21 AM
To: Edyta Frackiewicz
Subject: Fwd: SAE - BTET

FYI

Begin forwarded message:

From: (b) (6)
Date: February 13, 2012 12:19:13 PM EST
To: Thao <tle@hylands.com>
Subject: RE: SAE - BTET

Sent an email....Will wait until the afternoon to post on the fanpage the same message...

(b) (6)

From: tle@hylands.com
Subject: Fwd: SAE - BTET
Date: Mon, 13 Feb 2012 12:00:54 -0500
To: (b) (6)

Can you do this?

Begin forwarded message:

From: Edyta Frackiewicz <efrackiewicz@hylands.com>
Date: February 13, 2012 11:56:27 AM EST
To: Thao Le <tle@hylands.com>
Subject: RE: SAE - BTET

Hi Thao,

If possible let's private message them asking to call our Product Information Service at 1-800-624-9659 to let us know about their experience with the product and for more information. Let me know if we can do that. If not, then we'll have to post a reply and ask her to contact us.

Thanks,
Edyta

From: Thao Le [mailto:tle@hylands.com]
Sent: Sunday, February 12, 2012 7:59 PM

DSS
MAR 20 2012

MAR 19 2012

Individual Safety Report ID: 8455449
8224423-8-00-07

To: Jay Borneman; Iris Bell; Edyta Frackiewicz
Subject: SAE - BTET

Begin forwarded message:

From: (b) (6)
Date: February 12, 2012 10:06:41 PM EST
To: Thao <tle@hylands.com>
Subject: Teething Tabs page

Sorry...was at dinner in (b) (6)

(b) (6)

Used these for the first time yesterday for my 7 month old who is teething. 30 minutes later he had a seizure and we went to the ER!!! WARNING TO PARENTS: Belladonna, an ingredient in these tablets, is a poison!! The FDA recalled this product in 2010 because the ingredient was not properly regulated. Research this product and the ingredient Belladonna online and decide whether teething discomfort in your child is worth putting them in harm's way!!!

(b) (6)

DSS
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MAR 1 9 2012

(b) (6)

Individual Safety Report

8224423-8-00-08

DSS
MAR 20 2012

2/15/2012

MAR 19 2012

Individual Safety Report

8264172-3-00-01

CaseID: 8503620

Form Approved: OMB No. 09 10-0291, Expires 12/31/1
See OMB statement on reverse

TC

For use by user-facilities, rs, distributors and manufacturers r MANDATORY reporting

Page 1 of 5

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	6 Months	☑ Female	lbs
In confidence	or Date of Birth:	☐ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/00/2012 - 03/12/2012	03/21/2012

5. Describe Event or Problem

GIVING BABY TEETHING TABLETS FOR 1 MONTH. GIVES CHILD 2 TABLETS TWICE A DAY IN PM AS NEEDED. EVERY TIME SHE USES THEM, CHILD GET DROWSY, SLEEPS A LOT (2 - 3 HOURS AT A TIME), TROUBLE BREATHING (GASPING FOR AIR) WHILE SHE'S SLEEPING. HAS AN APPOINTMENT WITH DOCTOR TOMORROW.

03/20/12 FOLLOW-UP: PER GRANDMOTHER, DOCTOR SAID THAT BABY TEETHING TABLETS WERE NOT CAUSE OF SYMPTOMS. CHILD WAS ALSO BEING GIVEN TYLENOL AND DOCTOR SAID THAT THIS WAS THE REASON WHY CHILD WAS DROWSY AND SLEEPING.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2 TYLENOL

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2 TABLETS BID PRN X 1 MO	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 113477	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient ☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: APR 04 2012 *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)

Phone # (b) (6)

APR 0 3 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

y)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
03/12/2012

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 AE # 804

8. Adverse Event Term(s)
DROWSINESS, SOMNOLENCE, TROUBLE BREATHING

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 04 2012
APR 0 3 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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OMB Statement:
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FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

DSS

APR 04 2012

Other Remarks

APR 0 3 2012

CaseID: 8503620

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: 1340

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 03/12/12

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: 113477

REPORTER: (b) (6)

Individual Safety Report

8264172-3-00-04

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GIVING BABY TEETHING TABLETS FOR 1 MONTH. GIVES CHILD 2 TABLETS TWICE A DAY IN PM AS NEEDED. EVERY TIME SHE USES THEM, CHILD GETS DROWSY, SLEEPS A LOT (2 – 3 HOURS AT A TIME), TROUBLE BREATHING (GASPING FOR AIR) WHILE SHE'S SLEEPING. HAS AN APPOINTMENT WITH DOCTOR TOMORROW.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

03/13/12: NO ANSWER. LEFT MESSAGE.
03/20/12 FOLLOW-UP: PER GRANDMOTHER, DOCTOR SAID THAT BABY TEETHING TABLETS WERE NOT CAUSE OF SYMPTOMS. CHILD WAS ALSO BEING GIVEN TYLENOL AND DOCTOR SAID THAT THIS WAS THE REASON WHY CHILD WAS DROWSY AND SLEEPING.

PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) N

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE) N

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: PERFORMED ORGANOLEPTIC TESTING ON LOT #S 113477, 114226, AND 113472. TESTED LOTS MATCH MANUFACTURER SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 03/12/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

APR 04 2012

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 804

ADVERSE EVENT SERIOUS: (Y) / N

APR 0 3 2012

ADVERSE EVENT REPORTED ON: 03/12/12 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 03-26-12

BY: QA / QC DIRECTOR DATE: 03-26-12

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 8503620

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 804 COMPLAINT #: 1340

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

Individual Safety Report
8264172-3-00-05

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

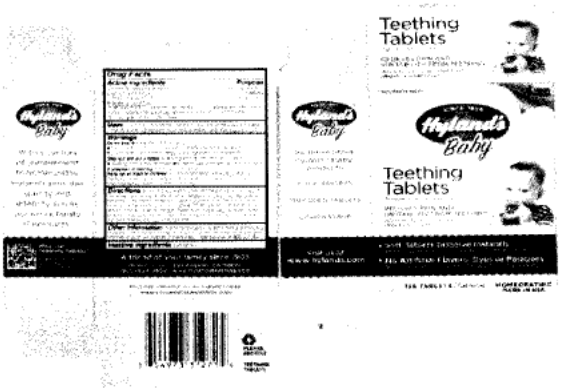
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
APR 04 2012

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 03-26-12

BY: QA / QC DIRECTOR DATE: 03-26-12

APR 0 3 2012

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 8505962

Individual Safety Report

8269798-9-00-01

FDA Facsimile Approval 07/13/2006 (Oracle)

Mfr report # 2012AP000827

UF/Importer Report #

"+" indicates item continued

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
In confidence	65 YEARS or Date of Birth:	[X] Female [ ] Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g. defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death (mm/dd/yyyy)
- [ ] Life-threatening
- [X] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)

4. Date of This Report (mm/dd/yyyy): 04/02/2012

5. Describe Event or Problem

Reference number 2012AP000827 is a literature case report received on 24-Mar-2012, pertaining to a 65-year-old female patient who developed reversible cerebral vasoconstriction syndrome, hyperacusis, photophobia, nausea, bilateral leg weakness and visual disturbances due to drug interaction between citalopram (strength and manufacturer unknown) and Hydroxycut.

The medical history of the patient includes migraines, hysterectomy, depression, hyperlipidaemia, lumbar spinal compression fractures and multiple miscarriages. She had no family history of migraines or strokes. Concomitant medication of the patient included simvastatin at a dose of 40 mg daily for hyperlipidaemia.

The patient was started on citalopram at a dose of 20mg daily for depression. She was taking citalopram for several years. On an unknown date she presented to a local hospital with sudden-onset, bifrontal, pounding headache described as getting hit in the head with an axe. The headache was described as the worst of her life and did not improve after she took acetaminophen, caffeine, and butalbital. There was hyperacusis (HYPERACUSIS), photophobia (PHOTOPHOBIA) and nausea (NAUSEA). Two weeks prior to her thunderclap headache the patient had started weight-loss supplement +

6. Relevant Tests/Laboratory Data, Including Dates

- body mass index was 22.3
- Noncontrast head computed tomography (CT) and brain magnetic resonance imaging (MRI) at the time of admission - Normal
- MRI revealed areas of restricted diffusion consistent with acute infarcts in the bilateral anterior cerebral artery territories and in right occipital lobe +

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

MIGRAINE
HYSTERECTOMY
DEPRESSION
HYPERLIPIDAEMIA
MISCARRIAGE
SPINAL COMPRESSION FRACTURE

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 CITALOPRAM HYDROBROMIDE TABLETS
#2 HYDROXYCUT

2. Dose, Frequency & Route Used
#1 20 MG;QD;
#2

3. Therapy Dates (If unknown, give duration)
#1 -
#2

4. Diagnosis for Use (Indication)
#1 DEPRESSION
#2 WEIGHT LOSS

5. Event Abated After Use Stopped or Dose Reduced?
#1 [X] Yes [ ] No [ ] doesn't apply
#2 [X] Yes [ ] No [ ] doesn't apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] doesn't apply
#2 [ ] Yes [ ] No [X] doesn't apply

9. NDC# or Unique ID
N/A

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
SIMVASTATIN - PRESENT

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
Apotex Inc.
150 Signet Drive
Toronto, Ontario M9L 1T9
CANADA

2. Phone Number: 416-749-9300

3. Report Source (Check all that apply)
- [ ] Foreign
- [ ] Study
- [X] Literature
- [ ] Consumer
- [X] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 03/24/2012

5. (A)NDA # 077046
IND #
STN #
PMA/510(k) #
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [ ] Yes

6. If IND, Give Protocol #: N/A

7. Type of Report (Check all that apply)
- [ ] 5-day
- [ ] 30-day
- [ ] 7-day
- [ ] Periodic
- [ ] 10-day
- [X] Initial
- [X] 15-day
- [ ] Follow-up #

8. Adverse Event Term(s)
Cerebrovascular spasm
Drug interaction
Hyperacusis
Photophobia
Nausea
Muscular weakness
Visual impairment

9. Manufacturer Report Number: 2012AP000827

E. INITIAL REPORTER

1. Name and Address: (b) (6)

Phone #

UNITED STATES

DSS

APR 06 2012 APR 09 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
[X] Yes [ ] No	HP	[ ] Yes [ ] No [X] Unk

FDA 3500A Facsimile

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.

Apotex Inc. - Mfr. report # 2012AP000827

B5. Describe Event or Problem - Continued

Hydroxycut. Non contrast head computed tomography (CT) and brain magnetic resonance imaging (MRI) at the time of admission were normal and she was treated with prednisone for presumed intractable migraine. She had milder headache one week prior to her current presentation. On admission, her body mass index was 22.3, and she was normotensive on lisinopril 10mg daily. She had not previously been on lisinopril, which was presumably initiated at the outside hospital for prednisone induced hypertension. Lisinopril was held during hospital stay given her normal to low blood pressures. Her fasting lipid panel revealed cholesterol 223mg/dL, triglycerides 141mg/dL, high density lipoprotein 61mg/dL, low density lipoprotein 134mg/dL, very low density lipoprotein 28mg/dL and lipoprotein(a) 6 mg/dL. Two days after admission, she developed bilateral leg weakness (LOWER EXTREMITIES WEAKNESS OF) and left-sided visual disturbances (VISUAL DISTURBANCES) that she described as blank lines. A repeat MRI revealed areas of restricted diffusion consistent with acute infarcts in the bilateral anterior cerebral artery territories and in her right occipital lobe. The following investigations were unrevealing: hypercoagulability studies, rheumatic and vasculitic screening labs, magnetic resonance venography, transthoracic echocardiogram with bubble contrast, and Holter monitoring. LA lumbar puncture, performed while the patient was being treated with prednisone, revealed 0 white blood cells (WBC), 48 red blood cells (RBC), cerebrospinal fluid (CSF) protein 27mg/dL, glucose 81 mg/dL and no xanthochromia. CT angiography (CTA) was obtained, which revealed multifocal segmental cerebral artery vasoconstriction, most prominent in the bilateral anterior and posterior cerebral arteries. The diagnosis of reversible cerebral vasoconstriction syndrome (RCVS) (CALL-FLEMING SYNDROME) was made and began treatment with nimodipine 30 mg three times daily. Over the subsequent days, her headache resolved and her vision and leg weakness improved. The patient's blood pressures at admission and prior to starting nimodipine were 92-116/54-58mmHg on no antihypertensive medications. After beginning nimodipine for RCVS, her systolic blood pressures ranged from the high 80s to low 100s (mmHg). The patient received intravenous fluid bolus as needed to keep her systolic blood pressure above 90mmHg, in an effort to balance maintaining adequate cerebral perfusion while continuing nimodipine treatment for RCVS. The patient tolerated this well without any clinical decline or symptomatic hypotension. She was discharged on nimodipine and advised not to take Hydroxycut and citalopram, which had been discontinued when a diagnosis of RCVS was first suspected. At the time of discharge, her systolic blood pressures remained in the 90s to low 100s mmHg. Therefore, she was advised to measure her blood pressure at home and take nimodipine only if systolic blood pressure was over 100 mmHg. Following discharge, the patient experienced no headaches and no recurrence of her presenting symptoms. At a follow-up appointment, she had no residual leg weakness and significant improvement of her left visual field deficit, although she reported that her vision had not returned to her baseline. CTA performed six weeks after discharge showed marked resolution of cerebral vasoconstriction, confirming the diagnosis of RCVS.

Author comment: Citalopram may have acted in concert with the newly initiated Hydroxycut to cause this patient's RCVS, though the fact that she tolerated citalopram well for several years before developing RCVS argues against the antidepressant drug as the sole trigger. Given the sparse data about the efficacy and safety of herbal supplements such as Hydroxycut, it is advisable to consider the potential roles of dietary supplements and drug interactions (DRUG INTERACTION) in cases of otherwise unexplained cerebrovascular disease.

Citation: Cvetanovich GL, Ramakrishnan P, Klein JP, Rao VR, Ropper AH. Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: A case report. Journal of Medical Case Reports. 2011; 5(548):1-5.

The manufacturer of citalopram was not identified; however, the Apotex brand of product cannot be excluded from consideration.

B6. Relevant Tests/Laboratory Data - Continued

- hypercoagulability studies, rheumatic and vasculitic screening labs, magnetic resonance venography, transthoracic echocardiogram with bubble contrast, and Holter monitoring- dose not reveal anything
- LA lumbar puncture- revealed 0 white blood cells (WBC), 48 red blood cells and no xanthochromia
- CT angiography revealed multifocal segmental cerebral artery vasoconstriction.
-Patient's blood pressures at admission and prior to starting nimodipine were 92-116/54-58 mmHg.
-After beginning nimodipine for RCVS, her systolic blood pressures ranged from the high 80s to low 100s (mmHg).
-At the time of discharge, her systolic blood pressures remained in the 90s to low 100s mmHg.

TEST NAME	DATE	RESULT	UNIT	LOW VALUE	HIGH VALUE
CHOLESTEROL		223	MG/DL		
TRIGLYCERIDES		141	MG/DL		
HIGH DENSITY LIPOPROTEIN		61	MG/DL		
LOW DENSITY LIPOPROTEIN		134	MG/DL		
VERY LOW DENSITY LIPOPROTEIN		28	MG/DL		
LIPOPROTEIN (A)		6	MG/DL		
CSF PROTEIN		27	MG/DL		
CSF GLUCOSE		81	MG/DL		

DSS
APR 09 2

APR 06 2012

Cvetanovich et al.: Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: a case report. Journal of Medical Case Reports 2011 5:548.

CaseID: 8610311

Individual Safety Report

8410059-2-00-01

OTC

...or use by consumer facilities, distributors and manufacturers MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 2280705-2012-00066

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (1/09)

Page 1 of 5

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: or Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☑ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 05/07/2012

4. Date of This Report (mm/dd/yyyy): 05/25/2012

5. Describe Event or Problem

Consumer reported son began shaking and twitching after the product was applied. Medical attention was sought. Son was fine at the time the incident was reported.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)

#1 Orajel® Daytime/Nighttime Twin Pack oral pain

#2 (continued) reliever for teething Benzocaine 7.5%/10%

2. Dose, Frequency & Route Used

#1 Oral application

#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

#1 5/07/2012

#2

4. Diagnosis for Use (Indication)

#1 Teething Pain Relief

#2

RECEIVED MAY 29 2012 CDR

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☑ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #

#1

#2

7. Exp. Date

#1

#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☑ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

NDC# 10237-716-36

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | Catalog # | Expiration Date (mm/dd/yyyy) | Serial # | Other #

5. Operator of Device

- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

DC

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

MAY 30 2012

2. Health Professional? ☐ Yes ☑ No

3. Occupation: NA

4. Initial Reporter Also Sent Report to FDA: ☐ Yes ☐ No ◉ Unk.

MAY 29 2012

PLEASE TYPE OR USE BLACK INK

Individual Safety Report

8410059-2-00-02

CaseID: 8610311

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. **Report Sent to FDA?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)* ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility
13. **Report Sent to Manufacturer?** ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
Jill D. Ferentz
Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543
2. **Phone Number** 609-497-7139
3. **Report Source** *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 05/08/2012
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number** 2280705-2012-00066

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☑ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

Orajel® Daytime/Nighttime Twin Pack oral pain reliever for teething labels are attached. Consumer did not report which product was used, the Daytime or the Nighttime.

This report and the information submitted under this report do not constitute an admission that the drug or Church & Dwight Co., Inc. or any of its employees caused or contributed to the event described herein or that the event as reported to Church & Dwight actually occurred.

DSS
MAY 30 2012

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 (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

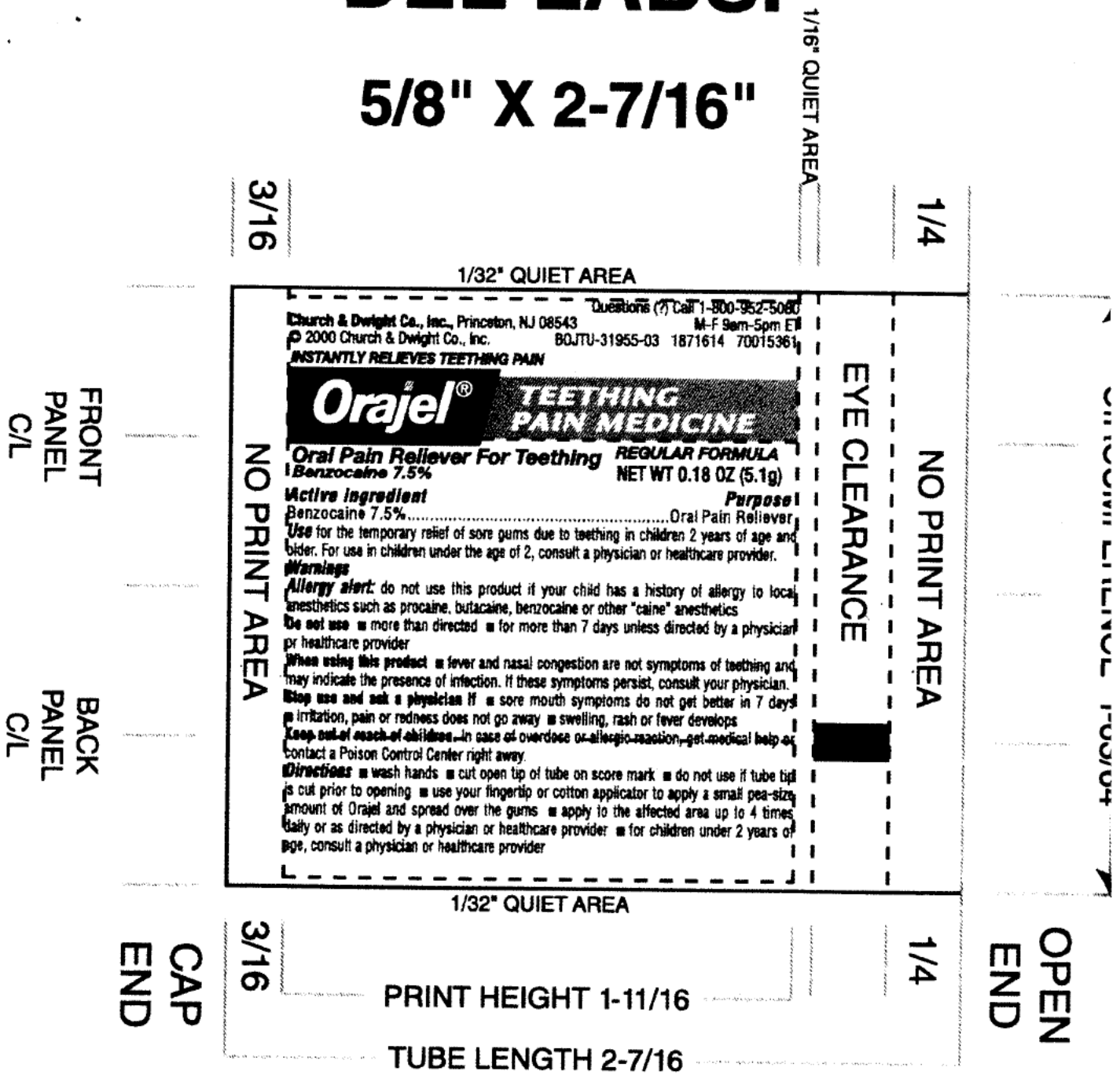
OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

MAY 29 2012

DEL LABS.

5/8" X 2-7/16"



Questions (?) Call 1-800-952-5080 M-F 9am-5pm ET

Church & Dwight Co., Inc., Princeton, NJ 08543

© 2000 Church & Dwight Co., Inc. BOJTU-31955-03 1871614 70015361

INSTANTLY RELIEVES TEETHING PAIN

Orajel® TEETHING PAIN MEDICINE

Oral Pain Reliever For Teething REGULAR FORMULA

Benzocaine 7.5% NET WT 0.18 OZ (5.1g)

Active Ingredient **Purpose**

Benzocaine 7.5% ..... Oral Pain Reliever

Use for the temporary relief of sore gums due to teething in children 2 years of age and older. For use in children under the age of 2, consult a physician or healthcare provider.

Warnings

Allergy alert: do not use this product if your child has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless directed by a physician or healthcare provider

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your physician.

Stop use and ask a physician if ■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ do not use if tube tip is cut prior to opening ■ use your fingertip or cotton applicator to apply a small pea-size amount of Orajel and spread over the gums ■ apply to the affected area up to 4 times daily or as directed by a physician or healthcare provider ■ for children under 2 years of age, consult a physician or healthcare provider

(b) (4)

CH & DWIGHT		JOB: Baby Orajel Teething Pain Medicine 5.1g			
	E.O.# 47-11-04404	CIRC: 1-63/64	SIZE: 5/8 x 2-7/16		SUB: WHITE
RS: (b) (4)	(b) (4)				
NS: DECK 1	DECK 2				

DSS

NOTE: Any ink deck location can change provided the color order

MAY 29 2012

MAY 2 9 2012

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5/8" X 2-7/16"

Individual Safety Report

8410059-2-00-04

1/16" QUIET AREA

3/16

1/4

1/32" QUIET AREA

FRONT PANEL C/L

BACK PANEL C/L

NO PRINT AREA

EYE CLEARANCE

NO PRINT AREA

CIRCUMFERENCE 1-63/64

Questions (?) Call 1-800-952-5080
M-F 9am-5pm ET

Church & Dwight Co., Inc., Princeton, NJ 08543
© 2000 Church & Dwight Co., Inc.
BOJTU-33940-03 1871615 70015362

INSTANTLY RELIEVES TEETHING PAIN

Orajel® **NIGHTTIME FORMULA**

Oral Pain Reliever For Teething
Benzocaine 10%

NET WT 0.18 OZ (5.1g)

Active Ingredient ***Purpose***
Benzocaine 10%.....Oral Pain Reliever

Use for the temporary relief of sore gums due to teething in children 2 years of age and older. For use in children under the age of 2, consult a physician or healthcare provider.

Warnings

Allergy alert: do not use this product if your child has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use ■ more than directed ■ for more than 7 days unless directed by a physician or healthcare provider

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your physician.

Stop use and ask a physician if ■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions ■ wash hands ■ cut open tip of tube on score mark ■ do not use if tube tip is cut prior to opening ■ use your fingertip or cotton applicator to apply a small pea-size amount of Orajel and spread over the gums ■ apply to the affected area up to 4 times daily or as directed by a physician or healthcare provider ■ for children under 2 years of age, consult a physician or healthcare provider

1/32" QUIET AREA

3/16

1/4

CAP END

OPEN END

PRINT HEIGHT 1-11/16

TUBE LENGTH 2-7/16

(b) (4)

VIGHT | JOB: Baby Orajel Nighttime Formula 5.1g | (b) (4) D/

O.# 47-11-04405 | CIRC: 1-63/64 | SIZE: 5/8 x 2-7/16 | SUB: WHITE

(b) (4) CK 1 | (b) (4) DECK 2

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MAY 29 2012 DSS

MAY 30 2012

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DEPTH 1/16" | SIDE SHOWN: printed

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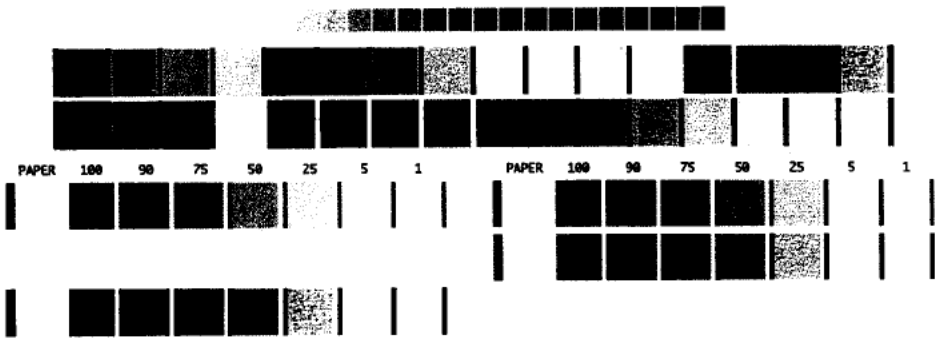
Page 5 of 5

Individual Safety Report
8410059-2-00-05



DSS
MAY 30 2012

MAY 29 2012

(b) (4)

MECHANICAL: ROUND 1

JOB INFORMATION

FRONT COLORS

(b) (4) Black Varnish

CaseID: 8666988

Form Approved: OMB No. 00 10-929 ; Expires 12/31/11
See OMB stat ement on reverse.

Individual Safety Report

8494792-2-00-01

For use by user facilities, distributors and manufacturers MANDATORY reporting

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	20 Months	☑ Female	____ lbs
In confidence	or ____	☐ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/04/2012	06/14/2012

5. Describe Event or Problem

(b) (6) PRESENTED WITH FEVER OF 101.4, ALTERED MENTAL STATUS (FUSSY, INCONSOLABLE), NOT SPEAKING AS MUCH, LIMP AND WEAK EXTREMITIES AND NECK. HOSPITALIZED AND UNDERGOING WORK-UP FOR INFECTIOUS DISEASE AND NEUROLOGY.

JUNE 11, 2012 FOLLOW-UP: SOME IMPROVEMENT NOTED.

RECEIVED
JUN 28 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

EXTENSIVE WORK-UP INCLUDING LOOKING FOR INFECTIOUS DISEASE, MRI OF HEAD AND SPINE (RESULTS DID NOT EXPLAIN SYMPTOMS), TOXICOLOGY SCREENS, THYROID SCREENING.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 112978	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

JUN 28 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☑ Yes ☐ No	Physician	☐ Yes ◉ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

JUN 28 2012

CaseID: 8666988

Individual Safety Report

8494792-2-00-02

FDA USE ONLY

F.

1. [illegible]
   ☐ User Facility ☐ Importer
2. [illegible]

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report**
   ☐ Initial
   ☐ Follow-up # _____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
    Patient Code ____ - ____ - ____
    Device Code ____ - ____ - ____

11. **Report Sent to FDA?**
    ☐ Yes _____ *(mm/dd/yyyy)*
    ☐ No

12. **Location Where Event Occurred**
    ☐ Hospital
    ☐ Home
    ☐ Nursing Home
    ☐ Outpatient Treatment Facility
    ☐ Outpatient Diagnostic Facility
    ☐ Ambulatory Surgical Facility
    ☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?**
    ☐ Yes _____ *(mm/dd/yyyy)*
    ☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number**
310-768-0700

3. **Report Source** *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
06/11/2012

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. **Adverse Event Term(s)**
ALTERED MENTAL STATUS, EXTREMITY WEAKNESS,

9. **Manufacturer Report Number**
54973 AE # 906

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   ☐ Death
   ☐ Serious Injury
   ☐ Malfunction
   ☐ Other: _____

2. **If Follow-up, What Type?**
   ☐ Correction
   ☐ Additional Information
   ☐ Response to FDA Request
   ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
   ☐ Not Returned to Manufacturer
   ☐ Yes ☐ Evaluation Summary Attached
   ☐ No *(Attach page to explain why not)* or provide code: _____

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?**
   ☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
   Method ____ - ____ - ____ - ____
   Results ____ - ____ - ____ - ____
   Conclusions ____ - ____ - ____ - ____

7. **If Remedial Action Initiated, Check Type**
   ☐ Recall
   ☐ Repair
   ☐ Replace
   ☐ Relabeling
   ☐ Notification
   ☐ Inspection
   ☐ Patient Monitoring
   ☐ Modification/Adjustment
   ☐ Other: _____

8. **Usage of Device**
   ☐ Initial Use of Device
   ☐ Reuse
   ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

JUN 28 2012

(CONTINUATION PAGE)
For use by user-facilities,
importers, distributors, and manufacturers
for MANDATORY reporting

MEDWATCH

FORM FDA 3500A (6/10) *(continued)*

Individual Safety Report
8494792-2-00-03

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)* *(continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)* *(For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSC

JUN 2 8 2012

8494792-2-00-04

R COMPLAINT RECORD

8666988

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: 1515

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 06/11/12

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: 112978

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GIVING TEETHING TABLETS ALTERED – MENTAL STATUS (VERY FUSSY, INCONSOLABLE), NOT SPEAKING AS MUCH, LIMP EXTREMITIES, HOLDING HEAD UP. INITIAL (b) (6) PRESENTATION ABNORMAL STRENGTH IN LOWER PROXIMAL EXTREMITIES AND NECK. HAS IMPROVED. HOSPITALIZED SINCE (b) (6) INFECTIOUS PROBLEMS. MRI / SPINE (NOT EXPLAIN), TOX SCREENS, THYROID. NO KNOWN ALLERGIES. PRESENTED WITH FEVER OF 101.4° ON (b) (6) NO TRAVEL.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

06/12/12: NO Δ FROM YESTERDAY PER DOCTOR. USING ARMS AND LEGS A LITTLE MORE BUT NOT SAME AS BASELINE. NEUROLOGIST AND INFECTIOUS DISEASE DOCTORS WILL HAVE A MEETING TO GO OVER PLAN FOR CHILD. PROVIDED DOCTOR WITH MORE INFORMATION REGARDING AMOUNTS OF INGREDIENTS ESPECIALLY BELLADONNA.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: INSPECTED RETAINED SAMPLES OF LOT #S 112957, 113050, AND 114079 AND EVERYTHING WAS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/11/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 906

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/11/12 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 06-22-12

QA / QC DIRECTOR DATE: 06-22-12

Packaging Production Shipping / Receiving

JUN 28 2012

CaseID: 8666988

Individual Safety Report

8494792-2-00-05

Hyland's

JS ADVERSE EVENT DATA FORM

AE #: 906 COMPLAINT #: 1515

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: UNKNOWN CHILD

ADDRESS:

CITY: STATE:

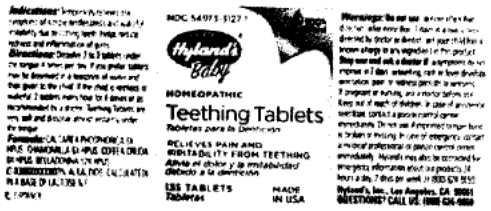
COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



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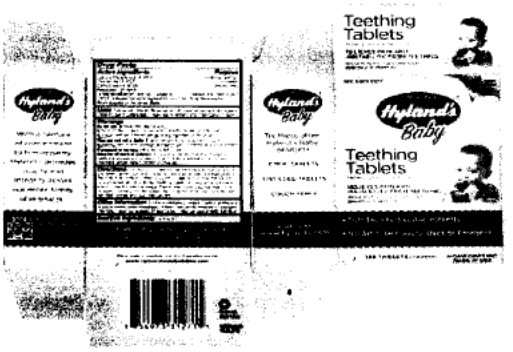
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
JUN 29 2012

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWall DATE: 06-22-12

BY: QA/QC DIRECTOR DATE: 06-22-12

JUN 28 2012

CaseID: 8708045

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Individual Safety Report

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8550033-9-00-01

by user-facilities,
outors and manufacturers
)ATORY reporting

OTC

Page 1 of 5

Mfr Report # 54973
UF/Importer Report #
FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence	2. Age at Time of Event: 9 1/2 Months or Date of Birth:	3. Sex ☑ Female ☐ Male	4. Weight ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/07/2012	07/03/2012

5. Describe Event or Problem

BABY BEING GIVEN BABY TEETHING TABLETS OCCASIONALLY FOR ABOUT 3 MONTHS WITH NO PROBLEMS. ON (b) (6) MOTHER GAVE CHILD 2 TABLETS AROUND 8:00 PM AND (b) (6) CHILD CONTINUED TO SLEEP AND WAS DIFFICULT TO ROUSE, WHEN SHE DID WAKE UP SHE WAS LETHARGIC, DID NOT RECOGNIZE MOTHER, "NOT REALLY THERE" PER MOTHER. MOTHER TOOK CHILD TO HER PEDIATRICIAN AND DOCTOR DECIDED TO HOSPITALIZE CHILD. CHILD STAYED IN HOSPITAL OVERNIGHT FOR TESTING AND THE NEXT DAY WAS BACK TO NORMAL. SAW A NEUROLOGIST AND CARDIOLOGIST WHO RULED OUT SEIZURES AND HEART CONDITIONS.

6. Relevant Tests/Laboratory Data, Including Dates

CT SCAN, BLOOD WORK, EKG, EEG. ALL RESULTS WERE NORMAL.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO FEVER OR OTHER ILLNESSES PRIOR TO SYMPTOMS.

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   #1 HYLAND'S BABY TEETHING TABLETS
   #2

2. Dose, Frequency & Route Used
   #1 2 TABLETS AT BEDTIME
   #2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
   #1 OCCASIONAL USE X 3 MOS.
   #2

RECEIVED
JUL 18 2012
CDR

4. Diagnosis for Use *(Indication)*
   #1 TEETHING PAIN
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   #1 113780
   #2

7. Exp. Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
   54973-3127-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Catalog #	Expiration Date *(mm/dd/yyyy)*	
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
    ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
   (b) (6)

Phone # (b) (6)

DSS
JUL 18 2012
JUL 19 2012

2. Health Professional? ☐ Yes ☑ No	3. Occupation	4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ◉ Unk.

ME
FOR

Individual Safety Report
8550033-9-00-02

FDA USE ONLY

F. F

1. Ch
☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | 5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* | 7. Type of Report ☐ Initial ☐ Follow-up # ____ | 8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device | 10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ – ____ – ____
Device Code ____ – ____ – ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
06/21/2012

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 AE # 922

8. Adverse Event Term(s)
LETHARGY, CONFUSION

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ – ____ – ____ – ____
Results ____ – ____ – ____ – ____
Conclusions ____ – ____ – ____ – ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DBS
JUL 19 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

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"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."

JUL 18 2012

Individual Safety Report

8550033-9-00-03

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B.5. Describe Event or Problem *(continued)*

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
JUL 19 2012

JUL 18 2012

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's®

SECTION I: **COMPLAINT**

COMPLAINT #: 1540

TAKEN BY: EDYTA FRACKIEWICZ
DATE OF COMPLAINT: 06/21/12

PRODUCT: BABY TEETHING TABLETS
ITEM CODE: BTET—T250

SIZE: 250 TABLETS
LOT NO.: 113780

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)
STATE: (b) (6)

COUNTRY: USA
ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: USED BABY TEETHING TABLETS BEFORE WITH NO PROBLEMS FOR 3 MONTHS. ON (b) (6) CHILD CONTINUED TO SLEEP, LETHARGIC, DIDN'T RECOGNIZE MOTHER, NO FEVER, "NOT REALLY THERE". TOOK TO PEDIATRICIAN WHO DECIDED TO HOSPITALIZE CHILD. IN THE HOSPITAL OVERNIGHT AND THEN BACK TO NORMAL. RULED OUT SEIZURES AND HEART CONDITIONS BY NEUROLOGIST AND CARDIOLOGIST. CT SCAN, BLOOD WORK, EKG, EEG ARE ALL NORMAL. WAS NOT SICK BEFORE THIS HAPPENED. WANTED TO KNOW ABOUT BELLADONNA IN TABLETS. EXPLAINED THE MEANING OF A BELLADONNA 12X POTENCY. BOTH CARDIOLOGIST AND NEUROLOGIST ATTRIBUTED SYMPTOMS TO BELLADONNA IN BABY TEETHING TABLETS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

NO KNOWN ALLERGIES. NOT SICK BEFORE IT HAPPENED.

NO OTHER MEDICATIONS.

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: INSPECTED LOT # 113780 FOR ORGANOLEPTIC TESTING AND EVERYTHING WAS OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 06/21/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:
DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 922

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 06/21/12
BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature]
DATE: 07-03-12

BY: [signature]
QA / QC DIRECTOR
DATE: 07-03-12

DSS
JUL 19 2012

Individual Safety Report
8550033-9-00-04

cc: QA / QC
Packaging

Production
Shipping / Receiving

Form # VD1

JUL 18 2012

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: 922 COMPLAINT #: 1540

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

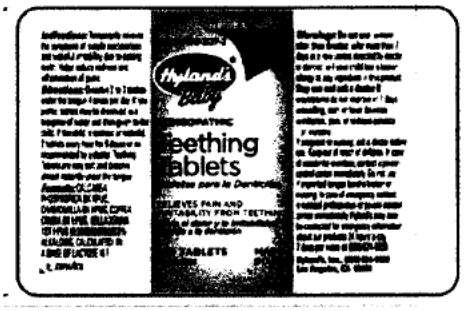
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

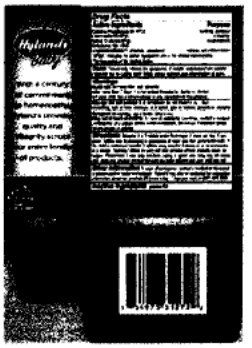
E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 07-03-12

BY: QA / QC DIRECTOR DATE: 07-03-12

DSS JUL 19 2012

Individual Safety Report

8550033-9-00-05

DISTRIBUTION: FDA ADVERSE EVENT FILE

JUL 18 2012

CaseID: 8736052

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

U.S. De
Food an

MED

FORM

Individual Safety Report

8598192-6-00-01

...facilities,
...rs and manufacturers
...reporting

of 5

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier (b) (6)
In confidence

2. Age at Time of Event: 10 Months
or
Date of Birth:

3. Sex: ☐ Female ☑ Male

4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☑ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 06/26/2012

4. Date of This Report *(mm/dd/yyyy)*: 07/19/2012

5. Describe Event or Problem

MOTHER GAVE HER SON THE FIRST DOSE OF TEETHING TABLETS AT THE SAME TIME HE WAS BEGINNING TO HAVE 'BREATHING PROBLEMS: GASPING FOR AIR, RETRACTION, HARD TO GET ENOUGH AIR'. HE WENT TO THE HOSPITAL (b) (6) WHERE HE WAS OBSERVED FOR (b) (6) HOURS THEN RELEASED. CHILD HAD FEVER OF 103F BEFORE GOING TO HOSPITAL WHERE AFTER (b) (6) HOURS HIS FEVER DROPPED TO 101F. MOTHER CONTINUED GIVING CHILD TEETHING TABLETS AGAIN ON 06/27/12 FOR 5 DAYS (1 TABLET PER DAY) AND SYMPTOMS DID NOT RETURN.

HOSPITAL THOUGHT IT MIGHT BE AN INFANT FORM OF ASTHMA, BUT DID DMAKE A DEFINITIVE DIAGNOSIS, SAYING CHILD WAS TOO YOUNG.

RECEIVED
AUG 0 2 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

OXYGENATION TEST = 87%
BREATHING TREATMENTS
PRESCRIBED STEROIDS FOR 5 DAYS

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

FATHER HAS A HISTORY OF INFANT ASTHMA WHEN HE WAS YOUNG.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABS X 2 DOSES
#2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1
#2

4. Diagnosis for Use *(Indication)*
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | Catalog # | Expiration Date *(mm/dd/yyyy)* | Serial # | Other #

5. Operator of Device
- ☐ Health Professional
- ☐ Lay User/Patient
- ☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS
AUG 03 2012

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

AUG 0 2 2012 USA

2. Health Professional? ☐ Yes ☑ No

3. Occupation

4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ◉ Unk.

Individual Safety Report

CaseID: 8736052

MED FORM 8598192-6-00-02

FDA USE ONLY

F. FO

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code _____ - _____ - _____ ; Device Code _____ - _____ - _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 07/06/2012

5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): BREATHING PROBLEMS, GASPING FOR AIR

9. Manufacturer Report Number: 54973 RAE070612TG001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: _____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method _____ - _____ - _____ - _____ ; Results _____ - _____ - _____ - _____ ; Conclusions _____ - _____ - _____ - _____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: _____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
AUG 03 2012

AUG 0 2 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

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Individual Safety Report

8598192-6-00-03

)NTINUATION PAGE)
se by user-facilities,
ributors, and manufacturers
NDATORY reporting

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

DSS
AUG 03 2012

Other Remarks

AUG 0 2 2012

CaseID: 8736052

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD070612TG-001

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 07/06/12

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: TEET---T135

SIZE: 135 TABLETS

LOT NO.: N/A

REPORTER: (b) (6)

ADDRESS:

Individual Safety Report
8598192-6-00-04

CITY:

COUNTRY: USA

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: MOTHER GAVE HER SON THE FIRST DOSE OF TEETHING TABLETS AT THE SAME TIME THAT HE WAS BEGINNING TO HAVE 'BREATHING PROBLEMS: GASPING FOR AIR, RETRACTION, HARD TO GET ENOUGH AIR'. HE WENT TO THE HOSPITAL (b) (6) WHERE HE WAS OBSERVED FOR (b) HOURS THEN RELEASED. HIS FATHER HAS A HISTORY OF INFANT ASTHMA WHEN HE WAS YOUNG. THE MOTHER CONTINUED GIVING CHILD THE TEETHING TABLETS ON THEIR RETURN HOME FOR THE NEXT 5 DAYS, WHEN SHE HEARD OF THE RECALL AND CALLED TO INQUIRE. MOTHER SAID HER SON WAS HAVING 6 TEETH COME THROUGH AT THE SAME TIME. IT WAS ALSO MENTIONED THAT THE MOTHER CALLED THE COMPANY HOTLINE AND HEARD THAT ALL TEETHING TABLET PRODUCTS WERE ON RECALL WHICH WORRIED HER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: INSPECTED RETAINED SAMPLES OF LOT #S 112344, 112957, AND 113050. INSPECTED LOTS WERE FOUND TO BE WITHIN STANDARD SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 07/06/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE070612TG-001

DSS

AUG 03 2012

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 07/06/12 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY: RWatt DATE: 07-20-12

BY: N/A 07-20-12 QA / QC DIRECTOR DATE: 07-20-12

cc: QA / QC, Packaging, Production, Shipping / Receiving

AUG 0 2 2012

Form # VD1

CaseID: 8736052

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Individual Safety Report

SERIC

8598192-6-00-05

AE #: RAE070612TG001

COMPLAINT #: RVD070612TG001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

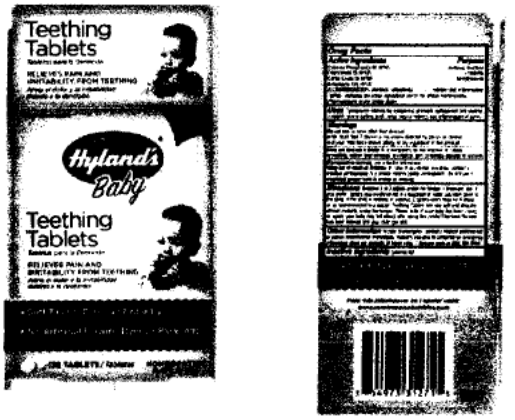
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS
AUG 03 2012

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 07-20-12

BY: N/A DATE: 07-20-12
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

AUG 0 2 2012

Individual Case Safety Report

8858739-01-00-01

CDER

OTC

CaseID: 8858739

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

VOLUNTARY reporting of events, product problems and product use errors

Internet Submission - Page 1

DQRS

FDA USE ONLY

Triage unit sequence # 491705

Adverse Event Reporting Program

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 7 Months	☑ Female ☐ Male	18.5 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   ☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
   ☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
   ☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
   ☑ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/25/2009	10/22/2012

5. Describe Event, Problem or Product Use Error

My daughter was diagnosed with kryptogenic infantile spasms -seizures-shortly after cutting her first tooth-9/8/2009- and while cutting her second tooth - (b) (6) Prior to this she had been perfectly healthy and on track with her development. We had used Hyland's Teething Tablets, which I was reading recently could be the cause of seizures in infants and any possible conections should be reported. We always followed the vague dosing instructions.

More

6. Relevant Tests/Laboratory Data, Including Dates

EEG - (b) (6) - confirmed seizures

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

N/A

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hyland's Teething Tablets
   #2

2.	Dose or Amount	Frequency	Route
#1	1-2 tablets	2-3 times per day	po
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
   #1 09/01/2009 -- 10/25/2009
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Teething
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☑ Doesn't Apply
   #2 ☐ Yes ☐ No ☑ Doesn't Apply

6. Lot #
   #1 105704
   #2

7. Expiration Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☑ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
   54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

CTU

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

OCT 23 2012

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

DSS

OCT 23 2012

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6) E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CaseID: 8901795

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Individual Case Safety Report

8901795-01-00-01

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...d user-facilities, ...butors and manufacturers ...DATFOR reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	9 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/21/2012	10/21/2012

5. Describe Event or Problem

(b) (6) FATHER CALLED ABOUT A WHITE TABLET WITH THE IMPRINT TARO-11 WHICH HE HAD GIVEN TO CHILD FROM A BOTTLE OF HYLAND'S BABY TEETHING TABLETS. (b) (6) CHILD EXHIBITING SYMPTOMS OF DIZZINESS AND VERTIGO AND FATHER WENT TO ER FOR EVALUATION BECAUSE UNSURE IF THSE SYMPTOMS DUE TO CONCURRENT EAR INFECTION OR TARO-11 TABLET THAT CHILD HAD TAKEN.

10/25/12 FOLLOW-UP: SYMPTOMS DUE TO TARO-11 TABLET WHICH WAS IDENTIFIED AS CARBAMAZEPINE AND CHILD WAS HOSPITALIZED FOR 2 DAYS WHILE LEVELS OF DRUG WERE MONITORED. SYMPTOMS RESOLVED. FATHER STATED THAT TARO-11 TABLETS WERE USED BY A MEMBER OF THE FAMILY.

RECEIVED
NOV 06 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2 CARBAMAZEPINE TABLETS

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 UNKNOWN	#1
#2 1 TABLET	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ANTICONVULSANT	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

CARBAMAZZEPINE TABLET

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS
NOV 07 2012
NOV 06 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 8901795

8901795-01-00-02

FDA USE ONLY

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____

11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/21/2012

5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
DIZZINESS, VERTIGO

9. Manufacturer Report Number
54973 AE # 1088

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: _____

2. If Follow-up, What Type?
☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method _____ - _____ - _____ - _____
Results _____ - _____ - _____ - _____
Conclusions _____ - _____ - _____ - _____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: _____

8. Usage of Device
☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

NOV 0 6 2012

NOV 07 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

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Individual Case Safety Report

8901795-01-00-03

NTINUATION PAGE)
se by user-facilities,
ributors, and manufacturers
NDATORY reporting

FORM FDA 3500A (6/10) *(continued)*

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
NOV 07 2012

NOV 0 6 2012

CaseID: 8901795

Individual Case Safety Report

8901795-01-00-04

R COMPLAINT RECORD

COMPLAINT #: 1831

DATE OF COMPLAINT: 10/21/12

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: DOESN'T HAVE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CALL CAME IN THROUGH THE BEEPER SERVICE ON (b) (6) A FATHER CALLED AND LEFT A MESSAGE ABOUT A WHITE TABLET HE GAVE HIS SON FROM OUR BTET BOTTLE WITH THE IMPRINT TARO-11. HE WAS INQUIRING WHETHER THIS WAS ACTUALLY A TEETHING TABLET BECAUSE HIS SONE WAS EXHIBITING SYMPTOMS AND HE WAS IN THE EMERGENCY ROOM WITH HIM. WHEN I CALLED BACK HE TOLD ME THAT HE WENT TO THE ER BECAUSE HE GAVE HIS SON THIS TABLET THAT WAS IN THE BTET BOTTLE ON 10/20/12 AND (b) (6) THE CHILD WAS SHOWING SOME DIZZINESS/VERTIFO AND HE WAS NOT SURE WHERE IT WAS DUE TO THIS TABLET OR AN EAR INFECTION THAT THE CHILD ALSO HAD. WHEN I QUESTIONED HIM ABOUT THE FOREIGHT TABLET IN THE BOTTLE, HE SAID THAT HE STRONGLY SUSPECTED THAT IT WAS HIS MOTHER-IN-LAW'S BECAUSE SHE WAS TAKING THIS MEDICATION. 10/25/12 FOLLOW-UP: FATHER TOLD ME THE CHILD'S SYMPTOMS WERE DETERMINED IN THE HOSPITAL TO BE DUE TO THE TABLET HE HAD GIVEN HIM AND THAT THE CHILD WAS HOSPITALIZED FOR 2 DAYS WHILE LEVELS OF THE DRUG WERE MONITORED. FATHER STATED THAT THE TABLET WAS TEGRETOL (WHICH IS CARBAMAZEPINE) AND CONFIRMED THAT THIS WAS A DRUG THAT HIS MOTHER-IN-LAW IS TAKING AND THAT SHE HAD PUT IT IN THE BOTTLE AND HE HAD GIVEN IT TO THE CHILD UNKNOWNINGLY. THE SYMPTOMS HAVE RESOLVED AND THE CHILD IS FINE. THE FATHER STATED "IT'S NOT Y'ALLS FAULT".

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

10/25/12: FATHER NO LONGER HAS BOTTLE TO PROVIDE LOT # BECAUSE HE LEFT IT IN THE HOSPITAL.

PRODUCT BEING RETURNED FOR INSPECTION: Y N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y N (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: INSPECTED LOT #S 115315, 114597, AND 112435 AND EVERYTHING LOOKS FINE.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/21/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1088

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/21/12 BY: EDYTA FRACKIEWICZ

DSS NOV 07 2012

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 10-30-12

BY: QA / QC DIRECTOR DATE: 10-30-12

cc: QA / QC, Packaging, Production, Shipping / Receiving

NOV 0 6 2012

Form # VD1

CaseID: 8901795

Individual Case Safety Report

8901795-01-00-05

Hyland's

:RSE EVENT DATA FORM

AE #: 1088

COMPLAINT #: 1831

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

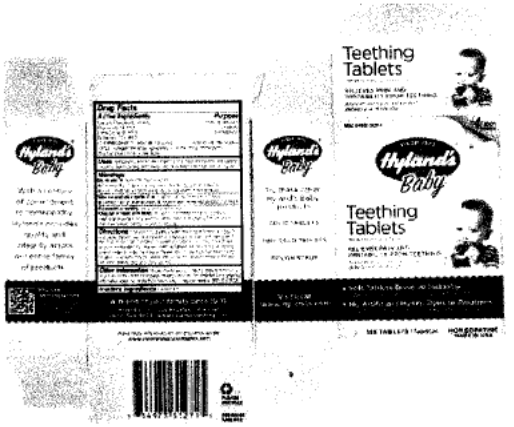
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWdH DATE: 10-30-12

BY: QA / QC DIRECTOR DATE: 10-30-12

DSS NOV 07 2012

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

NOV 0 6 2012

Individual Case Safety Report

8901795-01-00-06

Drugs.com

TARO 11

Pill imprint TARO 11 has been identified as **Carbamazepine 200 mg**.

Carbamazepine is used in the treatment of peripheral neuropathy; epilepsy; trigeminal neuralgia; bipolar disorder; schizoaffective disorder (and more), and belongs to the drug class dibenzazepine anticonvulsants. There is positive evidence of human fetal risk during pregnancy.

Carbamazepine 200 mg is not subject to the Controlled Substances Act.
See also related documents.

Images & Information

Carbamazepine

Imprint:
TARO 11

Strength:
200 mg

Color:
White

Shape:
Round

Availability:
Prescription only

Drug Class:
Dibenzazepine anticonvulsants

Pregnancy Category:
D - Positive evidence of risk

CSA Schedule:
N - Not a controlled drug

Manufacturer:
Taro Pharmaceuticals U.S.A., Inc.

View Details | Print Page

DSS
NOV 07 2012

NOV 0 6 2012

10/29/2012

Individual Case Safety Report

8901795-01-00-07

Search Again

Search by Imprint, Shape or Color

Note: All fields optional. Use the pill finder to identify medications by visual appearance or name.

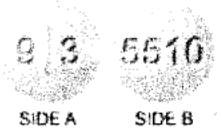
Imprint:

Color: --- optional ---

Shape: --- optional ---

Search

Enter the letters or numbers from your pill

Example 

SIDE A SIDE B

FOR THIS TABLET YOU WOULD ENTER
9 3 5510

HINT: To get more results, enter an imprint only. To further expand your search, try entering only part of your imprint.

Search by Drug Name

Drug Name:

Search

Search by National Drug Codes (NDC)

NDC:

Search

What is an NDC Number?

DSS
NOV 07 2012

NOV 0 6 2012

10/29/2012

CaseID: 8901821

Form Approved: OMB No. 09 10-029 1 , Expires 12/31/11
See OMB statement on reverse.

Individual Case Safety Report

8901821-01-00-01

MTC
r use by user facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	or Date of Birth:	☐ Female ☐ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☑ Death: (b) (6) *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☐ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/18/2012	10/19/2012

5. Describe Event or Problem

DETECTIVE RECEIVED A PHONE CALL FROM A HOSPITAL AFTER A BABY DIED. THEY NOTICED THE BABY HAD BEEN TAKING TEETHING TABELTS, AND WAS CONCERNED ABOUT THE PAST RECALL, AND THE REMEDY BELLADONNA.

RECEIVED
NOV 0 6 2012
CDR

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

DETECTIVE WANTED TO KNOW THE DATE OF MANUFACTURE OF THE PRODUCT WHICH WAS DECEMBER 13, 2011.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 UNKNOWN	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 RELIEF OF TEETHING PAIN	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 114255	#1	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

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)*

Dsc

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6) (b) (6)

7 2012

NOV 0 6 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

CaseID: 8901821

Individual Case Safety Report

ME

FOI

FDA USE ONLY

F.

8901821-01-00-02

1. C\
☐ User Facility ☐ Importer

2. Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

TUTTI GOULD
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/18/2012

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
DEATH

9. Manufacturer Report Number
54973 AE #1094

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: _____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
NOV 07 2012
NOV 0 6 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

Individual Case Safety Report

8901821-01-00-03

(CONTINUATION PAGE)
For use by user-facilities,
, distributors, and manufacturers
MANDATORY reporting

FORM FDA 3500A (6/10) (continued)

B.5. Describe Event or Problem *(continued)*

B.6. Relevant Tests/Laboratory Data, Including Dates *(continued)*

B.7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
NOV 07 2012

NOV 0 6 2012

Individual Case Safety Report

CaseID: 8901821

ER COMPLAINT RECORD

8901821-01-00-04

COMPLAINT #: 1840

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/18/12

PRODUCT: BABY TEETHING TABLET

ITEM CODE: BTET

SIZE:

LOT NO.:

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: I HAVE BEEN UNABLE TO REACH DETECTIVE (b) (6) BY PHONE, BUT HAVE ANSWERED HIS REQUESTS LEFT ON VOICE MAIL. HE SAID THE HOSPITAL CALLED HIM AFTER A BABY DIED. THEY NOTICED THE BABY HAD BEEN TAKING TEETHING TABLETS, AND WAS CONCERNED ABOUT THE PAST RECALL, AND THE REMEDY BELLADONNA. THE DETECTIVE WANTED TO KNOW THE DATE OF MANUFACTURE OF THE PRODUCT, AND IT WAS GIVEN: DEC. 13, 2011. HE MENTIONED ON THE PHONE, THAT THEY ARE NOT DRAWING ANY CONCLUSIONS ABOUT THE REMEDY, BUT JUST WANT THE INFORMATION. I LEFT A MESSAGE THAT THIS WAS A RE-FORMULATED PRODUCT, THE BELLADONNA WAS SAFE AT 12X, AND IT WAS NOT A RECALLED PRODUCT AS IS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

10/19/12: L/M
10/26/12: TRIED TO REACH DETECTIVE TWICE AND LEFT HIM A MESSAGE BUT ATTEMPTS AT REACHING HIM WERE UNSUCCESSFUL.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: INSPECTED LOT # 114255 AND EVERYTHING LOOKS FINE.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/18/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1094

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/18/12 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY: RWA DATE: 10-30-12

BY: QA / QC DIRECTOR DATE: 10-30-12

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

NOV 0 6 2012

DS

NOV 07 20

CaseID: 8901821

Individual Case Safety Report

8901821-01-00-05

Hyland's

SE EVENT DATA FORM

AE #: 1094 **COMPLAINT #:** 1840

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: UNKNOWN CHILD

ADDRESS:

CITY: STATE: (b) (6)

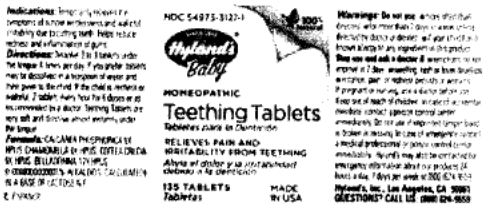
COUNTRY: USA ZIP CODE:

PHONE #:

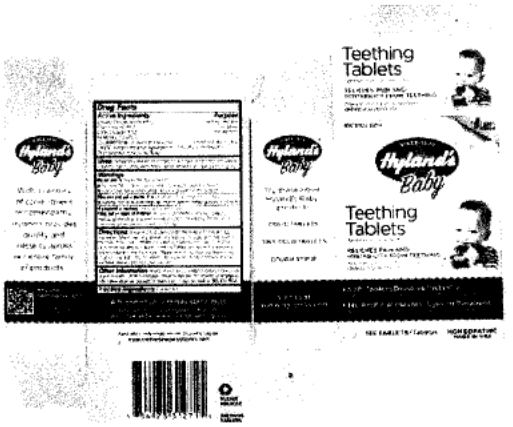
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10-30-12

BY: QA / QC DIRECTOR DATE: 10-30-12

DSS NOV 07 201

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

NOV 0 6 2012

Individual Case Safety Report

CaseID: 8994666

Form Approved: OMB No. 09 10-029 1 , Expires 12/31/11
See OMB statement on reverse.

8994666-01-00-01

For use by user-facilities, s, distributors and manufacturers MANDATORY reporting

FORM FDA 3500A (6/10)

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	8 Months or Date of Birth:	☐ Female ☑ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/27/2012	12/04/2012

5. Describe Event or Problem

APPROXIMATELY 4 HOURS AFTER A DOSE OF BABY TEETTHING TABLETS CHILD BECAME PALE, FEVER OF 102.3F, DEHYDRATION (NO WET DIAPERS), LETHARGY, SCREAMING AND INCONSOLABLE. CHILD WAS ADMITTED FOR 2 NIGHTS TO THE HOSPITAL AND UNDERWENT TESTS SUCH AS LP AND BLOODWORK. CHILD GIVEN ROCEPHIN AND IV HYDRATION. SYMPTOMS RESOLVED AND CHILD DISCHARGED ON (b) (6) TESTS NORMAL AND NO INFECTION FOUND AND NO MEDICAL EXPLANATION FOR SYMPTOMS. PHYSICIAN BELIEVED THAT SYMPTOMS SECONDARY TO BELLADONNA.

6. Relevant Tests/Laboratory Data, Including Dates

BLOODWORK AND LUMBAR PUNCTURE

CHILD GIVEN ROCEPHIN AN DIV HYDRATION

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO OTHER MEDICATIONS. NO KNOWN ALLERGIES. NO NEW FOODS. FORMULA FED.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 2 TABLETS ORALLY ONCE	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS

USA DEC 26 2012

DEC 27 2012

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 8994666

8994666-01-00-02

FDA USE ONLY

B. REPORTER (Primary Source)

1. **Check One**
   - ☐ User Facility
   - ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report**
   - ☐ Initial
   - ☐ Follow-up # _____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
   - Patient Code: ____ – ____ – ____
   - Device Code: ____ – ____ – ____

11. **Report Sent to FDA?**
   - ☐ Yes _____ *(mm/dd/yyyy)*
   - ☐ No

12. **Location Where Event Occurred**
   - ☐ Hospital
   - ☐ Home
   - ☐ Nursing Home
   - ☐ Outpatient Treatment Facility
   - ☐ Outpatient Diagnostic Facility
   - ☐ Ambulatory Surgical Facility
   - ☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?**
   - ☐ Yes _____ *(mm/dd/yyyy)*
   - ☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number**
310-768-0700

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☐ Study
   - ☐ Literature
   - ☑ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
11/30/2012

5.
   - (A)NDA # _____
   - IND # _____
   - STN # _____
   - PMA/ 510(k) # _____
   - Combination Product ☐ Yes
   - Pre-1938 ☐ Yes
   - OTC Product ☑ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day
   - ☐ 30-day
   - ☐ 7-day
   - ☐ Periodic
   - ☐ 10-day
   - ☑ Initial
   - ☑ 15-day
   - ☐ Follow-up # ____

8. **Adverse Event Term(s)**
LETHARGY, PALLOR, FEVER, DEHYDRATION

9. **Manufacturer Report Number**
54973 AE # 1137

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - ☐ Death
   - ☐ Serious Injury
   - ☐ Malfunction
   - ☐ Other: _____

2. **If Follow-up, What Type?**
   - ☐ Correction
   - ☐ Additional Information
   - ☐ Response to FDA Request
   - ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
   - ☐ Not Returned to Manufacturer
   - ☐ Yes ☐ Evaluation Summary Attached
   - ☐ No *(Attach page to explain why not)* or provide code: _____

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?**
   - ☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
   - Method: ____ – ____ – ____ – ____
   - Results: ____ – ____ – ____ – ____
   - Conclusions: ____ – ____ – ____ – ____

7. **If Remedial Action Initiated, Check Type**
   - ☐ Recall
   - ☐ Repair
   - ☐ Replace
   - ☐ Relabeling
   - ☐ Notification
   - ☐ Inspection
   - ☐ Patient Monitoring
   - ☐ Modification/ Adjustment
   - ☐ Other: _____

8. **Usage of Device**
   - ☐ Initial Use of Device
   - ☐ Reuse
   - ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS
DEC 26 2012

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

DEC 27 2012

FORM FDA 3500A (6/10) *(continued)*

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

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DEC 26 2012

Other Remarks

DEC 21 2012

Individual Case Safety Report

CaseID: 8994666

CUSTOMER COMPLAINT RECORD

8994666-01-00-04

COMPLAINT #: 1926

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 11/30/12

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: DOES NOT HAVE WITH HER PURCHASED 3 WEEKS AGO

REPORTER: (b) (6)

ADDRESS:

RECEIVED
DEC 21 2012
CDR

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: (b) (6) CHILDREN'S HOSPITAL. GAVE CHILD 2 TABLETS AT 9 AM AND APPROXIMATELY 1 PM PALE, FEVER (102.3°F), EXTREME DEHYDRATION (NO WET DIAPER), LETHARGY, SCREAMING AND INCONSOLABLE. CHILD WAS NOT SICK AT THE TIME. TOOK TO PEDIATRICIAN AND THEN TO ER AND THEN LIFE FLIGHTED TO (b) (6) HOSPITAL. STAYED IN-PATIENT FOR 2 NIGHTS. WENT THROUGH TESTS, LUMBAR PUNCTURE, I/O. GAVE HIM AN ANTIBIOTIC, ROCEPHIN AND IV'S. SYMPTOMS RESOLVED. DISCONTINUED USE OF PRODUCT ON (b) (6) HOSPITALIZED ON (b) (6) DOCTOR TEAM SAID THAT CHILD HAD A REACTION TO THE BELLA-DONNA. BLOODWORK WAS NORMAL. NO INFECTION. NO EXPLANATION FOR SYMPTOMS. BLODES NEGATIVE COMMENTS ON (b) (6) AND SHE WANTED TO POST ON (b) (6) AND COMMENTS WERE BLOCKED. WANTS TO KNOW WHY WE CONTINUE TO PUT BELLADONNA IN TABLETS. I EXPLAINED TO CUSTOMER THE 12X POTENCY, THE NECESSITY TO EAT 800 TABLETS FOR FIRST SYMPTOMS OF BELLADONNA TOXICITY, OFFERED TO SPEAK WITH HER DOCTORS AND OFFERED HER A REFUND THAT SHE DECLINED. SHE DENIES THAT ANY BLOODWORK SHOWED PRESENCE OF BELLADONNA.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

NO OTHER MEDICATIONS. NO KNOWN ALLERGIES. NO NEW FOODS. FORMULA FED.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: REVIEWED BATCH RECORDS AND TESTING RECORDS, ALSO INSPECTED RETAINED SAMPLES FROM LOTS # 114022, 114597, AND 112370 AND EVERYTHING LOOKED OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 11/30/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1137

DSS
DEC 26 2012

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/30/12 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: RWalt DATE: 12-11-12

BY: QA / QC DIRECTOR DATE: 12-10-12

DEC 21 2012

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

Individual Case Safety Report

CaseID: 8994666

8994666-01-00-05

; ADVERSE EVENT DATA FORM

AE #: 1137 **COMPLAINT #:** 1926

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

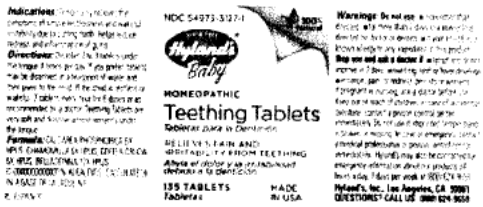
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

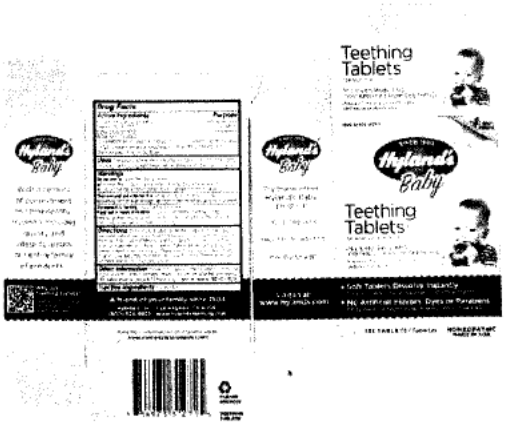
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 12-11-12

BY: QA / QC DIRECTOR DATE: 12-10-12

DSS DEC 26 2012

DEC 21 2012

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

CaseID: 9026575

Individual Case Safety Report

9026575-01-00-01

CDER

)LUNTARY reporting of ents, product problems and product use errors

Page 1 of 1 DQRS

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 496893

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
In confidence	8 months	☑ Female ☐ Male	lb or 9 kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☑ Death: (b) (6) *(mm/dd/yyyy)*
☑ Life-threatening
☐ Hospitalization - Initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
10/7/12	10/8/12

5. Describe Event, Problem or Product Use Error

Baby died on (b) (6) after taking teething tablets for two weeks. Product was recalled but its still on the market.

6. Relevant Tests/Laboratory Data, Including Dates

Autopsy (b) (6)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

CTU

DEC 14 2012

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

(1)
#1 Name: Teething Tablets
Strength:
Manufacturer: Hyland

#2 Name:
Strength:
Manufacturer:

OTC

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 Past 2 weeks	#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☑ Doesn't Apply

4. Diagnosis or Reason for Use *(Indication)*
#1 Teething
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Name: (b) (6)
Address: (b) (6)
City: (b) (6) State: (b) (6) ZIP: (b) (6)

USE

DEC 14 2012

Phone #: (b) (6)
E-mail:

2. Health Professional?	3. Occupation	4. Also Reported to:
☑ Yes ☐ No	Physician	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

REPORT TAKEN BY PHONE. MAY RPTR'S IDENTITY BE DISCLOSED TO MFR? (YES) or NO

CaseID: 9028016

Individual Case Safety Report

9028016-01-00-01

FDA Use Only

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statem ent on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence
2. Age at Time of Event: 5 Months or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: ____ (mm/dd/yyyy)
- ☐ Life-threatening
- ☑ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 12/14/2012

4. Date of This Report (mm/dd/yyyy): 12/17/2012

5. Describe Event or Problem

A MOTHER CALLED TO REPORT HER CHILD HAD BEEN HOSPITALIZED WITH BABY BOTULISM. THE CHILD WENT TO THE ER ON (b) (6) IN THE EVENING WITH SYMPTOMS OF CONSTIPATION FOR 1 WEEK, HEAD LAG, INABILITY TO REACH OR GRAB, NOT RESPONDING, NOT EATING OR SUCKING. CHILD WAS ADMITTED TO THE HOSPITAL AND BOTULISM WAS CONFIRMED, HOWEVER THEY ARE WAITING FOR RESULTS OF STOOL SAMPLES FOR CONFIRMATION.

6. Relevant Tests/Laboratory Data, Including Dates

CHILD RECEIVING IV FLUIDS AND WILL BE GIVEN A FEEDING TUBE. RESULTS OF BLOOD WORK EXPECTED IN A COUPLE OF WEEKS. RESULTS OF STOOL SAMPLES PENDING.
CHILD GIVEN IMMUNOGLOBULIN AND IS STARTING TO FEEL BETTER.

HOSPITALIZATION EXPECTED FOR 1 WEEK AND MAY HAVE DEVELOPMENTAL DELAYS FOR UP TO 3 MONTHS.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CHILD HAD MENINGITIS WHEN HE WAS 7 WEEKS OLD

CHILD IS BREASTFED AND STARTED CEREAL ABOUT 1 MONTH AGO. MOTHER REPORTS THAT CHILD ALSO TAKES ZANTAC 1 ML BID.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S BABY TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2TABS/NEEDED HS 2-5X/WK
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-3127-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone # (b) (6)

DSS
JAN 07 2013
JAN 04 2012

2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☑ Unk.

JAN 04 2012

Individual Case Safety Report

9028016-01-00-02

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Request
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- [ ] Yes [ ] No

6. Evaluation Codes *(Refer to coding manual)*

Method [ ] - [ ] - [ ] - [ ]

Results [ ] - [ ] - [ ] - [ ]

Conclusions [ ] - [ ] - [ ] - [ ]

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/ Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360I(f), list correction/ removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

1. Check One
- [ ] User Facility
- [ ] Importer

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code [ ] - [ ] - [ ]

Device Code [ ] - [ ] - [ ]

11. Report Sent to FDA?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Home
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Outpatient Diagnostic Facility
- [ ] Ambulatory Surgical Facility
- [ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
12/15/2012

5.
- (A)NDA # ____
- IND # ____
- STN # ____
- PMA/ 510(k) # ____
- Combination Product [ ] Yes
- Pre-1938 [ ] Yes
- OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- [ ] 5-day
- [ ] 7-day
- [ ] 10-day
- [x] 15-day
- [ ] 30-day
- [ ] Periodic
- [x] Initial
- [ ] Follow-up # ____

9. Manufacturer Report Number
54973 AE # 1162

8. Adverse Event Term(s)
BABY BOTULISM

DSS
JAN 07 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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"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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JAN 04 2012

Individual Case Safety Report

9028016-01-00-03

(CONTINUATION PAGE)
r use by user-facilities,
listributors, and manufacturers
fANDATORY reporting

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
JAN 07 2013

JAN 04 2012

Individual Case Safety Report

CaseID: 9028016

ÞMER COMPLAINT RECORD

9028016-01-00-04

COMPLAINT #: 1962

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/15/12

PRODUCT: BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: UNABLE TO PROVIDE. HOSPITAL KEPT BOTTLE.

REPORTER: (b) (6)

ADDRESS:

RECEIVED

JAN 04 2013

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

CDR

E-MAIL:

NATURE OF COMPLAINT: A MOTHER CALLED TO REPORT THAT HER 5 MONTH OLD HAS BEEN HOSPITALIZED WITH BABY BOTULISM. CHILD WENT TO THE ER ON (b) (6) IN THE EVENING WITH SYMPTOMS OF CONSTIPATION X 1 WEEK, HEAD LAG, INABILITY TO REACH OR GRAB, NOT RESPONDING, NOT EATING OR SUCKING. CHILD WAS ADMITTED TO THE HOSPITAL AND BOTULISM WAS CONFIRMED, HOWEVER THEY ARE WAITING FOR RESULTS OF STOOL SAMPLES FOR CONFIRMATION. CHILD IS RECEIVING IV FLUIDS AND WILL BE GIVEN A FEEDING TUBE. THE MOTHER HAD BEEN USING THE BABY TEETHING TABLETS 2 TABLETS AS NEEDED AT BEDTIME 2 – 5 TIMES A WEEK FOR 1 MONTH. CHILD IS BREASTFED AND STARTED CEREAL ABOUT 1 MONTH AGO. THE MOTHER REPORTS THAT THE CHILD ALSO TAKES ZANTAC 1 ML TWICE A DAY. HE HAD MENINGITIS WHEN HE WAS 7 WEEKS OLD AND WAS TREATED. CHILD HAS NOT EATEN ANY CANNED FOODS OR HONEY. BECAUSE OF INTERNET REPORTS ON BOTULISM FOR TEETHING TABLETS PRIOR TO THE RECALL, THE DOCTORS HAVE SUSPECTED THE TEETHING TABLETS AND HAVE FILED A REPORT WITH THE FDA ACCORDING TO THE MOTHER, BUT AFTER AN INFECTIOUS DISEASE CONSULT THE DOCTORS ARE NOW LEANING TOWARD BREASTFEEDING AS BEING THE POSSIBLE CAUSE, BUT HAVE NOT RULED OUT THE TEETHING TABLETS ENTIRELY. THE MOTHER WAS UNABLE TO PROVIDE A LOT # BUT STATED THEY PURCHASED PRODUCT FROM RITEAID A FEW WEEKS AGO. OUR PHARMACIST ASKED HER TO TRY TO GET THE LOT # FOR OUR INVESTIGATION. SHE SAID THAT THE HOSPITAL TOOK THE BOTTLE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

12/15/12 2ND FOLLOW-UP CALL: CHILD WAS TAKING 2 TABLETS AS NEEDED AT BEDTIME 2 – 5 TIMES A WEEK FOR 1 MONTH.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: INSPECTED RETAINED SAMPLE OF ALL BABY TEETHING TABLETS PACKAGED AND DISTRIBUTED FROM 06/15/12 TO 12/15/12 (6 MONTHS) AND EVERYTHING LOOKS FINE.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 12/15/12

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1162

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/15/12 BY: EDYTA FRACKIEWICZ

DSS

JAN 07 2013

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE:

BY: QA / QC DIRECTOR DATE: 12-27-12

JAN 04 2012

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 9028016

Individual Case Safety Report

9028016-01-00-05

Hyland's

US ADVERSE EVENT DATA FORM

AE #: 1162 **COMPLAINT #:** 1962

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

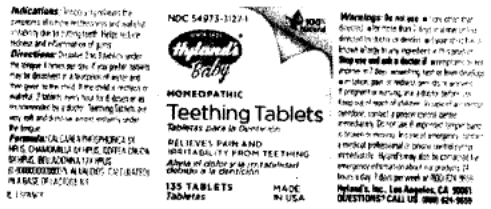
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

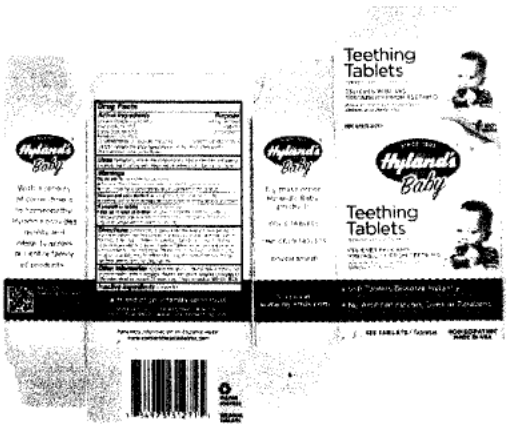
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

BY: QA / QC DIRECTOR DATE: 12-27-12

DCS JAN 07 2013

JAN 04 2012

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

9037214-01-00-01

CDER

OTC

CaseID: 9037214

VOLUNTARY reporting of events, product problems and product use errors

Form approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence # 500433

Adverse Event Reporting Program

Internet Submission - Page 1

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6) 10 Months	☐ Female ☑ Male	18 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/17/2013	01/18/2013

5. Describe Event, Problem or Product Use Error

After taking product my son who was in perfect health devoloped an irritation of the skin mor commonly known as hives. After being brought to the emergancy room the doctor had question the use of belladonna in an infant pain remedy resulting in my child being prescribed two different medications.

More

6. Relevant Tests/Laboratory Data, Including Dates

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

No other preexisting medical cinditions

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 hyland's teething tablets hyland's inc.
#2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
#1 --
#2 --

4. Diagnosis or Reason for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

CTU

JAN 23 2013

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

DSS

JAN 23 2013

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

Phone # (b) (6)

E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

CaseID: 9046531

9046531-01-00-01

TC CDER

VOLUNTARY reporting of serious product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 501059

The FDA Safety Information and Adverse Event Reporting Program

Internet Submission - Page 1/3

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	(b) (6)	☑ Female ☐ Male	23 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)

☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
	01/23/2013

5. Describe Event, Problem or Product Use Error

My two year old daughter has been tested for every possible disease and medical problem that you could possible think of. She's had seizures, GI problems-absorption, constipation, severe pain-, muscle weakness-recieved Early Intervention-, extremely high body temperatures, increased heart rate, sleep apnea, and not growing at the proper rate of a child her age. With all the different testing that they have done on her most have come back inconclusive. They classified her seizures as febrile even though her neurologist said they were not "typical". Doctors suggested that her tonsils and adenoids be removed for the apnea but breathing problems

More

6. Relevant Tests/Laboratory Data, Including Dates

She has had so many tests done from hospital ER visits, neurology, geneticist, infectious disease, visits to specialists at hospitals away from home, as well as from her own PCP that test/lab results will take some time to gather, due to the fact that she as been so many places and has had so many

More

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 teething tablets NA Hylands
#2

2.	Dose or Amount	Frequency	Route
#1	2-3 tablets	4xs per day	Dental
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 --
#2 --

4. Diagnosis or Reason for Use (Indication)
#1 teething
#2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
54973-7504-1

E. SUSPECT MEDICAL DEVICE

1. Brand Name
Hlands teething tablets

2. Common Device Name

3. Manufacturer Name, City and State
Hyland's, Inc. LA, CA 90061

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☑ Other: Mother
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

CTU
JAN 28 2013

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

JAN 28 2013

More

G. REPORTER (See confidentiality section on back)

1. Name and Address
(b) (6)

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

still exist. It has been brought to my attention that the Belladonna, that is in Hylands teething tablets, has been known to cause some of these problems. During the time my daughter was sick she was taking these.

DSS

JAN 28 2013

B6. Relevant tests/laboratory data, including dates continued

things done to her.

DSS

JAN 28 2013

Individual Case Safety Report

9053810-01-00-01

CDER

CaseID: 9053810

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

LUNTARY reporting of
ents, product problems and
product use errors

The FDA Safety Information and
Adverse Event Reporting Program

Internet Submission - Page 1

FDA USE ONLY
Triage unit sequence # 501605

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	(b) (6) 9 Months	☑ Female ☐ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ Adverse Event ☑ Product Problem *(e.g., defects/malfunctions)*
   ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   ☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
   ☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
   ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
01/31/2013	01/31/2013

5. Describe Event, Problem or Product Use Error

I have been giving my daughter hylands teething tabs for about three months, she has had a rash and hives pretty much the entire time she has been taking them. I didn't realize it was an allergic reaction the doctor kept telling me it was eczema. She breaks out really bad and turns super red after she takes them. She hasn't been urinating like normal. She's been constipated. After I give them to her she's wide awake freaking out screaming and crying. Doesn't want to eat like normal. She's been dehydrated.

More

6. Relevant Tests/Laboratory Data, Including Dates

CTU
FEB 01 2013

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
   #1 Hylands teething tabs
   #2

2.	Dose or Amount	Frequency	Route
#1	3 at a time	Once or twice a da	
#2			

3. Dates of Use *(If unknown, give duration)* from/to (or best estimate)
   #1 10/01/2012 -- 01/31/2013
   #2 --

4. Diagnosis or Reason for Use *(Indication)*
   #1 Cutting teeth
   #2

5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   #1 115545
   #2

7. Expiration Date
   #1
   #2

8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
   54973-3127-2

E. SUSPECT MEDICAL DEVICE

1. Brand Name
   Hylands
2. Common Device Name
   Teething tabs
3. Manufacturer Name, City and State
   Hylands, Los Angela's, CA

4. Model #	Lot # 115545	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

DSS
FEB 01 2013

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
   (b) (6)

Phone # (b) (6)	E-mail (b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

CaseID: 9233387

9233387-01-00-01

OTC

LUNTARY reporting of
ents, product problems and
product use errors

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence # 509060

The FDA Safety Information and
Adverse Event Reporting Program

Internet Submission - Page 1 / CDER

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
Unspecified In confidence	5 Months	☑ Female ☐ Male	15 lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
☐ Death: ____ *(mm/dd/yyyy)* ☐ Disability or Permanent Damage
☑ Life-threatening ☐ Congenital Anomaly/Birth Defect
☑ Hospitalization - initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*
04/08/2013	04/12/2013

5. Describe Event, Problem or Product Use Error

(b) (6) was given Hylands teething tablets on Saturday, Sunday and Monday -April 6, 7, 8,- On (b) (6) at approx 4:30 pm the baby uncharacteristically fell asleep while in play. She was picked up by the mother and was lifeless and floppy. She did not respond to verbal cues nor to visual cues. She was taken to the Emergency Room. Upon examination, (b) (6) was found to have rapid heartrate and dialated pupils. She was in and out of a deep, confused sleep and awakened dazed and without recognition of parents. She had at this point vomited approximately 5 times. She would not feed nor urinate. She had one bought of diarhea. (b) (6) was admitted to

More

6. Relevant Tests/Laboratory Data, Including Dates

Blood work (b) (6) catscan (b) (6) urinalysis (b) (6) EKG (b) (6) EEG (b) (6) spinal tap (b) (6) MRI (b) (6) abdominal ultrasound (b) (6)

More

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

NONE

More

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☑ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*
#1 Hylands teething tablets
#2

2.	Dose or Amount	Frequency	Route
#1	2 on Saturday, 3 ~~Sunday, 3 Mon~~		
#2			

3. Dates of Use *(If unknown, give duration) from/to (or best estimate)*
#1 04/06/2013 -- 04/08/2013
#2 04/07/2013 -- 04/08/2013

4. Diagnosis or Reason for Use *(Indication)*
#1 teething pain
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date
#1 AO3013	#1
#2	#2

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

CTU

2. Common Device Name

3. Manufacturer Name, City and State

APR 15 2013

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

More

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

DSS

APR 15 2013

Phone #	E-mail
(b) (6)	(b) (6)

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☑ No	Consumer/Non-Health	☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

B5. Describe event or problem continued

the hospital where her symptoms worsened. She was put on IV and had one dose of broad spectrum antibiotic. There was no CHANGE. She continued to vomit and her vomit became coffee grind looking. She was given blood work, urinalysis, Catscan,EKG,EEG catheterization, MRI and a spinal tap. All were normal. By the 4th day (b) (6) was beginning to respond and seemed less lethargic. Eventually, she was given and abdominal ultrasound and by this point her intestines had folded in on themselves and required surgery. (b) (6) is at this point recovering. She is a breast fed baby, only watched by mother and grandmother. No other issues and the tablets are the only out of the ordinary thing.

DSS

APR 15 2013

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Case Safety Report

CaseID: 9275279

9275279-01-00-01

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

r use by user-facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	8 Months or Date of Birth:	☐ Female ☑ Male	lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/11/2013	01/17/2013

5. Describe Event or Problem

INFANT HAS HAD 3 EPISODES OF HEAD JERKING AND LEFT OR RIGHT ARM JERKING LASTING FOR ABOUT 30 SECONDS WHILE TRYING TO FALL ASLEEP. MOTHER THINKS THIS COULD BE A SEIZURE BUT HAS NOT CONSULTED A PHYSICIAN YET.

6. Relevant Tests/Laboratory Data, Including Dates

BORN 6 WEEKS PREMATURE.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NO ILLNESS. BROTHER HAS A HISTORY OF CHILDHOOD SEIZURES AND OUTGREW THEM.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 2 TABS AM, PM, HS, QD, EOD	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 RELIEF OF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

FEB 01 2013

USA

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ◉ No ☐ Unk.

JAN 31 2013

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Request
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- [ ] Yes [ ] No

6. Evaluation Codes *(Refer to coding manual)*

Method ____ - ____ - ____ - ____

Results ____ - ____ - ____ - ____

Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/ Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

DSS

FEB 01 2013

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
01/11/2013

5. (A)NDA # ____
IND # ____
STN # ____
PMA/ 510(k) # ____
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- [ ] 5-day [ ] 30-day
- [ ] 7-day [ ] Periodic
- [ ] 10-day [x] Initial
- [x] 15-day [ ] Follow-up # ____

8. Adverse Event Term(s)
SEIZURE

9. Manufacturer Report Number
54973 AE # 1208

1. FOR USE BY USER FACILITY

1. Check One
- [ ] User Facility
- [ ] Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Home
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Outpatient Diagnostic Facility
- [ ] Ambulatory Surgical Facility
- [ ] Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- [ ] Yes ____ *(mm/dd/yyyy)*
- [ ] No

14. Manufacturer Name/Address

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

JAN 31 2013

B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS

FEB 01 2013

JAN 31 2013

Individual Case Safety Report

CaseID: 9275279

R COMPLAINT RECORD

9275279-01-00-04

COMPLAINT #: 2045

DATE OF COMPLAINT: 01/11/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T250

SIZE: 250 TABLETS

LOT NO.: CAN'T FIND SAYS IT'S NOT THERE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

JAN 31 2013

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: HAS HAPPENED 3 TIMES. LAST OCCURRENCE ON 01/11/13 AT APPROXIMATELY 3 AM. CHILD'S HEAD STARTS JERKING AND MOVES DOWN TO LEFT OR RIGHT ARM. HAPPENS WHEN HE'S TRYING TO FALL ASLEEP OR HAS JUST FALLEN ASLEEP. LAST 30 SECONDS. MOTHER WANTS TO KNOW IF THIS IS A SEIZURE. TOLD HER TO CONTACT HER DOCTOR. OLDER SON HAD A HISTORY OF SEIZURES AS A CHILD AND GREW OUT OF THEM. NO FEVERS. NO ILLNESS. BOTTLE HAS A CHILD RESISTANT CAP PER CUSTOMER SO NEW BOTTLE OF BABY TEETHING TABLETS. CHILD GIVEN 2 TABLETS AM, PM, AND AT BEDTIME EVERY DAY OF EVERY OTHER DAY FOR A COUPLE OF MONTHS. TOLD HER TO STOP USING TABLETS. SHE DID NOT REQUEST A REFUND OR REPLACEMENT. CHILD WAS 6 WEEKS PREMATURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: ALL BABY TEETHING TABLET BATCHES ARE MANUFACTURED AND PACKAGED ACCORDING TO SOP AND PROCEDURES ARE IN PLACE TO PREVENT CONTAMINATION. ALL BABY TEETHING TABLET BATCHES ARE TESTED FOR BELLADONNA ALKALOID ASSAY AND MICROBIAL, AND BATCHES ARE RELEASED AFTER TEST RESULTS FALL WITHIN PRODUCT SPECIFICATIONS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 01/11/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1208

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/11/13 BY: EDYTA FRACKIEWICZ

DSS

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 01-21-13

FEB 01 2013

BY: QA / QC DIRECTOR DATE: 01-18-13

JAN 31 2013

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

CaseID: 9275279

Individual Case Safety Report

9275279-01-00-05

Hyland's®

)VERSE EVENT DATA FORM

AE #: 1208 **COMPLAINT #:** 2045

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

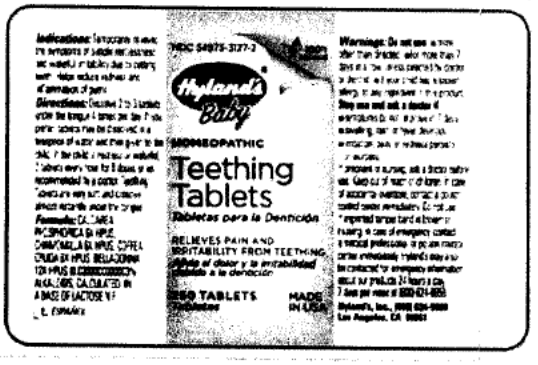
COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

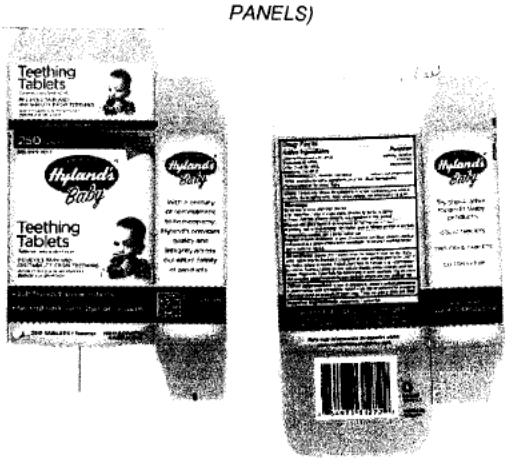
E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWdH DATE: 01-21-13

BY: QA / QC DIRECTOR DATE: 01-18-13

DSS FEB 01 2013

JAN 31 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

9275377-02-00-01

OTC

CaseID: 9275377

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

For use by user-facilities, s, distributors and manufacturers or MANDATORY reporting

Mfr Report # 54973 See page 2

UF/Importer Report #

FDA Use Only

MEDWATCH

FORM FDA 3500A (6/10)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	6 Months	☑ Female ☐ Male	lbs / kgs
In confidence	or Date of Birth:		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☑ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
01/20/2013 & 01/27/2013	08/22/13

5. Describe Event or Problem

MOTHER WAS GIVING 2 TABLETS EVERY 4 HOURS (TID) X 4 DAYS STARTING 01/16/13. ON 01/19/13 THE CHILD BECAME INCREASINGLY IRRITABLE. ON (b) (6) THE CHILD WAS LIMP IN THE NECT, EYES WERE IN A DAZE AND ROLLING AROUND. CHILD WENT TO THE ER BUT NOT ADMITTED. PER MD SYMPTOMS A POSSIBLE REACTION TO THE BELLADONNA. MOTHER DISCONTINUED TEETHING TABLETS. CHILD CONTINUED TO BE WEAK WITH DAZED EYES THAT WANDER AND CAN'T FOCUS. (b) (6) MOTHER REPORTED THAT THE CHILD STOPPED BREATHING AND BECAME FROZEN AND STILL UNTIL SHE SWATTED HER ON THE REAR END AND SHE CAME TO. THEY WENT TO THE ER AND THERE THE CHILD WAS FINE AND ALL VITALS WERE NORMAL.

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 2 TABS TID X 4 DAYS	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 A13812	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS

SEP 06 2013

SEP 09 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		☐ Yes ☐ No ◉ Unk.

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*:
7. Type of Report: ☐ Initial ☐ Follow-up # _____
8. Date of This Report *(mm/dd/yyyy)*:
9. Approximate Age of Device:
10. Event Problem Codes *(Refer to coding manual)*: Patient Code _____ - _____ - _____ Device Code _____ - _____ - _____
11. Report Sent to FDA? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: _____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*:

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 01/28/2013
5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes
6. If IND, Give Protocol #:
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☑ Follow-up # 1
8. Adverse Event Term(s): LIMP EYES ROLLING, STOPPED BREATHING
9. Manufacturer Report Number: 54973 AE # 1247

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:
4. Device Manufacture Date *(mm/yyyy)*:
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method _____ - _____ - _____ - _____ Results _____ - _____ - _____ - _____ Conclusions _____ - _____ - _____ - _____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
SEP 09 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

OMB Statement:
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SEP 06 2013

9275377-02-00-03

ITOMER COMPLAINT RECORD

02-1213 Case

Hyland's

COMPLAINT #: 2095

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 01/28/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET---T135

SIZE: 135 TABLETS

LOT NO.: PURCHASED JAN. 14TH A13812

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE 2 TABLETS EVERY 4 HOURS FOR 4 DAYS. JAN 16TH STARTED. TABS ON (b) (6) SHE WAS IRRITABLE AND (b) (6) SHE WAS LIMP IN THE NECK (HOLDING TO SIDE), EYES WERE IN A DAZE, ROLLING AROUND. WENT TO ER. DOCTOR SAID IT WAS A REACTION TO BELLADONNA. PUPILS WERE REACHING AND DILATED. CHILD CONTINUES TO BE WEAK AND HAS DAZED EYES, WANDERING, CAN'T FOCUS. STARTED TO HOLD HEAD UP; WAS STANDING BEFORE AND NOW WON'T STAND. WENT TO ER (b) (6) BUT WHEN SHE GOT THERE SHE WAS OK. SHE HAD STOPPED BREATHING AND SHE FROZE, STILL, NOT MOVING. SHE CAME TO AND STARTED CRYING. CAN'T GET TO PEDIATRICIAN. VITALS WERE NORMAL. FATHER. WILL SEEK AN ATTORNEY AND WILL CALL THE FDA. WANTS A REFUND. I OFFERED IT TO HER. SHE WANTED MONEY BUT I TOLD HER I WAS NOT AUTHORIZED TO SEND ANYTHING BUT A REFUND. SHE WILL HOLD THE CHECK FOR EVIDENCE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

01/28/13: SPOKE WITH BABY'S FATHER, (b) (6) BECAUSE HE LEFT A MESSAGE. HE WANTED TO KNOW IF WE WOULD REMOVE PRODUCT FROM SHELF BECAUSE IT MADE HIS CHILD ILL.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: REVIEWED BATCH RECORD FOR PACKAGING LOT # A13812 (BULK LOT # 117120). BULK WAS MANUFACTURED ACCORDING TO MANUFACTURING INSTRUCTIONS. ATTACHED IS A COPY OF BELLADONNA ALKALOID ASSAY. RESULT WAS WITHIN SPECIFICATIONS. AFTER PACKAGING SAMAPLES WERE SENT OUT FOR MICRO TEST ACCORDING TO SPECIFICATIONS (SEE ATTACHED FOR MICRO C OF A). RESULTS ARE ARE WITHIN SPECIFICATION. INSPECTED RETAINED SAMPLES AND EVERYTHING LOOKED OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 01/28/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

01/30/13: PREPARED REFUND REQUEST DATED 02/01/13 TOTALING $ 9.19.

CORRECTIVE ACTION(S) COMPLETED BY: VALERIE MAC LEAN DATE: 01/30/13

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1247

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/28/13 BY: Edyta Frackiewicz

SECTION V:

REVIEWED BY MANAGEMENT BY: ~~01/28/13~~ EE Rev 02-11-13 DATE: ~~EDYTA FRACKIEWICZ~~ EERW 02-11-13

BY: QA / QC DIRECTOR DATE: 02-08-13

cc: QA / QC Packaging Production Shipping / Receiving

Form # VD1

SEP 06 2013

DS SEP 09

Individual Case Safety Report

9275377-02-00-04

CaseID: 9275377

Hylands®

SERIOUS ADVERSE EVENT DATA FORM

AE #: 1247 COMPLAINT #: 2095

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

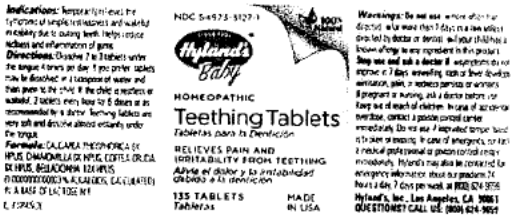
COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS SEP 09 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: R Wall DATE: 02-11-13

BY: QA / QC DIRECTOR DATE: 02-08-13

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

SEP 06 2013

Individual Case Safety Report

CaseID: 9275377

9275377-02-00-05

MER COMPLAINT RECORD

Hyland's

COMPLAINT #: 2095

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 01/28/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: PURCHASED JAN. 14TH A13812

REPORTER: (b) (6)

ADDRESS: (b) (6)

RECEIVED

CITY: (b) (6)

STATE: (b) (6)

SEP 0 3 2013

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

CDR

E-MAIL:

NATURE OF COMPLAINT: GAVE 2 TABLETS EVERY 4 HOURS FOR 4 DAYS. JAN 16TH STARTED. TABS ON (b) (6) SHE WAS IRRITABLE AND (b) (6) SHE WAS LIMP IN THE NECK (HOLDING TO SIDE), EYES WERE IN A DAZE, ROLLING AROUND. WENT TO ER. DOCTOR SAID IT WAS A REACTION TO BELLADONNA. PUPILS WERE REACHING AND DILATED. CHILD CONTINUES TO BE WEAK AND HAS DAZED EYES, WANDERING, CAN'T FOCUS. STARTED TO HOLD HEAD UP; WAS STANDING BEFORE AND NOW WON'T STAND. WENT TO ER (b) (6) BUT WHEN SHE GOT THERE SHE WAS OK. SHE HAD STOPPED BREATHING AND SHE FROZE, STILL, NOT MOVING. SHE CAME TO AND STARTED CRYING. CAN'T GET TO PEDIATRICIAN. VITALS WERE NORMAL. FATHER. WILL SEEK AN ATTORNEY AND WILL CALL THE FDA. WANTS A REFUND. I OFFERED IT TO HER. SHE WANTED MONEY BUT I TOLD HER I WAS NOT AUTHORIZED TO SEND ANYTHING BUT A REFUND. SHE WILL HOLD THE CHECK FOR EVIDENCE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

01/28/13: SPOKE WITH BABY'S FATHER, (b) (6) BECAUSE HE LEFT A MESSAGE. HE WANTED TO KNOW IF WE WOULD REMOVE PRODUCT FROM SHELF BECAUSE IT MADE HIS CHILD ILL.

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: REVIEWED BATCH RECORD FOR PACKAGING LOT # A13812 (BULK LOT # 117120). BULK WAS MANUFACTURED ACCORDING TO MANUFACTURING INSTRUCTIONS. ATTACHED IS A COPY OF BELLADONNA ALKALOID ASSAY. RESULT WAS WITHIN SPECIFICATIONS. AFTER PACKAGING SAMPLES WERE SENT OUT FOR MICRO TEST ACCORDING TO SPECIFICATIONS (SEE ATTACHED FOR MICRO C OF A). RESULTS ARE ARE WITHIN SPECIFICATION. INSPECTED RETAINED SAMPLES AND EVERYTHING LOOKED OK.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON:** 01/28/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY:** EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

01/30/13: PREPARED REFUND REQUEST DATED 02/01/13 TOTALING $ 9.19. 03/11/13: MAILED REFUND CHECK # 509098 TOTALING $ 9.19.

CORRECTIVE ACTION(S) COMPLETED BY: VALERIE MAC LEAN

DATE: 01/30/13 & 08/22/13

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: 1247

DSS

SEP 0 9 2013

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 01/28/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 08-27-13

BY:

QA / QC DIRECTOR

DATE: 08-23-13

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

SEP 0 6 2013

Individual Case Safety Report

CaseID: 9275491

9275491-01-00-01

PG 3/04 OTC

r use by user-facilities, distributors and manufacturers MANDATORY reporting

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (6/10)

Page 1 of 5

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	10 Months	☐ Female	____ lbs
In confidence	or ____	☑ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☐ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
02/27/2013	03/04/2013

5. Describe Event or Problem

CHILD GIVEN 1 TEETHING TABLET AND BECAME LIMP, LIFELESS AND UNABLE TO WAKE UP. WENT TO (b) (6) HOSPITAL ER.

6. Relevant Tests/Laboratory Data, Including Dates

UNKNOWN

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

UNKNOWN

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S BABY TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 1 TABLET ON 02/27/13	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEMP. RELIEF TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	

DSS

MAR 25 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☑ No		◉ Yes ☐ No ☐ Unk.

MAR 2 2 2013

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual) Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply)
☐ Foreign ☐ Study ☐ Literature ☑ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 02/28/2013

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☑ Initial ☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s): LIMP, LIFELESS, UNABLE TO WAKE UP

9. Manufacturer Report Number: 54973 AE # 1290

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual) Method ___ - ___ - ___ - ___ Results ___ - ___ - ___ - ___ Conclusions ___ - ___ - ___ - ___
7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
MAR 25 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

Please DO NOT RETURN this form to this address.

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"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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B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS

MAR 25 2013

MAR 2 2 2013

Individual Case Safety Report

CaseID: 9275491

9275491-01-00-04

R COMPLAINT RECORD

COMPLAINT #: 2173

DATE OF COMPLAINT: 02/28/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #:

E-MAIL: (b) (6)

NATURE OF COMPLAINT: MOTHER AND GRANDMOTHER POSTED ON (b) (6) AND GRANDMOTHER POSTED A PRODUCT REVIEW.

CHILD TOOK 1 TABLET AND WAS LIMP, LIFELESS, UNABLE TO WAKE UP. ACCORDING TO POST CHILD WENT TO (b) (6) HOSPITAL ER. ATTEMPTS MADE TO CONTACT THESE CUSTOMERS VIA (b) (6) AND E-MAIL BUT THEY HAVE NOT CALLED OR E-MAILED TO PROVIDE MORE INFORMATION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: ALL LOTS OF BABY TEETHING TABLETS PRODUCED WERE TESTED FOR BELLADONNA ALKALOIDS AND WERE WITHIN SPECIFICATIONS. ALL PACKAGED TEETHING TABLETS WERE TESTED FOR MICRO AND ARE RELEASED BASED ON RESULTS WITHIN PRODUCT SPECIFICATIONS. NO LOT NUMBER PROVIDED TO INSPECT RETAINED SAMPLES.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 02/28/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

RECEIVED

MAR 22 2013

CDR

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: 1290

ADVERSE EVENT SERIOUS: (Y) / N

DSS

MAR 25 2013

ADVERSE EVENT REPORTED ON: 02/28/13

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 03-06-13

BY:

QA / QC DIRECTOR

DATE: 03-06-13

cc: QA / QC, Production, Packaging, Shipping / Receiving

Form # VD1

MAR 22 2013

Individual Case Safety Report

CaseID: 9275491

9275491-01-00-05

Hyland's®

DVERSE EVENT DATA FORM

AE #: 1290 COMPLAINT #: 2173

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: UNKNOWN MALE CHILD

ADDRESS:

CITY: STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS

MAR 25 2013

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 03-06-13

BY: QA / QC DIRECTOR DATE: 03-06-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

MAR 2 2 2013

Individual Case Safety Report

Form Approved: OMB No. 0910-0291 Expires: 7/31/08
See OMB statement on reverse.

Case ID: 9282572

9282572-01-00-01

use by user-facilities, istributors and manufacturers ANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 9 Months — or — Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - ☐ Death: ____ (mm/dd/yyyy)
   - ☒ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy): 09/01/2010
4. Date of This Report (mm/dd/yyyy): 03/23/2011
5. Describe Event or Problem

GAVE CHILD 3 TABS 4X DAILY FOR 1 TO 2 WEEKS IN 09/10. MOTHER HAD USED IN THE PAST AS NEEDED, BUT FOR A 1-2 WEEK PERIOD SHE INCREASED THE DOSE AND FREQUENCY. CHILD HAD 2 SEIZURES; ONE LASTER ABOUT 90 SECONDS AND THE OTHER 45 SECONDS. SEIZURES OCCURRED ON A DAY WHEN HE HAD THE TABLETS, BUT SHE COULD NOT REMEMBER THE PROXIMITY TO TAKING THE TABLETS. TOOK CHILD TO THE DOCTOR ON OCTOBER 1ST. CHILD HAD EEG AND CT SCAN.

HAS NOT USED TEETHING TABLETS SINCE 09/10. CHILD HAS NOT EXPERIENCED ANY SEIZURES SINCE THIS EPISODE. RESULTS OF EEG AND CT SCAN WERE NORMAL. MD DOESN'T KNOW WHAT CAUSED THE SEIZURES.

6. Relevant Tests/Laboratory Data, Including Dates

10/10. EEG AND CT SCAN

APR 06 2011

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
   - #1 HYLAND'S TEETHING TABLETS
   - #2
2. Dose, Frequency & Route Used
   - #1 3 TABS 4 X DAILY
   - #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
   - #1
   - #2
4. Diagnosis for Use (Indication)
   - #1 TEETHING PAIN
   - #2
5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☒ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot #
   - #1 109519
   - #2
7. Exp. Date
   - #1
   - #2
8. Event Reappeared After Reintroduction?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# or Unique ID: 54973-7504-8
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
   Phone #: (b) (6)

USDSS APR 07 2011

2. Health Professional? ☐ Yes ☒ No
3. Occupation: MOTHER
4. Initial Reporter Also Sent Report to FDA: ☐ Yes ☒ No ☐ Unk.

APR 06 2011

Individual Case Safety Report

CaseID: 9282572

9282572-01-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ (mm/dd/yyyy)
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ (Specify)

13. Report Sent to Manufacturer?
☐ Yes ____ (mm/dd/yyyy)
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

EDYTA FRACKIEWICZ
HYLAND'S, INC.
204 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
03/19/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 RAE031911EF001

8. Adverse Event Term(s)
SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code: ____

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Individual Safety Report

7414661-6-00-02

APR 06 2011

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APR 07 2011

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 - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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"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."

APR 06 2011

Individual Case Safety Report

Ca[redacted]282572

9282572-01-00-03

COMPLAINT #: RVD031911EF001

DATE OF COMPLAINT: 03/19/2011

ITEM CODE: TEET

SIZE: 125 TABS

LOT NO.: 109519

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY:

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WAS GIVING CHILD 3 TABS 4 X DAY FOR APPROXIMATELY 1 – 2 WEEKS IN SEPTEMBER 2010. MOTHER HAD USED PRODUCT IN THE PAST AS NEEDED, BUT FOR 1 - 2 WEEK PERIOD, SHE INCREASED THE DOSE AND FREQUENCY. CHILD HAD 2 SEIZURES; ONE LASTED ABOUT 90 SECONDS AND THE OTHER 45 SECONDS. SEIZURES OCCURRED ON A DAY WHEN HE HAD THE TABLETS, BUT SHE COULD NOT REMEMBER THE PROXIMITY TO TAKING THE TABLETS. TOOK CHILD TO THE DOCTOR ON OCTOBER 1ST. CHILD HAD AN EEG AND CT SCAN. HAS NOT USED TEETHING TABLETS SINCE SEPTEMBER 2010. CHILD HAS NOT EXPERIENCED ANY SEIZURES SINCE THIS EPISODE. RESULTS OF EEG AND CT SCAN WERE NORMAL. MD DID NOT KNOW WHAT CAUSED THE SEIZURES.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Safety Report

7414661-6-00-03

REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION .. INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION. CANNOT CONDUCT AN INVESTIGATION. ALL BULK AND FINISHED RETAINS WERE PLACED UNDER QUARANTINE DUE TO THE RECALL. PLEASE REFER TO RECALL PRESS RELEASE FOR DETAILS.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 03/19/2011

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE031911EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 03/19/2011 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 03-31-11

DSS

BY: QA / QC DIRECTOR DATE: 03/31/11

APR 07 2011

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

APR 06 2011

Individual Case Safety Report

9282572-01-00-04

9282572

ADVERSE EVENT DATA FORM

COMPLAINT #: RVD031911EF001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Safety Report

7414661-6-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

DSS

REVIEWED BY MANAGEMENT BY: DATE: APR 07 2011

BY: QA / QC DIRECTOR DATE: 03/31/11

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 06 2011

9282572-01-00-05

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
- ☐ Initial
- ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code ____ - ____ - ____

Device Code ____ - ____ - ____

11. Report Sent to FDA?
- ☐ Yes ____ *(mm/dd/yyyy)*
- ☐ No

12. Location Where Event Occurred
- ☐ Hospital
- ☐ Home
- ☐ Nursing Home
- ☐ Outpatient Treatment Facility
- ☐ Outpatient Diagnostic Facility
- ☐ Ambulatory Surgical Facility
- ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
- ☐ Yes ____ *(mm/dd/yyyy)*
- ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

Frank Hannon
Alva-Amco Pharmacal Companies, Inc.
7711 Merrimac Ave.
Niles, IL 60714

2. Phone Number

847-663-0700

3. Report Source *(Check all that apply)*
- ☐ Foreign
- ☐ Study
- ☐ Literature
- ☑ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

03/29/2011

5.
- (A)NDA # ____
- IND # ____
- STN # ____
- PMA/ 510(k) # ____
- Combination Product ☐ Yes
- Pre-1938 ☐ Yes
- OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
- ☐ 5-day
- ☐ 30-day
- ☐ 7-day
- ☐ Periodic
- ☐ 10-day
- ☐ Initial
- ☑ 15-day
- ☐ Follow-up # ____

8. Adverse Event Term(s)

9. Manufacturer Report Number

2011-001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- ☐ Death
- ☐ Serious Injury
- ☐ Malfunction
- ☐ Other:

2. If Follow-up, What Type?
- ☐ Correction
- ☐ Additional Information
- ☐ Response to FDA Request
- ☐ Device Evaluation

3. Device Evaluated by Manufacturer?
- ☐ Not Returned to Manufacturer
- ☐ Yes ☐ Evaluation Summary Attached
- ☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
- ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*

Method ____ - ____ - ____ - ____

Results ____ - ____ - ____ - ____

Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
- ☐ Recall
- ☐ Repair
- ☐ Replace
- ☐ Relabeling
- ☐ Notification
- ☐ Inspection
- ☐ Patient Monitoring
- ☐ Modification/ Adjustment
- ☐ Other:

8. Usage of Device
- ☐ Initial Use of Device
- ☐ Reuse
- ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

Individual Safety Report

7414661-6-00-05

APR 06 2011

DSS

APR 07 2011

APR 06 2011

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

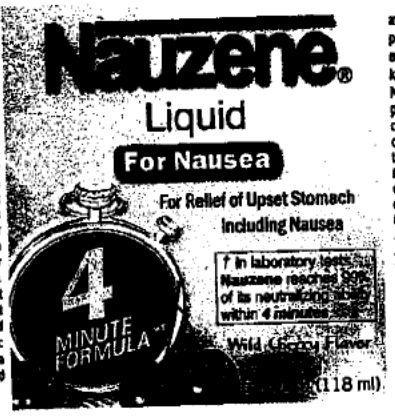
Please DO NOT RETURN this form to this address.

9282572-01-00-06

Active Ingredient (in each 15-mL tablespoon): Dextrose (Glucose) 4.35 g, Levulose (Fructose) 4.17 g, Sodium citrate dihydrate 0.921 g. ***Uses:*** For the relief of nausea associated with upset stomach, including that due to overindulgence in food or drink. **Warnings:** Do not use if you have Hereditary Fructose Intolerance (HFI). This product contains fructose. Ask a doctor before use if you have diabetes because this product contains sugar or are on a sodium-restricted diet. Ask a doctor or pharmacist before use if you are taking any other medications. Antacids may interact with certain prescription drugs. While using this product do not take more than 6 doses in a 24-hour period. Stop use and ask a doctor if nausea lasts more than two weeks or recurs frequently. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ***Directions:*** Read all package directions and warnings before use and use only as directed. Adults: 1 – 2 tablespoons (15 – 30 ml). Children: Consult a doctor for appropriate dosage. Dosage may be repeated after 30 minutes not to exceed 6 doses in a 24-hour period unless advised by a doctor. For maximum effectiveness never dilute NAUZENE or drink fluids of any kind immediately before or after taking NAUZENE. NAUZENE Liquid is intended for use by normally healthy persons only. Persons under 18 years of age should use only as directed by a doctor. ***Other Information:*** Sodium content 193 mg/tablespoon (15 mL). Store at room temperature. ****Contents sealed:*** Each bottle of NAUZENE Liquid has a tamper evident seal around the cap and a safety seal under the cap. Do not use if either of these seals appears broken. NOTE: NAUZENE is not intended as a substitute for a balanced nutritional diet or as an electrolyte replenishment. Serious side effects associated with the use of this product may be reported to the phone number provided below. ***Inactive Ingredients:*** Corn syrup, FD&C Red No. 40 Lake, flavor, fructose syrup, glycerin, methylparaben, phosphoric acid, purified water.

Questions? 1-800-732-2582

Dist.: ALVA-AMCO Pharmacal Cos., Inc.
Niles, IL 60714, U.S.A. © 1998-2009 ALVA
® Reg. U.S. Patent Office 872-4R, 0409



DSS

APR 07 2011

APR 06 2011

Individual Case Safety Report

CaseID: 9282572

9282572-01-00-07

Consumer Carton

172004R4

72-4R
0209

Nauzene® Liquid — Wild Cherry Flavor

Drug Facts

Active ingredients (in each 15-mL tablespoon)	Purpose
Dextrose (Glucose) 4.35 g	Anti-nausea
Levulose (Fructose) 4.17 g	Anti-nausea
Sodium citrate dihydrate, 0.921 g	Antacid

Uses For the relief of nausea associated with upset stomach, including that due to overindulgence in food or drink.

Warnings

Do not use if you have Hereditary Fructose Intolerance (HFI). This product contains fructose.

Ask a doctor before use if you ▪ have diabetes because this product contains sugar ▪ are on a sodium-restricted diet.

Ask a doctor or pharmacist before use if you are taking any other medications. Antacids may interact with certain prescription drugs.

When using this product do not take more than 6 doses in a 24-hour period.

Stop use and ask a doctor if nausea lasts more than two weeks or recurs frequently.

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ▪ Read all package directions and warnings before use and use only as directed. ▪ Adults: 1 - 2 tablespoons (15 - 30 mL). ▪ Children: Consult a doctor for appropriate dosage. ▪ Dosage may be repeated after 30 minutes not to exceed 6 doses in a 24-hour period unless advised by a doctor. ▪ For maximum effectiveness never dilute Nauzene or drink fluids of any kind immediately before or after taking Nauzene. ▪ Nauzene Liquid is intended for use by normally healthy persons only. ▪ Persons under 18 years of age should use only as directed by a doctor.

Drug Facts (continued)

Other Information: ▪ Sodium content 193 mg/tablespoon (15 mL) ▪ Store at room temperature ▪ ****Contents sealed:** Each bottle of Nauzene Liquid has a tamper evident seal around the cap and a safety seal under the cap. Do not use if either of these seals appears broken. NOTE: Nauzene is not intended as a substitute for a balanced nutritional diet or as an electrolyte replenishment. ▪ Serious side effects associated with the use of this product may be reported to the phone number provided below.

Inactive Ingredients Corn syrup, FD&C Red No. 40 lake, flavor, fructose syrup, glycerin, methylparaben, phosphoric acid, purified water.

Questions? 1-800-792-2582

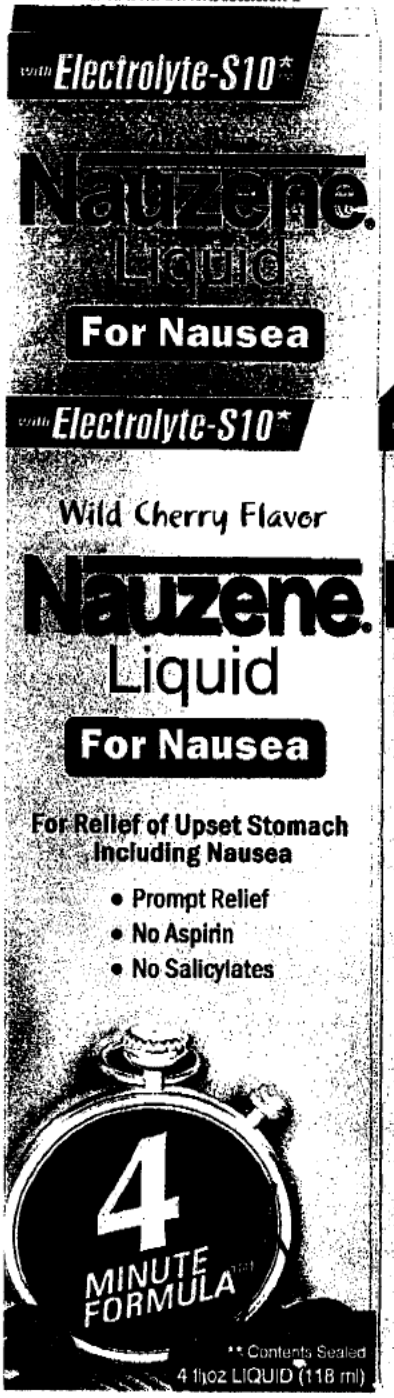
*ALVA-AMCO trade name for sodium citrate dihydrate is **Electrolyte-S10™**.

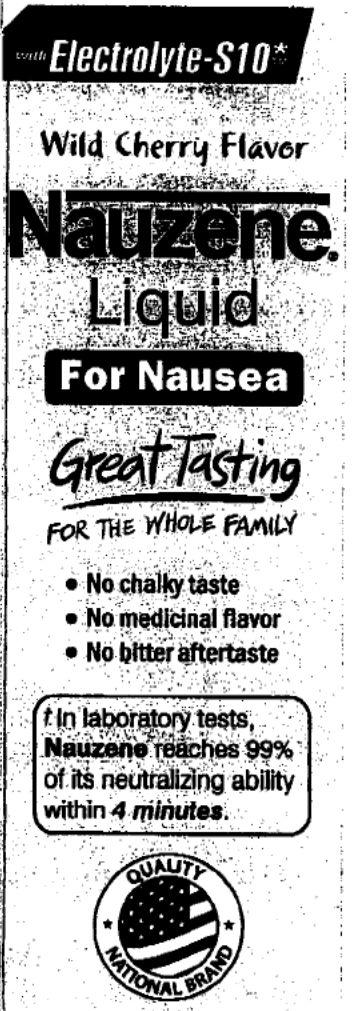
KEEP TIGHTLY CLOSED WHEN NOT IN USE. STORE AWAY FROM EXCESSIVE HEAT AND COLD.

www.NAUZENE.com

Mfg. by: ALVA-AMCO Pharmacal Cos., Inc. Niles, IL 60714, U.S.A.

©1999 - 2009 ALVA ®Reg. U.S. Patent Office





LOT NO.:

EXP:

PROD. NO: 72004

0 72959 72004 9

456
789ABC 09
123456 10
789ABC 11
123456 12
789ABC

4

172004R4

DSS

APR 07 2011

APR 06 2011

Individual Case Safety Report

9282598-02-00-01

Form Approved: OMB No. 0910-0291 Expires: 10/31/08
See OMB statement on reverse.

...or use by user-facilities, ..., distributors and manufacturers MANDATORY reporting

Page ___ of ___

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) In confidence

2. Age at Time of Event: 5 Months or Date of Birth:

3. Sex: [X] Female [ ] Male

4. Weight: 15 lbs or ___ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: ___ (mm/dd/yyyy)
- [X] Life-threatening
- [X] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 10/23/2010

4. Date of This Report (mm/dd/yyyy): 11/23/2010

5. Describe Event or Problem

CHILD GIVEN TEETHING TABLETS IN LESS THAN RECOMMENDED DOSE (OT MORE THAN 12 PER DAY). ON THE THIRD DAY CHILD LYING ON BED AND HER LIPS TURNED BRIGHT BLUE AND FACE TURNED GRAY. MOTHER PICKED HER UP AND COLOR CAME BACK. CHILD WAS BREATHING REGULARLY DURING THE EVENT. EPISODE LASTED 2 MINUTES. MOTHER TOOK CHILD TO EMERGENCY ROOM AND CHILD WAS ADMITTED TO THE HOSPITAL AND STAYED IN THE HOSPITAL 18 HOURS. CHILD ALSO DEVELOPED A RASH WHILE IN THE HOSPITAL. BETWEEN 7 PM AND 1 AM IN THE HOSPITAL BLOOD OXYGEN LEVEL WAS DROPPING SPORADICALLY. SYMPTOMS STARTED 5 MINUTES AFTER LAST DOSE OF TEETHING TABLETS. SYMPTOMS RESOLVED AFTER DISCONTINUED USE. ER DOCTOR FOLLOWED-UP WITH MOTHER 2-3 WEEKS AFTER EPISODE STATING THAT REACTION WAS DUE TO BELLADONNA IN TEET TABS.

6. Relevant Tests/Laboratory Data, Including Dates

2 X-RAYS, BLOOD WORK, IV, EKG, TELEMETRY.

ALL WERE NORMAL EXCEPT FOR OXYGEN LEVELS.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

MOM WAS TAKING PRENATAL VITAMINS AND [illegible]

RECEIVED

APR 19 2013

CDR

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABS 2-3 HRS X 3 DAYS
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [X] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 109080
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:

Catalog # | Expiration Date (mm/dd/yyyy)

Serial # | Other #

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [ ] No [ ] Returned to Manufacturer on: ___ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

DSS

APR 22 2013

2. Health Professional? [ ] Yes [X] No

3. Occupation: MOTHER

4. Initial Reporter Also Sent Report to FDA: [X] Yes [ ] No [ ] Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282598

9282598-02-00-02

FDA USE ONLY

G. ALL MANUFACTURERS

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy):
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy):
9. Approximate Age of Device:
10. Event Problem Codes (Refer to coding manual): Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices):

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 11/23/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☒ Yes

6. If IND, Give Protocol #:

7. Type of Report (Check all that apply): ☐ 5-day ☐ 7-day ☐ 10-day ☐ 15-day ☐ 30-day ☐ Periodic ☐ Initial ☒ Follow-up # 1

9. Manufacturer Report Number: 54973 RAE112310EF001

8. Adverse Event Term(s): LIPS TURNED BLUE, FACE TURNED GRAY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☒ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:
4. Device Manufacture Date (mm/yyyy):
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual): Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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Please DO NOT RETURN this form to this address.

APR 19 2013

Article [illegible] 8628878
12/1/10

STANDARD HOMEOPATHIC MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's®

SECTION I: **COMPLAINT**

COMPLAINT #: RVD112310EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 11/23/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 109180

REPORTER: (b) (6) [redacted]

ADDRESS: [redacted]

CITY: (b) (6) [redacted]

STATE: (b) (6) [redacted]

COUNTRY: USA

ZIP CODE: (b) (6) [redacted]

PHONE #: (b) (6) [redacted]

E-MAIL:

NATURE OF COMPLAINT: CHILD GIVEN TEETHING TABLETS IN LESS THAN RECOMMENDED DOSE (NOT MORE THAN 12 PER DAY). ON THE THIRD DAY CHILD LYING ON THE BED AND HER LIPS TURNED BRIGHT BLUE AND FACE TURNED GRAY. MOTHER PICKED HER UP AND COLOR CAME BACK. CHILD WAS BREATHING REGULARLY DURING THE EVENT. EPISODE LASTED 2 MINUTES. MOTHER TOOK CHILD TO EMERGENCY ROOM AND CHILD WAS ADMITTED INTO THE HOSPITAL AND STAYED IN THE HOSPITAL 18 HOURS. CHILD ALSO DEVELOPED A RASH WHILE IN THE HOSPITAL. BETWEEN 7 PM AND 1 AM IN THE HOSPITAL BLOOD OXYGEN LEVEL WAS DROPPING SPORADICALLY. DOSAGE: 2 TABS EVERY 2-3 HOURS X 3 DAYS. SYMPTOMS STARTED 5 MINUTES AFTER LAST DOSE OF TEET. SYMPTOMS RESOLVED AFTER DISCONTINUED USE. ER DOCTOR FOLLOWED-UP WITH MOTHER 2-3 WEEKS AFTER EPISODE STATING THAT REACTION WAS DUE TO BELLADONNA IN TEET TABS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282598-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 11/23/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE112310EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/23/10

BY: EDYTA FRACKIEWICZ

DSS

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature]

DATE: 11/30/10

APR 22 2013

BY: N/A

QA / QC DIRECTOR

DATE:

APR 19 2013

cc: QA / QC
Packaging

Production
Shipping / Receiving

Form # VD1

CaseID: 9282598

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE112310EF001

COMPLAINT #: RVD112310EF001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Case Safety Report

9282598-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 4/20/10

DSS
APR 22 2013

BY: N/A
QA / QC DIRECTOR

DATE:

APR 19 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9282606

9282606-02-00-01

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

For use by user-facilities, [illegible]s, distributors and manufacturers MANDATORY reporting

JTC

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6) In confidence	14 Months or Date of Birth:	☒ Female ☐ Male	19 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/01/2010	12/02/2010

5. Describe Event or Problem

STARTED TEETHING TABLETS IN FEB. 2010 AND GAVE THEM FOR A MONTH. CHILD DEVELOPED URINATION PROBLEMS (BURNING, SCREAMING UPON URINATION, RED AND DRY IN URETHRAL AREA). AGITATION DESCRIBED AS 'SNAPPING' AT ANYTHING, HITTING, KICKING. MUSCLE WEAKNESS IN ARMS AND LEGS BECAUSE SHE WAS UNABLE TO CRAWL. 'MILD SEIZURES' DESCRIBED BY MOTHER AS SLIGHT TWITCHING AND SHAKING OF THE MUSCLES OF THE ARMS AND LEGS. AGITATION CONTINUES BUT OTHER SYMPTOMS ENDED ON 11/30/10 WHEN MOTHER FOUND OUT ABOUT RECALL. CHILD TOOK 3 TABS QID DAILY WHEN SHE WAS TEETHING. SYMPTOMS WENT AWAY AFTER DISCONTINUED USE OF PRODUCT. RESTARTED USE OF PRODUCT IN SEPT. 2010 AND SYMPTOMS RETURNED. CHILD HAS HAD LOW GRADE FEVER (99.8 - 100.8 OVER LAST 3 MONTHS FOR WHICH CHILD WAS GIVEN IBUPROFEN OR INFANT TYLENOL. ALSO ON PREVACID FOR ACID REFLUX. ALL URINE TESTS WERE CLEAR SO NOT BACTERIAL INFECTION.

6. Relevant Tests/Laboratory Data, Including Dates

URINE TESTS TO CHECK FOR UTI.

ALL URINE TESTS CLEAR SO NOT BACTERIAL INFECTION.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

ACID REFLUX

TAKING PREVACID FOR ACID REFLUX.

RECEIVED
APR 19 2013
CDR

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 3 TABS QID WHEN TEETHNG	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 109014	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS
APR 19 2013
APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☐ Yes ☒ No ☐ Unk.

Individual Case Safety Report

CaseID: 9282606

9282606-02-00-02

FDA USE ONLY

y)

☐ User Facility ☐ Importer

2. Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
09/01/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/ 510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # 1

9. Manufacturer Report Number
54973 RAE120210EF001

8. Adverse Event Term(s)
UTI, MILD SEIZURE, IRRITABILITY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/ Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 19 2013

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

12/8/10 Article # CaseID: 9282606 8628
0263

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's®

SECTION I: **COMPLAINT**

COMPLAINT #: RVD120210EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 12/02/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 109014

REPORTER: (b) (6) [redacted]

ADDRESS: [redacted]

CITY: (b) (6) [redacted]

STATE: (b) (6) [redacted]

COUNTRY: USA

ZIP CODE: (b) (6) [redacted]

PHONE #: (b) (6) [redacted]

E-MAIL:

NATURE OF COMPLAINT: STARTED TEETHING TABLETS IN FEB. 2010 AND GAVE THEM FOR A MONTH. CHILD DEVELOPED URINATION PROBLEMS (BURNING, SCREAMING UPON URINATION, RED AND DRY IN THE URETHRAL AREA). AGITATION DESCRIBED AS 'SNAPPING' AT ANYTHING, HITTING, KICKING. MUSCLE WEAKNESS IN ARMS AND LEGS BECAUSE SHE WAS UNABLE TO CRAWL. 'MILD SEIZURES' DESCRIBED BY MOTHER AS SLIGHT TWITCHING AND SHAKING OF THE MUSCLES OF THE ARMS AND LEGS. AGITATION CONTINUES BUT OTHER SYMPTOMS ENDED ON 11/30/10 WHEN MOTHER FOUND OUT ABOUT RECALL. CHILD TOOK 3 TABS QID DAILY WHEN SHE WAS TEETHING. SYMPTOMS WENT AWAY AFTER DISCONTINUED USE OF PRODUCT. RESTARTED USE OF PRODUCT IN SEPT. 2010 AND SYMPTOMS RETURNED. CHILD HAS HAD LOW GRADE FEVER (99.9 – 100.8) OVER LAST 3 MONTHS FOR WHICH CHILD WAS GIVEN IBUPROFEN OR INFANT TYLENOL. ALSO ON PREVACID FOR ACID REFLUX. ALL URINE TESTS WERE CLEAR SO NOT BACTERIAL INFECTION.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282606-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 12/02/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE120210EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 12/02/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature] DATE: 12/09/10

DSS APR 22 2013

BY: N/A DATE:

QA / QC DIRECTOR

cc: QA / QC
Packaging

Production
Shipping / Receiving

APR 19 2013

Form # VD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE120210EF001 **COMPLAINT #:** RVD120210EF001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9282606-02-00-04

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 12/7/10

BY: N/A DATE:

QA / QC DIRECTOR

DCS
APR 22 2013

APR 19 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9282612

9282612-03-00-01

For use by [illegible] facilities, [illegible]ters, distributors and manufacturers for MANDATORY reporting

OTC

Page 1 of 1 3

Form Approved: OMB No. 0910-0291, Expires: 10/31
See OMB statement on reve

Mfr Report # 54973

UF/Importer Report #

FDA Use Or

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 12 Months — or — Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Life-threatening
- [X] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 10/21/2010

4. Date of This Report (mm/dd/yyyy): 11/08/2010

5. Describe Event or Problem

FEVER, ACHINESS, AND RUNNY NOSE. CHILD HAD BEEN TAKING APPROX. 1 TABLET QD OR QOD PM FOR ABOUT A MONTH, UNTIL TEETHING TABLETS WERE DISCONTINUED ABOUT FIVE DAYS AGO. CHILD EXPERIENCED A FEVER OF 103 THAT BEGAN MONDAY, 10/18/10 AND ACHINESS IN HER BODY. WHEN CHILD STOOD UP TO WALK SHE BEGAN SCREAMING IN PAIN AND WOULD ONLY STAND UP HALFWAY. CHILD TAKEN TO DOCTOR ON 10/19/10 AND ADMITTED TO HOSPITAL FOR APPROX. 24 HOURS ON (b) (6) HOSPITAL RAN TESTS AS CHILD'S HANDS WERE TURNING BLUE. TESTS CAME BACK NORMAL. F/U APPROT. WITH DOCTOR ON 10/25/10. HYLANDS TEETHING TABLETS WERE DISCONTINUED AND SYMPTOMS DID NOT RESOLVE THEMSELVES.

6. Relevant Tests/Laboratory Data, Including Dates

HEMOGLOBIN TEST ON (b) (6)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CHILD HAS AN EAR INFECTION. THIS IS HER 3RD IN FOUR MONTHS. FIRST TWO TREATED WITH AMOXICILLIN; THIRD WAS TREATED WITH CEFDINIR. CHILD ALSO TAKING MOTRIN TO REDUCE FEVER.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 1 TAB QD OR QOD PM/1 MO
#2

3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [X] Yes [ ] No [ ] Doesn Apply
#2 [ ] Yes [ ] No [ ] Doesn Apply

6. Lot #
#1 109341
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [X] No [ ] Doesn Apply
#2 [ ] Yes [ ] No [ ] Doesn' Apply

9. NDC# or Unique ID
54973-7504-1

ent of event)

(b) (6)

I don't believe C-5-1 is yes from notes

Isee teet dc and Sy did not resolve.

(b) (6)

(b) (6) 1/22/10

erator of Device
Health Professional
Lay User/Patient
Other:

e (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

DSS

APR 19 2013 APR 22 2013

2. Health Professional? [ ] Yes [X] No

3. Occupation: FATHER

4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [X] Unk.

CaseID: 9282612

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's®

SECTION I: COMPLAINT

COMPLAINT #: RVD102610LW-001

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 10/26/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 109341

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: FEVER, ACHINESS, RUNNY NOSE. CHILD HAD TAKEN APPROX. 1 TAB QD OR QOD PM FOR ABOUT A MONTH UNTIL TEETHING TABLETS WERE DISCONTINUED ABOUT 5 DAYS AGO. FEVER OF 103 EXPERIENCED ON 10/18/10 AND ACHINESS IN HER BODY. WHEN CHILD STOOD UP TO WALK SHE BEGAN SCREAMING IN PAIN AND WOULD ONLY STAND UP HALFWAY. CHILD WAS TAKEN TO DOCTOR ON 10/19/10 AND WAS ADMITTED TO HOSPITAL FOR APPROX. 24 HOURS ON (b) (6) HEMOGLOBIN TESTS WERE RUN BY HOSPITAL AS CHILD'S HANDS WERE TURNING BLUE. TESTS CAME BACK NORMAL. F/U APPT. WITH DR ON 10/25/10. TEETHING TABLETS WERE DISCONTINUED AND SYMPTOMS HAD NOT RESOLVED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: (Y) N (CIRCLE ONE)

Individual Case Safety Report

9282612-03-00-02

DATE REQUESTED PRODUCT BE RETURNED: 10/26/10

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/26/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102610LW-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/26/10 BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

DSS

BY:

QA / QC DIRECTOR

DATE: APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282612

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RSAE102610LW-001 **COMPLAINT #:** RVD102610LW-001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

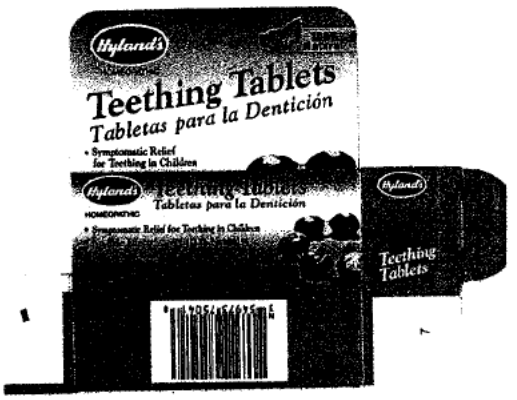
PHONE #: (b) (6)

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282612-03-00-03

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: DSS APR 22 2013

BY: DATE:
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

m/d 4/18/10

CaseID: 9282625

Form Approved: OMB No. 0910-0291, Expires: 10/31/
See OMB statement on revers

9282625-02-00-01

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

OTC

Page 1 of 4

Mfr Report # 54973

UF/Importer Report #

FDA Use Onl

FORM FDA 3500A (10/05)

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence

2. Age at Time of Event: 5 Months
or
Date of Birth:

3. Sex: [X] Female [ ] Male

4. Weight: 14 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- [ ] Death: ____ *(mm/dd/yyyy)*
- [X] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 05/10/2010

4. Date of This Report *(mm/dd/yyyy)*: 11/02/2010

5. Describe Event or Problem

GAVE TEETHING TABS AND TYLENOL, ORAGEL, AFTER 2 HOUR NAP, BABY SCREAMING, 'HALLUCINATORY', EYES ROLLING, LIPS BLUE.

TOOK CHILD TO DOCTOR 2 DAYS LATER AS THEY WERE 2 HOURS AWAY ON A CAMPING TRIP WHEN INCIDENT OCCURRED.

DOCTOR CONDUCTED FULL CHECK-UP AND BABY WAS FINE.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 3 TABS EVERY 2 HRS
#2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
#1
#2

4. Diagnosis for Use *(Indication)*
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model # | Lot # | Catalog # | Expiration Date *(mm/dd/yyyy)* | Serial # | Other #

5. Operator of Device
- [ ] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*

7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

DSS

APR 22 2013

APR 19 2013

2. Health Professional? [ ] Yes [X] No

3. Occupation: MOTHER

4. Initial Reporter Also Sent Report to FDA: [X] Yes [ ] No [ ] Unk.

Individual Case Safety Report

CaseID: 9282625

9282625-02-00-02

FDA USE ONLY

nly)

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
05/10/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
FEBRILE CEREBRAL EPISODE

9. Manufacturer Report Number
54973

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:

2. If Follow-up, What Type?
☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other:

8. Usage of Device
☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DQS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

CaseID: 9282625

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: RVD102510TG-003

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.:

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: GAVE TEETHING TABLETS AND TYLENOL, ORAGEL, AFTER 2 HOUR NAP, BABY SCREAMING, 'HALLUCINATORY', EYES ROLLING, LIPS BLUE. WENT TO DOCTOR'S OFFICE 2 DAYS LATER AS THEY WERE 2 HOURS AWAY ON A CAMPING TRIP WHEN INCIDENT OCCURRED. DR. CONDUCTED FULL CHECK-UP AND BABY WAS FINE. CHILD HAD 102 F (AXILLARY FEBRILE CEREBRAL EPISODE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Individual Case Safety Report

9282625-02-00-03

SECTION II: **INVESTIGATION**

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON:** 10/25/2010

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY:** TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE102510TG-003

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

DSS

BY:

QA / QC DIRECTOR

DATE: APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282625

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102510TG-003

COMPLAINT #: RVD102510TG-003

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

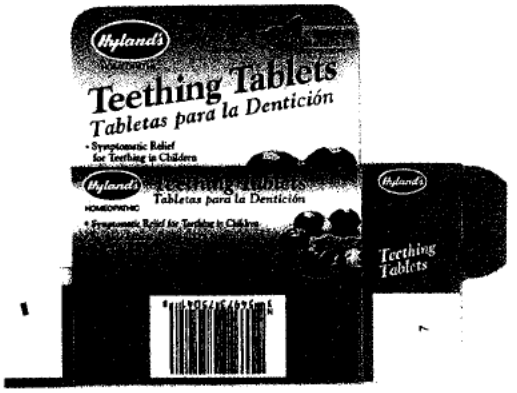
PHONE #: (b) (6)

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282625-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: _____ DATE: _____

SECTION IV:

REVIEWED BY MANAGEMENT BY: _____ DATE: _____ DSS

BY: _____ DATE: APR 22 2013
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 19 2013

Individual Case Safety Report

9282632-02-00-01

OTC

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

CaseID: 9282632

Form Approved: OMB No. 0910-0291, Expires: 10/31/0
See OMB Statement on reverse

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	8 Months	☐ Female	____ lbs
In confidence	or ____	☒ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/26/2010	11/04/2010

5. Describe Event or Problem

APNEA AND SEIZURES IN HER 8 MONTH OLD SON. PRODUCT USED SINCE 08/20/10. WITHIN (b) (6) OF STARTING TABLETS BABY STOPPED BREATHING AND TURNED BLUE WHILE IN HIS CAR SEAT. CHILD WAS REVIVED BY MOM WHO CALLED PEDIATRICIAN. BABY HAD SECOND EPISODE 10 MINS. LATER WHILE DRIVE TO PEDIATRICIANS. CHILD TAKEN TO HOSPITAL BY PARAMEDICS. CHILD HAD 3 - 4 MORE EPISODES WHILE IN HOSPITAL. IN ER FOR 2 DAYS; HOSPITALIZED FOR 1 WEEK. CHILD TAKING 2 - 3 TABLETS UP TO 6 TIMES PER DAY WHILE IN HOSPITAL. CHILD RELEASED FROM HOSPITAL. CHILD RE-ADMITTED TO HOSPITAL AFTER ADDITIONAL SEIZURES AND CONTINUED USE OF PRODUCT. DISCONTINUED USE OF PRODUCT. CHILD CONTINUES TO BE TREATED AS HAVING SEIZURES. APNEA AND SEIZURE ACTIVITY RESOLVED AFTER DISCONTINUED USE.

6. Relevant Tests/Laboratory Data, Including Dates

IN ER: BLOOD WORK, CXR. NEGATIVE RESULTS

CHILD MEDICATED WITH KEPRA 0.4ML OR 0.6ML IN HOSPITAL. INCREASED TO KEPRA 1.4ML TO 1.6 ML. DISCHARGED AFTER 24 HOURS WITH INCREASED MEDICATION.

RE-ADMIT: GIVEN KEPRA 2.6ML BID AND TRILEPTAL 300MG/5ML 1.4ML BID.
TEST RESULTS: NEGATIVE
EEG SHOWS SEIZURE ACTIVITY.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2-3 TABS X 6 / DAY	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 N/A	#1	#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

(b) (6)

D. SU

1. Brand
2. Comn
3. Manu
4. Model
Catal
Serial
6. If Imp

It is not clear to me that C-8-1 is yes. I don't see seizures reoccurring in notes.

(b) (6)

f Device
rofessional
r/Patient
d/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

APR 19 2013

DSS

APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	APR 19 2013 ☐ Yes ☐ No ☒ Unk.

Individual Case Safety Report

CaseID: 9282632

FDA USE ONLY

9282632-02-00-02

...Only)

...iber

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EXPERT RECALL
C/O HYLAND'S, INC.
210 W.131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/26/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
APNEA, SEIZURES, STOPPED BREATHING

9. Manufacturer Report Number
54973

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSG
APR 22 2013

APR 1 ...

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9282632

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD102610SC-001

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 10/26/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.:

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: APNEA AND SEIZURES IN HER 8 MONTH OLD SON. PRODUCT USED SINCE 08/2010. WITHIN (b) (6) OF STARTING TABLETS BABY STOPPED BREATHING AND TURNED BLUE WHILE IN HIS CAR SEAT. CHILD WAS REVIVED BY MOM. BABY HAS SECOND EPISODE 10 MINS. LATER WHILE DRIVING TO PEDIATRICIANS. CHILD TAKEN TO HOSPITAL BY PARAMEDICS. CHILD HAD 3 – 4 MORE EPISODES WHILE IN HOSPITAL. IN ER FOR 2 DAYS; HOSPITALIZED FOR 1 WEEK. CHILD TAKING 2 – 3 TABLETS UP TO 6X/ DAY WHILE IN HOSPITAL. CHILD RE-ADMITTED TO HOSPITAL AFTER ADDITIONAL SEIZURES AND CONTINUED USE OF PRODUCT. DISCONTINUED USE OF PRODUCT. CHILD CONTINUES TO BE TREATED AS HAVING SEIZURES. APNEA AND SEIZURE ACTIVITY RESOLVED AFTER DISCONTINUED USE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282632-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/26/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102610SC-001

ADVERSE EVENT SERIOUS: Y / (N)

ADVERSE EVENT REPORTED ON: 10/25/10

BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

DSS

BY:

QA / QC DIRECTOR

DATE: APR 19 2013 APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102610SC-001

COMPLAINT #: RVD102610SC-001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

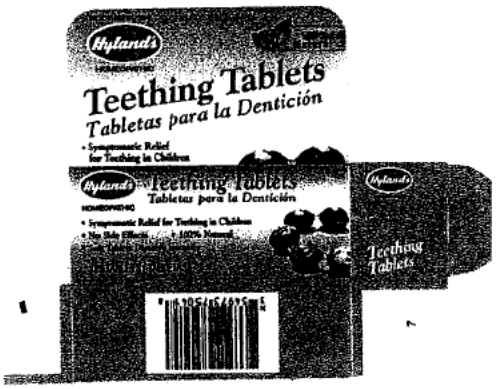
SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9282632-02-00-04

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

DSS

APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

9282641-01-00-01

butors and manufacturers
)ATORY reporting

54973 CaseID: 9282641

UF/Importer Report #

OTC

FDA Use On

(b) (6)

In confidence

of Event: 7 Months
or
Date of Birth:

☐ Female ☒ Male

Weight: 26 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1 ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☒ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 11/02/2010

4. Date of This Report *(mm/dd/yyyy)*: 11/02/2010

5. Describe Event or Problem

CHILD HAVING SEIZURES. MOTHER WANTED TO KNOW IF TEETHING TABLETS CAUSED THEM. FIRST SEIZURE OCCURRED JUNE 2009, 2 WEEKS AFTER CHILD RECEIVED THE H1N1 FLU VACCINE, BEFORE EVEN STARTING ON TEETHING TABLETS. 6 MONTHS LATER, SON STARTED TAKING TEETHING TABLETS AND HAS BEEN ON THEM CONSTANTLY FOR 10 MONTHS TWICE A DAY. SUBSEQUENT SEIZURES (2) OCCURRED IN (b) (6) AND 3 IN AUG./SEPT. 2010 WITHIN 2 DAYS OF EACH OTHER. SECOND SEIZURE WAS ASSOCIATED WITH THE HIGHEST TEMPERATURE OF 105F. WITH LAST 3 SEIZURES, CHILD DEVELOPED RIGHT ARM PAIN THAT PRECEDED THE SEIZURE. SYMPTOMS OF SEIZURES: DROWSY, 'OUT OF IT', PAINFUL LOOK ON CHILD'S FACE, DOZES OFF AND WAKES SCREAMING/CONVULSING.

DIAGNOSIS: FEBRILE SEIZURE

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD TESTS AND X-RAYS TAKEN TO RULE OUT PNEUMONIA.

RECEIVED
NOV 30 2010
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD HAD EARACHE AND RED THROAT.

CHILD TAKING LITTLE CRITTERS VITAMINS. ALSO GIVEN ACETOMENOPHEN TO KEEP FEVER DOWN.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 TWICE A DAY X 10 MOS.
#2

3. Therapy Dates *(If unknown, give duration, from/to (or best estimate))*
#1
#2

4. Diagnosis for Use *(Indication)*
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn Apply
#2 ☐ Yes ☐ No ☐ Doesn Apply

6. Lot #
#1 108661
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn Apply
#2 ☐ Yes ☐ No ☐ Doesn Apply

9. NDC# or Unique ID
54973-7504-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

DSS
DEC 01 2010

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

NOV 30 2010

2. Health Professional? ☐ Yes ☒ No
3. Occupation: MOTHER
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☒ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

9282641-01-00-02

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ (mm/dd/yyyy)
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ (Specify)

13. Report Sent to Manufacturer?
☐ Yes ____ (mm/dd/yyyy)
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
11/02/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973
RSAE1102107G001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 01 2010

NOV 30 2010

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 - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Individual Case Safety Report

Ca[redacted]9282641

9282641-01-00-03

COMPLAINT #: RVD110210TG001

DATE OF COMPLAINT: 11/02/10

ITEM CODE: TEET

SIZE: 250 TABLETS

LOT NO.: 108661

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: MOTHER WANTED TO KNOW IF TEETHING TABLETS CAUSED THEM. FIRST SEIZURE OCCURRED JUNE 2009, 2 WEEKS AFTER CHILD RECEIVED THE H1N1 FLU VACCINE, BEFORE EVEN STARTING ON TEETHING TABLETS. 6 MONTHS LATER, SON STARTED TAKING TEETHING TABLETS AND HAS BEEN ON THEM CONSTANTLY FOR 10 MONTHS TWICE A DAY. SUBSEQUENT SEIZURES (2) OCCURRED IN (b) (6) AND 3 IN AUG./SEPT/ 2010 WITHIN 2 DAYS OF EACH OTHER. SECOND SEIZURE WAS ASSOCIATED WITH THE HIGHEST TEMPERATURE OF 105F. WITH LAST 3 SEIZURES, CHILD DEVELOPED RIGHT ARM PAIN THAT PRECEDED THE SEIZURE. SYMPTOMS OF SEIZURES: DROWSY, 'OUT OF IT', PAINFUL LOOK ON CHILD'S FACE, DOZES OFF AND WAKES SCREAMING/CONVULSING.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/01/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE110210TG001 DSS

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/01/10 BY: TUTTI GOULD DEC 01 2010

SECTION V:

REVIEWED BY MANAGEMENT BY: [signature] DATE: 11/7/10

BY: N/A QA / QC DIRECTOR DATE: NOV 30 2010

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

Individual Case Safety Report

9282641-01-00-04

9282641

RSE EVENT DATA FORM

AE #: RAE110210TG001

COMPLAINT #: RVD110210TG001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

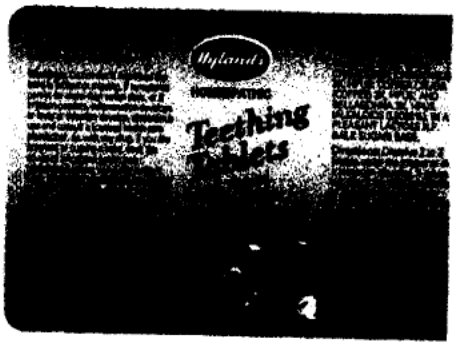
COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS

DEC 01 2010

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

BY: N/A DATE:

QA / QC DIRECTOR

NOV 30 2010

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

9282648-02-00-01

CaseID: 9282648

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

OTC

Page 1 of 4

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (10/05)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	8 Months	☐ Female ☒ Male	22 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
11/04/2010	01/03/2011

5. Describe Event or Problem

STARTED GIVING 8 MONTH OLD SON 2 TABS EVERY HOUR THEN 1 TAB EVERY HOUR. CHILDS MOUTH AND GUMS BECAME INFLAMMED AND RED; HE WASN'T "PEEING", DIARRHEA AND THROWING UP. TOOK HIM TO ER AND WAS TOLD THAT IT WAS A REACTION FROM THE TEETHING TABS. STAYED OVERNIGHT IN ER BUT WAS NOT ADMITTED TO THE HOSPITAL.

SYMPTOMS STARTED ON 11/04/2010 -- 4 DAYS AFTER STARTING USE OF PRODUCT -- AND ENDED AT END OF NOVEMBER.

6. Relevant Tests/Laboratory Data, Including Dates

NONE

RECEIVED
APR 19 2013
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2 TAB EVY HR;1 TABEVYHR	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 N/A	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 549973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)

Phone #: (b) (6)

DSS
APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No		☐ Yes ☒ No ☐ Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282648

9282648-02-00-02

FDA USE ONLY

1. **Check One** ☐ User Facility ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report** ☐ Initial ☐ Follow-up # _____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____

11. **Report Sent to FDA?** ☐ Yes _____ *(mm/dd/yyyy)* ☐ No

12. **Location Where Event Occurred**
☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?** ☐ Yes _____ *(mm/dd/yyyy)* ☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number**
310-768-0700

3. **Report Source** *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
01/03/2011

5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☐ Follow-up # 1

8. **Adverse Event Term(s)**
LACK OF URINATION, INFLAMMED GUMS, DIARRHEA, AND VOMITING

9. **Manufacturer Report Number**
54973 RAE010311EF001

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:

2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?** ☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*
Method _____ - _____ - _____ - _____
Results _____ - _____ - _____ - _____
Conclusions _____ - _____ - _____ - _____

7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:

8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

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APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

C[redacted]282648

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD010311EF001

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 01/03/2011

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABS

LOT NO.: NOT SURE IF HAS BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: STARTED GIVING 8 MONTH OLD SON 2 TABS EVERY HOUR THEN 1 TAB EVERY HOUR. CHILDS MOUTH AND GUMS BECAME INFLAMMED AND RED; HE WASN'T "PEEING", DIARRHEA AND THROWING UP. TOOK HIM TO ER AND WAS TOLD THAT IT WAS A REACTION TO THE TEETHING TABS. CHILD STAYED OVERNIGHT IN ER BUT WAS NOT ADMITTED TO HOSPITAL.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282648-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 01/03/2011

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE010311EF001

ADVERSE EVENT SERIOUS: Y / (N)

ADVERSE EVENT REPORTED ON: 01/03/2011

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

DSS

APR 22 2013

BY: N/A
QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE010311EF001 **COMPLAINT #:** RVD010311EF001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9282648-02-00-04

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 04/06/11

DSS
APR 22 2013

BY: N/A DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

9282654-02-00-01

CaseID: 9282654

Form Approved: OMB No. 0910-0291 Expires 10/31/08
See OMB statement on reverse.

user-facilities,
tors and manufacturers
TORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 4 Months — or — Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: 18 lbs — or — kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- [ ] Death: _____ *(mm/dd/yyyy)*
- [X] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 12/31/2010

4. Date of This Report *(mm/dd/yyyy)*: 01/13/2011

5. Describe Event or Problem

HAS AN ANGEL CARE UNIT AND IF SHE STOPS BREATHING IT GOES OFF AND SHE STOPPED BREATHING FOR 20 SECONDS AND MOTHER HAD TO STARTLE HER. USED TEETHING GEL FOR THE FIRST TIME 2X ON 12/31/10. GOING TO SEE THE DOCTOR ON 1/4/11. HAD DECREASED URINATION AND DOESNT WANT TO EAT AND SLEEPING ALL WEEKEND. RECOMMENDED SHE SEE HER DOCTOR.

6. Relevant Tests/Laboratory Data, Including Dates

NONE

RECEIVED
APR 19 2013
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

LARYNGOMALACIA SINCE BORN. HAD SURGERY (b) (6)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING GEL
#2

2. Dose, Frequency & Route Used
#1 1 DOSE EVRY 4HRS X 3DYS
#2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
#1
#2

4. Diagnosis for Use *(Indication)*
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [X] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 10175F
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID: 54937-7521-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device: [ ] Health Professional [ ] Lay User/Patient [ ] Other:
Catalog #	Expiration Date *(mm/dd/yyyy)*	
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* [ ] Yes [ ] No [ ] Returned to Manufacturer on: _____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone # (b) (6)

DSS
APR 19 2013
APR 22 2013

2. Health Professional? [ ] Yes [X] No	3. Occupation	4. Initial Reporter Also Sent Report to FDA [ ] Yes [ ] No [X] Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9282654

FDA USE ONLY

9282654-02-00-02

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

EDYTA FRACKIEWICZ
HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
01/03/2011

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # 1

9. Manufacturer Report Number
54973 SAE018

8. Adverse Event Term(s)
DECREASED URINATION, BREATHING DIFFICULTIES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☒ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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"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."

APR 19 2013

Individual Case Safety Report

MPLAINT RECORD

Ca[illegible]282654

9282654-02-00-03

COMPLAINT #: 668

TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 01/03/2011

PRODUCT: TEETHING GEL ITEM CODE: TGEL

SIZE: LOT NO.: 10175F

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: INFANT WITH PRE-EXISTING LARYNGOMALACIA. MOTHER STATED THAT INFANT STOPPED BREATHING FOR 20 SECONDS. HAD USED TEETHING GEL EARLIER IN THE DAY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

1-6-11: MOTHER SAID TO MONITOR HER IS WHAT THE DOCTOR SAID.

CAN'T TELL IF IT'S DUE TO TGEL.

PRODUCT BEING RETURNED FOR INSPECTION: (Y) N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED: 1/3/2011

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: GEL MANUFACTURED AND FILLED AT PRODUCT QUEST. LOT # MATCHES PRODUCT SPECIFICATIONS. (SEE ATTACHED C OF A). PH 5:18.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**:

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 350

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: BY:

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 01/12/11 DSS

BY: N/A DATE: APR 22 2013

QA / QC DIRECTOR

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

APR 19 2013

Individual Case Safety Report

9282654-02-00-04

CaseID: 9282654

Hyland's

ERSE EVENT DATA FORM

AE #: 350

COMPLAINT #: 668

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

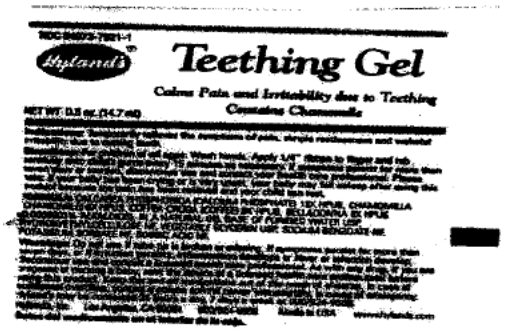
ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 4/12/13

DSS

APR 22 2013

BY: N/A
QA / QC DIRECTOR

DATE:

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

9282659-02-00-01

e by user-facilities,
ributors and manufacturers
DATORY reporting

ge 1 of 4

Mfr Report # 54973 CaseID: 9282659

UF/Importer Report #

OTC

FDA Use Only

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	3 Months	☐ Female	16 lbs
In confidence	or Date of Birth:	☒ Male	or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

☒ Death: (b) (6) *(mm/dd/yyyy)*
☐ Disability or Permanent Damage
☒ Life-threatening
☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
09/16/2007	11/02/2010

5. Describe Event or Problem

INFANT WAS FOUND LIFELESS, BLUE, WAS REVIVED AND LATER DIED OF SEIZURES IN HOSPITAL.

PETIT MALL SEIZURES, OBSERVED HIM. CHILD HAD 102 DEGREE FEVER AND WAS PLACED ON LIFE SUPPORT.

DRS. DIAGNOSIS: SIDS

RECEIVED
NOV 30 2010
CDR

6. Relevant Tests/Laboratory Data, Including Dates

MRI, CAT SCAN, AND SPINAL TAP. RESULTS WERE NEGATIVE

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 NOT SURE BUT POSSIBLY	#1
#2 DAY OF INCIDENT	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: DSS *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

DEC 01 2010

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

NOV 30 2010

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☒ Yes ☐ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9282659

9282659-02-00-02

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report
☐ Initial
☐ Follow-up # _____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code
Device Code

11. Report Sent to FDA?
☐ Yes _____ (mm/dd/yyyy)
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ (Specify)

13. Report Sent to Manufacturer?
☐ Yes _____ (mm/dd/yyyy)
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source (Check all that apply)
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
10/25/2010

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☒ Follow-up # 1

8. Adverse Event Term(s)
SEIZURES, DEATH

9. Manufacturer Report Number
54973

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:

Corrected MCN 54973 RSAE102510TG-002

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes (Refer to coding manual)
Method
Results
Conclusions

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
DEC 01 2010

NOV 30 2010

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

9156446-A-00-03

C[redacted]82659

COMPLAINT #: RVD102510TG-002

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.:

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: SEIZURES, DILATED PUPILS, DISORIENTED, CRANKY, LETHARGIC, DEATH. INFANT WAS FOUND LIFELESS, BLUE, WAS REVIVED AND LATER DIED OF SEIZURES IN HOSPITAL. PETIT MAL SEIZURES, OBSERVED HIM. CHILD HAD 102 FEVER AND WAS PLACED ON LIFE SUPPORT. MRI, CAT SCAN, SPINAL TAP WERE CONDUCTED AND RESULTS WERE NEGATIVE. DIAGNOSIS: SIDS

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

DATE REQUESTED PRODUCT BE RETURNED:

9282659-02-00-03

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE102510TG-002

DSS

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10 BY: TUTTI GOULD

DEC 01 2010

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/17/10

BY: N/A

QA / QC DIRECTOR

DATE:

NOV 30 2010

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

9282659

9282659-02-00-04

ADVERSE EVENT DATA FORM

AE #: RAE102510TG-002

COMPLAINT #: RVD102510TG-002

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

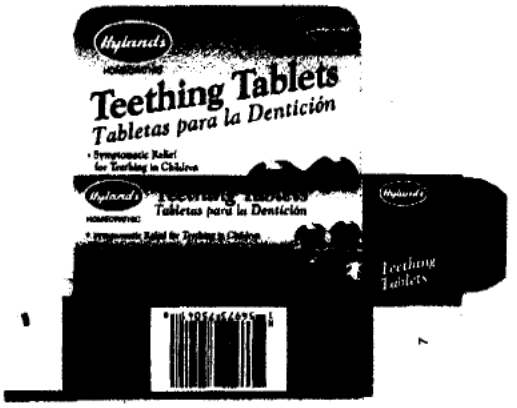
PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

DSS

DEC 01 2010

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

BY: DATE:

QA / QC DIRECTOR

NOV 30 2010

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9282670

9282670-02-00-01

OTC

For use by user facilities, distributors and manufacturers MANDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

Page 1 of 4

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: or Date of Birth: (b) (6)
3. Sex: [X] Female [ ] Male
4. Weight: 21 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: ____ (mm/dd/yyyy)
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [ ] Hospitalization - initial or prolonged
- [ ] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 10/10/2010

4. Date of This Report (mm/dd/yyyy): 11/17/2010

5. Describe Event or Problem

QUESTIONING LINK BETWEEN SEIZURES AND TEETHING TABLETS. SON TAKING TEET TABLETS FROM AUG. 23 - OCT. 3 AS NEEDED. DOSAGE: 2 TABS Q4H. SYMPTOMS STARTED SHOWING AROUND 10/10/10 AND STOPPED SHORTLY AFTER DISCONTINUING USE OF PRODUCT ON 10/13/10. CHILD TAKEN TO PEDIATRICIAN AND HAS AN MRI SCHEDULED FOR 11/19/10.

6. Relevant Tests/Laboratory Data, Including Dates

MRI SCHEDULED FOR 11/19/10

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABS Q4H
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
#1 UNKNOWN
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [ ] Doesn't Apply
#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device
- [ ] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS

APR 22 2013

2. Health Professional? [ ] Yes [X] No
3. Occupation: MOTHER
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [X] No [ ] Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282670

9282670-02-00-02

FDA USE ONLY

B. USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person
5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

HYLAND'S, INC.
210 W. 131T STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 11/06/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number: 54973 RSAE110610JAB 003

8. Adverse Event Term(s): POSSIBLE SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

APR 19 2013

CaseID: 9282670

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: RVD110610JAB003

TAKEN BY: JACK BORNEMAN

DATE OF COMPLAINT: 11/04/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: UNKNOWN

LOT NO.: UNKNOWN

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: QUESTIONING LINK BETWEEN SEIZURES AND TEETHING TABLETS. SON TAKING TEET TABS FROM AUG. 23 - OCT. 3 AS NEEDED. DOSAGE: 2 TABS Q4H. SYMPTOMS STARTED SHOWING AROUND 10/10/10 AND STOPPED SHORTLY AFTER DISCONTINUING USE OF PRODUCT ON 10/13/10. CHILD TAKEN TO PEDIATRICIAN AND HAS AN MRI SCHEDULED FOR 11/19/10.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282670-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/06/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: JACK BORNEMAN

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE110610JAB003

ADVERSE EVENT SERIOUS: Y / (N)

ADVERSE EVENT REPORTED ON: 11/04/10

BY: JACK BORNEMAN

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/19/10

BY: N/A
QA / QC DIRECTOR

DATE:

DSS
APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282670

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE110610JAB001 COMPLAINT #: RVD110610JAB001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

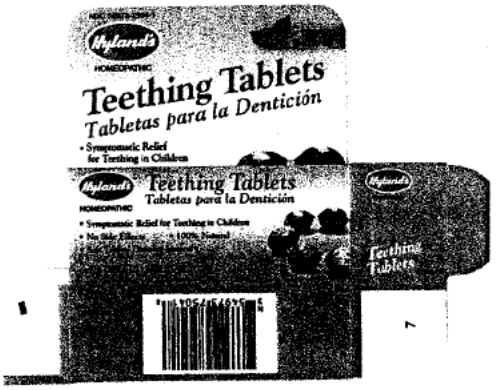
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282670-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/9/10

BY: N/A DATE:
QA / QC DIRECTOR

DSS
APR 22 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

APR 19 2013

Individual Case Safety Report

9282690-01-00-01

...by user-facilities, ...ibutors and manufacturers ...DATORY reporting

...e 1 of 4

Mfr Report # 549732

CaseID: 9282690

UF/Importer Report

OTC

FDA Use

PLEASE TYPE OR USE BLACK INK

1. (b) (6) In confidence

2. Age at Time of Event: 1 Years or Date of Birth:

3. Sex: [X] Female [ ] Male

4. Weight: 26 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- [ ] Death: (mm/dd/yyyy)
- [X] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 10/18/2010

4. Date of This Report (mm/dd/yyyy): 11/03/2010

5. Describe Event or Problem

USING NEW BOTTLE FOR 1 WEEK AND CHILD HAS DIFFICULTY BREATHING, FLUSHED SKIN, DRY SKIN, FEVER, RESTLESS SLEEP, NIGHT TERRORS.

SAW PHYSICIAN WHO WAS UNSURE WHAT THE CAUSE IS. PERHAPS THE CROUP? PRESCRIBED A STEROID.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 USING NEW BTTL FOR 1 WK
#2

3. Therapy Dates (If unknown, give durat... from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [ ] No [X] Doe... App...
#2 [ ] Yes [ ] No [ ] Doe... App...

6. Lot #
#1 109493
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Does Appl...
#2 [ ] Yes [ ] No [ ] Does Appl...

9. NDC# or Unique ID: 54973-7504-2

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #
Lot #
Catalog #
Expiration Date (mm/dd/yyyy)
Serial #
Other #

5. Operator of Device
[ ] Health Professiona...
[ ] Lay User/Patient
[ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

DSS

NOV 22 201...

10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

NOV 19 2010

2. Health Professional? [ ] Yes [X] No

3. Occupation: MOTHER

4. Initial Reporter Also Sent Report to FDA: [ ] Yes [X] No [ ] Unk.

9282690-01-00-02

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report
- [ ] Initial
- [ ] Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
- [ ] Yes ____ (mm/dd/yyyy)
- [ ] No

12. Location Where Event Occurred
- [ ] Hospital
- [ ] Home
- [ ] Nursing Home
- [ ] Outpatient Treatment Facility
- [ ] Outpatient Diagnostic Facility
- [ ] Ambulatory Surgical Facility
- [ ] Other: ____ (Specify)

13. Report Sent to Manufacturer?
- [ ] Yes ____ (mm/dd/yyyy)
- [ ] No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source (Check all that apply)
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. Date Received by Manufacturer (mm/dd/yyyy)
10/25/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [x] Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply)
- [ ] 5-day
- [ ] 7-day
- [ ] 10-day
- [ ] 15-day
- [ ] 30-day
- [ ] Periodic
- [ ] Initial
- [ ] Follow-up # ____

9. Manufacturer Report Number
54973
RSAE102510EF-007

8. Adverse Event Term(s)
DIFFICULTY BREATHING

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. If Follow-up, What Type?
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Reques
- [ ] Device Evaluation

3. Device Evaluated by Manufacturer?
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use?
- [ ] Yes
- [ ] No

6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/Adjustment
- [ ] Other:

8. Usage of Device
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

DSS
NOV 22 2010

NOV 19 2010

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 - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

MADE IN THE USA SINCE 1903

Individual Case Safety Report

Cas[redacted]390

9282690-01-00-03

SECTION I: **COMPLAINT**

TAKEN BY: EDYTA F

PRODUCT: TEETHIN

SIZE: 250 TABLETS

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

/D102510EF-007

/25/10

:ET

LOT NO.: 109493

NATURE OF COMPLAINT: USING NEW BOTTLE FOR 1 WEEK AND CHILD HAS DIFFICULTY BREATHING, FLUSHED SKIN, DRY SKIN, FEVER, RESTLESS SLEEP, NIGHT TERRORS. SAW PHYSICIAN WHO WAS UNSURE WHAT THE CAUSE IS. PERHAPS THE CROUP? PRESCRIBED A STEROID.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

DSS

CORRECTIVE ACTION(S) COMPLETED BY:

DATE: NOV 22 2010

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE102510EF-007

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10

BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: NOV 19 2010

BY:

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

Individual Case Safety Report

9282690-01-00-04

Case No. 2690

OUS ADVERSE EVENT DATA FORM

RAET02510EF-007

COMPLAINT #: RVD102510EF-007

SECTION I: **PATIENT INFORMATION (IF DIFFERENT FROM REPORTER ON FORM VD1)**

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

DSS

NOV 22 2010

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

BY: NOV 19 2010

QA / QC DIRECTOR DATE:

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9282725

Form Approved: OMB No. 0910-0291. Expires: 10/31
See OMB statement on reve

9282725-02-00-01

For use by user-facilities, ...rters, distributors and manufacturers fo... MANDATORY reporting

OTC

Mfr Report # 54973

UF/Importer Report #

FDA Use On

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 2 Years — or — Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- [ ] Death: ____ (mm/dd/yyyy)
- [X] Life-threatening
- [ ] Hospitalization - initial or prolonged
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- [ ] Disability or Permanent Damage
- [ ] Congenital Anomaly/Birth Defect
- [ ] Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 10/25/2010

4. Date of This Report (mm/dd/yyyy): 11/08/2010

5. Describe Event or Problem:

BREATHING DIFFICULTIES. GASPING 11/09 TO 07/10.
AGITATED SLEEP 08/10.

6. Relevant Tests/Laboratory Data, Including Dates:

X-RAY, BRONCOSCOPY, TESTED FOR ASTHMA AND ALLERGIES.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

NONE

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABS 4-6 HRS OFF/ON
#2

3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 [ ] Yes [X] No [ ] Doesn Apply
#2 [ ] Yes [ ] No [ ] Doesn Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 [ ] Yes [ ] No [X] Doesn' Apply
#2 [ ] Yes [ ] No [ ] Doesn' Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
Catalog #
Serial #
Lot #
Expiration Date (mm/dd/yyyy)
Other #
5. Operator of Device
- [ ] Health Professional
- [ ] Lay User/Patient
- [ ] Other:

6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
[ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA)
[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS
APR 19 2013 APR 22 2013

2. Health Professional? [ ] Yes [X] No
3. Occupation: MOTHER
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [X] No [ ] Unk.

PLEASE TYPE OR USE BLACK INK

Only)

☐ User Facility ☐ Importer

Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ (mm/dd/yyyy)
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ (Specify)

13. Report Sent to Manufacturer?
☐ Yes ____ (mm/dd/yyyy)
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
210 W.131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/25/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973

8. Adverse Event Term(s)
BREATHING DIFFICULTIES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 22 2013

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Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: RVD102610EF-011

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 108995

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: BREATHING DIFFICULTIES. GASPING FROM 11/09 TO 07/10. AGITATED SLEEP AUG. 2010. AGITATION MAKES HER WAKE UP IN THE MIDDLE OF THE NIGHT ANGRY 3X / NIGHT. SAW PHYSICIAN ABOUT BREATHING. DIAGNOSTIC TESTS PERFORMED WERE: X-RAY, BRONCOSCOPY, TESTED FOR ASTHMA AND ALLERGIES. GIVEN ADVAIR FOR SMALL POCKET OF BACTERIA FOUND ON BRONCOSCOPY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282725-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE102510EF-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: DSS

BY:
QA / QC DIRECTOR

DATE: APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CaseID: 9282725

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102510EF-011

COMPLAINT #: RVD102510EF-011

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Case Safety Report

9282725-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: DSS

BY: DATE: APR 22 2013

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

CaseID: 9282737

Form Approved: OMB No. 0910-0291, Expires: 10/31
See OMB statement on reve

9282737-03-00-01

For use by user-facilities, ...rters, distributors and manufacturers for MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use O

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 5 Months — or — Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: 20 lbs — or — kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: (mm/dd/yyyy)
- ☐ Life-threatening
- ☒ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 09/28/2010

4. Date of This Report (mm/dd/yyyy): 11/02/2010

5. Describe Event or Problem

NEPHEW HAD A SEIZURE 1 MONTH AGO. HE HAD BEEN TAKING TEETHING TABLETS THE PREVIOUS MONTHS FOR HIS TEETHING PROBLEMS. AT THE TIME OF THE SEIZURE, HOWEVERR, HE HAD NOT CONSUMED ANY TEETHING TABLETS WITHIN THE PREVIOUS 24 HOURS, OR LONGER. SYMPTOMS OF SEIZURE: LASTED ONE MINUTE, AND HE WAS SHAKING ON ONLY THE RIGHT SIDE OF HIS BODY. HIS EYES ROLLED BACK. HE HAD A LOW GRADE FEVER. HIS MOTHER PUT HIM IN DAYCARE AND WAS TRANSITIONING BETWEEN BREASTFEEDING AND INTRODUCING FORMUL. CHILD WAS IN DAYCARE AND FINE THE DAY OF THE SEIZURE.

CHILD HOSPITALIZED FOR TREATMENT.

6. Relevant Tests/Laboratory Data, Including Dates

CAT SCAN, BLOOD WORK, X-RAYS WERE ALL NEGATIVE WHILE AT THE HOSPITAL, AND 1 SCAN A WEEK LATER. STILL WAITING ON FOLLOW-UP SCAN RESULTS.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

GI GAS DUE TO FORMULA INTRODUCTION.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 3 TABS 1-2 TIMES / DAY
#2

3. Therapy Dates (If unknown, give duration from/to (or best estimate))
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS

APR 22 2013

2. Health Professional? ☐ Yes ☒ No
3. Occupation: AUNT
4. Initial Reporter Also Sent Report to FDA: ☐ Yes ☒ No ☐ Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282737

9282737-03-00-02

FDA USE ONLY

nly)

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/28/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURE

9. Manufacturer Report Number
54973

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

CaseID: 9282737

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's®

SECTION I: **COMPLAINT**

COMPLAINT #: RVD102810TG-001

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/28/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: UNKNOWN

LOT NO.: BOTTLE THROWN OUT

REPORTER: (b) (6)

ADDRESS:

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: NEPHEW HAD A SEIZURE 1 MONTH AGO. HE HAD BEEN TAKING TEETHING TABLETS THE PREVIOUS MONTHS FOR HIS TEETHING PROBLEMS. AT THE TIME OF THE SEIZURE, HOWEVER, HE HAD NOT CONSUMED ANY TEETHING TABLETS WITHIN THE PREVIOUS 24 HOURS, OR LONGER. SYMPTOMS OF SEIZURE: LASTED ONE MINUTE, AND HE WAS SHAKING ON ONLY THE RIGHT SIDE OF HIS BODY. HIS EYES ROLLED BACK, HE HAD A LOW GRADE FEVER. HIS MOTHER PUT HIM IN DAYCARE AND WAS TRANSITIONING BETWEEN BREASTFEEDING AND INTRODUCING FORMULA. CHILD WAS IN DAYCARE AND FINE ON THE DAY OF THE SEIZURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282737-03-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/28/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE102810TG-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/28/10 BY: TUTTI GOULD

DSS

APR 22 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

BY:

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

APR 1 5 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102810TG-001 COMPLAINT #: RVD102810TG-001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: STATE:

COUNTRY: USA ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9282737-03-00-04

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

DSS
APR 22 2013

BY: DATE:
QA / QC DIRECTOR

APR 19 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

CaseID: 9282744

9282744-02-00-01

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

OTC

Form Approved: OMB No. 0910-0291, Expires: 10/31/
See OMB statement on rever

Mfr Report # 54973

UF/Importer Report #

FDA Use Onl

FORM FDA 3500A (10/05)

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 1 Years or Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: 23 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - ☐ Death: (mm/dd/yyyy)
   - ☐ Life-threatening
   - ☒ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other Serious (Important Medical Events)
3. Date of Event (mm/dd/yyyy): 10/22/2010
4. Date of This Report (mm/dd/yyyy): 11/02/2010
5. Describe Event or Problem

2 SEIZURES 2 DAYS AFTER TEETHING TABLETS, 30 MINS. AFTER TYLENOL. PATIED HAD A FEVER OF 98.8F.

CHILD TAKEN TO ER AND RELEASED BUT PARENTS CONCERNED NEXT DAY. CHILD RETURNED NEXT NIGHT AND WAS ADMITTED FOR 1 NIGHT. BLOOD, URINE, AND X-RAYS WERE TAKEN. RESULTS WERE NEGATIVE. DR. DIAGNOSED AS VIRUS.

CHILD ON ANTIBIOTICS FOR ALLERGIES.

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD, URINE, AND X-RAY WERE TAKEN. RESULTS WERE NEGATIVE.

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

TEAR DUCT BLOCKAGE FOR WHICH ANESTHETIC AND DILATION PROCEDURES WERE RECEIVED.

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
   - #1 HYLAND'S TEETHING TABLETS
   - #2
2. Dose, Frequency & Route Used
   - #1 4 TABLETS ONCE
   - #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
   - #1
   - #2
4. Diagnosis for Use (Indication)
   - #1 TEETHING PAIN
   - #2
5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot #
   - #1
   - #2
7. Exp. Date
   - #1
   - #2
8. Event Reappeared After Reintroduction?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# or Unique ID: 54973-7504-1
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
   Phone #: (b) (6)

APR 22 2013

APR 19 2013

2. Health Professional? ☐ Yes ☒ No
3. Occupation: GRANDMOTHER/MOTHER
4. Initial Reporter Also Sent Report to FDA: ☒ Yes ☐ No ☐ Unk.

FDA USE ONLY

Only)

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report ☐ Initial ☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/22/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973

8. Adverse Event Term(s)
SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 19 2013 APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9282744

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hylands®

SECTION I: COMPLAINT

COMPLAINT #: RVD102510TG-001

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.:

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 2 SEIZURES 2 DAYS AFTER TEETHING TABLETS. 30 MINUTES AFTER TYLENOL. CHILD TAKEN TO ER. RELEASED BUT PARENTS CONCERNED NEXT DAY. CHILD ON ANTIBIOTICS FOR ALLERGIES. PRE-EXISTING CONDITION: TEAR DUCT BLOCKAGE FOR WHICH CHILD HAS BEEN TREATED WITH ANESTHETIC AND DILATION PROCEDURE.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282744-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102510TG-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

DSS

BY:

QA / QC DIRECTOR

DATE: APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282744

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102510TG-001

COMPLAINT #: RVD102510TG-001

SECTION I: **PATIENT INFORMATION** *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

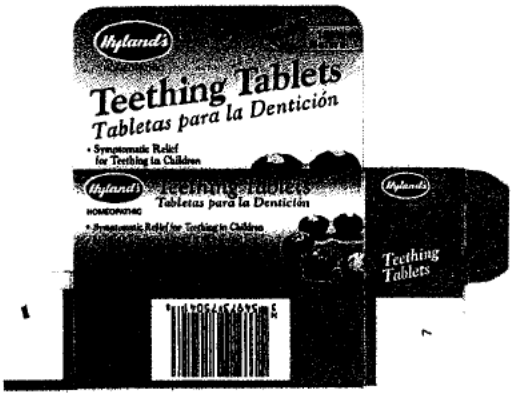
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282744-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

DSS
APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 19 2013

FORM SAE01

Individual Case Safety Report

11/9/10 CaseID: 9282750

9282750-02-00-01

08 1830 0004 8628 7637

OTC

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 10/31/
See OMB statement on rever

Mfr Report # 54973

UF/Importer Report #

FORM FDA 3500A (10/05)

Page 1 of 4

FDA Use On

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 17 Months or Date of Birth:
3. Sex: [X] Female [ ] Male
4. Weight: 22 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - [ ] Death: (mm/dd/yyyy)
   - [X] Life-threatening
   - [ ] Hospitalization - initial or prolonged
   - [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - [ ] Disability or Permanent Damage
   - [ ] Congenital Anomaly/Birth Defect
   - [ ] Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 08/01/2010

4. Date of This Report *(mm/dd/yyyy)*: 10/25/2010

5. Describe Event or Problem:

SEIZURES (STARING PROBLEM, TRANCE), VOMITING, URINATES

6. Relevant Tests/Laboratory Data, Including Dates:

PLANS TO DO BLOOD WORK TO TEST FOR BELLADONNA

TESTS FOR AUTISM, SCHEDULED FOR MRI

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*:

EVALUATED FOR AUTISM

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 HYLAND'S TEETHING TABLETS
   - #2

2. Dose, Frequency & Route Used
   - #1 AS NEEDED ON DLY BASIS
   - #2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
   - #1
   - #2

4. Diagnosis for Use *(Indication)*
   - #1 TEETHING PAIN
   - #2

5. Event Abated After Use Stopped or Dose Reduced?
   - #1 [ ] Yes [ ] No [X] Doesn't Apply
   - #2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #
   - #1 106560
   - #2

7. Exp. Date
   - #1
   - #2

8. Event Reappeared After Reintroduction?
   - #1 [ ] Yes [ ] No [X] Doesn't Apply
   - #2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model #
   Lot #
   Catalog #
   Expiration Date *(mm/dd/yyyy)*
   Serial #
   Other #
5. Operator of Device
   - [ ] Health Professional
   - [ ] Lay User/Patient
   - [ ] Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
   [ ] Yes [ ] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)*
    [ ] Yes [ ] No [ ] Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)
   Phone #: (b) (6)
   DECLINED TO PROVIDE ADDRESS

DSS

APR 19 2013 APR 22 2013

2. Health Professional? [ ] Yes [X] No
3. Occupation: FATHER
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [X] Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9282750

9282750-02-00-02

FDA USE ONLY

B. REPORTER (Only)

1. Check One: ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/25/2010

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method _____ - _____ - _____ - _____
Results _____ - _____ - _____ - _____
Conclusions _____ - _____ - _____ - _____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 22 2013

APR 19 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

CaseID: 9282750

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD102510EF006

TAKEN BY: EDYTA FRACKIEWICZ

DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.: 106560

REPORTER: (b) (6)

ADDRESS: DECLINED TO PROVIDE

CITY:

STATE:

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SEIZURES (STARING PROBLEM, TRANCE), VOMITING, URINATES

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) N

Individual Case Safety Report

9282750-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE) N

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102510EF006

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

BY:
QA / QC DIRECTOR

DATE:

DSS
APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

APR Firm# 2013

CaseID: 9282750

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102510EF006

COMPLAINT #: RVD102510EF006

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS: DECLINED TO STATE

CITY: STATE:

COUNTRY: USA ZIP CODE:

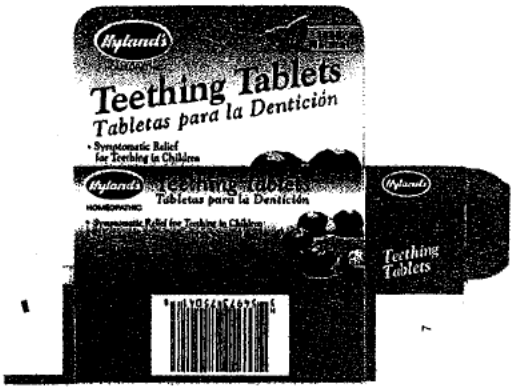
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282750-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

BY: DATE:
QA / QC DIRECTOR

DSS
APR 22 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 19 2013

FORM 0400

Individual Case Safety Report

CaseID: 9282756

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

9282756-03-00-01

OTC

For use by user facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	21 Months or Date of Birth:	☐ Female ☒ Male	24 lbs or kgs
In confidence			

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☐ Life-threatening
- ☐ Congenital Anomaly/Birth Defect
- ☒ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/24/2010	11/02/2010

5. Describe Event or Problem

GRANDSON, WHO LIVES WITH HIM, HAS BEEN TAKING TEETHING TABLETS FOR HIS TEETHING PROBLEMS OVER THE LAST COUPLE OF MONTHS. AS OF WEEK OF (b) (6) HE BEGAN VOMITING, HAD 'LIGHT FEVER' AND NOT EATING, HE HAD FATIGUE, DRY MOUTH, WAS PALE AND DID NOT WANT TO DO ANYTHING. FAMILY BROUGHT HIM TO THE HOSPITAL (b) (6) DAYS LATER AND BLOOD TESTS REVEALED WBC COUNT OF OVER 26,000. HE HAD EATEN A 'CALACHI', A BREAD LIKE BISCUIT WITH HAM AND CHEESE JUST BEFORE HE BEGAN VOMITING. HE IS STILL IN THE HOSPITAL AND IS WHINY, LETHARGIC AND ARCHES HIS BACK.

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD CULTURES, CHEST AND STOMACH X-RAYS.

WBC COUNT OVER 26,000

ANTIBIOTICS, FLUIDS VIA IV

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD TAKING FLINTSTONES CHEWABLE VITAMINS; CHILDREN'S COUGH TYLENOL, BUT NOT SURE.

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 3 TABS FOR 1 WEEK	#1
#2	#2

4. Diagnosis for Use *(Indication)*
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS

APR 22 2013

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2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	GRANDFATHER	☐ Yes ☐ No ☒ Unk.

Individual Case Safety Report

CaseID: 9282756

9282756-03-00-02

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
   - ☐ Death
   - ☐ Serious Injury
   - ☐ Malfunction
   - ☐ Other:

2. **If Follow-up, What Type?**
   - ☐ Correction
   - ☐ Additional Information
   - ☐ Response to FDA Request
   - ☐ Device Evaluation

3. **Device Evaluated by Manufacturer?**
   - ☐ Not Returned to Manufacturer
   - ☐ Yes ☐ Evaluation Summary Attached
   - ☐ No *(Attach page to explain why not)* or provide code:

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?** ☐ Yes ☐ No

6. **Evaluation Codes** *(Refer to coding manual)*

Method				
Results				
Conclusions				

7. **If Remedial Action Initiated, Check Type**
   - ☐ Recall
   - ☐ Repair
   - ☐ Replace
   - ☐ Relabeling
   - ☐ Notification
   - ☐ Inspection
   - ☐ Patient Monitoring
   - ☐ Modification/ Adjustment
   - ☐ Other:

8. **Usage of Device**
   - ☐ Initial Use of Device
   - ☐ Reuse
   - ☐ Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:**

10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

DSS

APR 22 2013

1. **Check One** ☐ User Facility ☐ Importer

2. **UF/Importer Report Number**

3. **User Facility or Importer Name/Address**

4. **Contact Person**

5. **Phone Number**

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. **Type of Report** ☐ Initial ☐ Follow-up # _____

8. **Date of This Report** *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. **Event Problem Codes** *(Refer to coding manual)*

Patient Code			
Device Code			

11. **Report Sent to FDA?**
   - ☐ Yes _____ *(mm/dd/yyyy)*
   - ☐ No

12. **Location Where Event Occurred**
   - ☐ Hospital
   - ☐ Home
   - ☐ Nursing Home
   - ☐ Outpatient Treatment Facility
   - ☐ Outpatient Diagnostic Facility
   - ☐ Ambulatory Surgical Facility
   - ☐ Other: _____ *(Specify)*

13. **Report Sent to Manufacturer?**
   - ☐ Yes _____ *(mm/dd/yyyy)*
   - ☐ No

14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number**
310-768-0700

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☐ Study
   - ☐ Literature
   - ☒ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
10/28/2010

5.
   - (A)NDA # _____
   - IND # _____
   - STN # _____
   - PMA/ 510(k) # _____
   - Combination Product ☐ Yes
   - Pre-1938 ☐ Yes
   - OTC Product ☒ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☐ Initial
   - ☐ 15-day ☒ Follow-up # 1

8. **Adverse Event Term(s)**
VOMITING & FEVER

9. **Manufacturer Report Number**
54973

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 - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

Ca[illegible]9282756

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD102810TG-002

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/28/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE:

LOT NO.: DID NOT HAVE BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GRANDSON, WHO LIVES WITH HIM, HAS BEEN TAKING TEETHING TABLETS FOR HIS TEETHING PROBLEMS OVER THE LAST COUPLE OF MONTHS. AS OF WEEK OF OCTOBER 17TH, HE BEGAN CUTTING HIS 'JAW TEETH', AND TOOK THE TEETHING TABS. (b) (6) LATER HE BEGAN VOMITING, HAD 'LIGHT FEVER' AND NOT EATING, HE HAD FATIGUE, DRY MOUTH, WAS PALE AND DID NOT WANT TO DO ANYTHING. FAMILY BROUGHT HIM TO THE HOSPITAL (b) (6) DAYS LATER AND BLOOD TESTS REVEALED WBC COUNT OF OVER 26,000. HE HAD EATEN A 'CALACHI', A BREAD LIKE BISCUIT WITH HAM AND CHEESE JUST BEFORE HE BEGAN VOMITING. HE IS STILL IN THE HOSPITAL AND IS WHINY, LETHARGIC AND ARCHES HIS BACK.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Individual Case Safety Report

9282756-03-00-03

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/28/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102810TG-002

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/28/10 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/7/6

DSS APR 22 2013

BY: N/A
QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282756

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102810TG-002 **COMPLAINT #:** RVD102810TG-002

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

Individual Case Safety Report

9282756-03-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

DSS
APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

CaseID: 9282761

9282761-02-00-01

OTC

For use by user-facilities, distributors and manufacturers MANDATORY reporting.

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

Page 1 of 4

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 19 Months or Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: 30 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: (mm/dd/yyyy)
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 05/08/2008

4. Date of This Report (mm/dd/yyyy): 11/12/2010

5. Describe Event or Problem

2 YEARS AGO, SON WAS TEETHING AND TAKING TEETHING TABLETS. AT 1 OR 2 AM, HE WAS PANTING AND BREATHING HEAVILY, SHAKING, AND WAS HAVING A 'FEBRILE SEIZURE'. THEY TOOK HIM TO THE ER, AND OVER THE NEXT 3-4 DAYS HE HAD 4 SEIZURES, WITH A FEVER SPIKING AT 102 - 103F.

6. Relevant Tests/Laboratory Data, Including Dates

EKG, SPINAL TAP, CAT SCAN DONE IN ER AROUND (b) (6)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

WAS ON FORMULA

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 3 TABS 1-2 X A DAY
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 88528
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS
APR 22 2013

2. Health Professional? ☐ Yes ☒ No
3. Occupation: FATHER
4. Initial Reporter Also Sent Report to FDA? ☐ Yes ☒ No ☐ Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282761

9282761-02-00-02

FDA USE ONLY

1. Check One: ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code _____ - _____ - _____
Device Code _____ - _____ - _____

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home
☐ Nursing Home ☐ Ambulatory Surgical Facility
☐ Outpatient Treatment Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/20/2010

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/ 510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
SEIZURES

9. Manufacturer Report Number
54973

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: _____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: _____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method _____ - _____ - _____ - _____
Results _____ - _____ - _____ - _____
Conclusions _____ - _____ - _____ - _____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/ Adjustment
☐ Other: _____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

CaseID: 9282761

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD102910TG003

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 10/29/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 88528

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL: (b) (6)

NATURE OF COMPLAINT: 2 YEARS AGO, SON WAS TEETHING AND TAKING TEETHING TABLETS. AT 1 OR 2 AM, HE WAS PANTING AND BREATHING HEAVILY, SHAKING, AND WAS HAVING A 'FEBRILE SEIZURE'. THEY TOOK HIM TO THE ER, AND OVER THE NEXT 3-4 DAYS HE HAD 4 SEIZURES, WITH A FEVER SPIKING AT 102-103F. CHILD WAS TAKING 3 TABLETS 1-2 TIMES A DAY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282761-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARD DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/29/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102910TG003

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/29/10 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/19/10

BY: N/A
QA / QC DIRECTOR

DATE:

DSS

APR 22 2013

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282761

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102910TG003 COMPLAINT #: RVD102910TG003

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

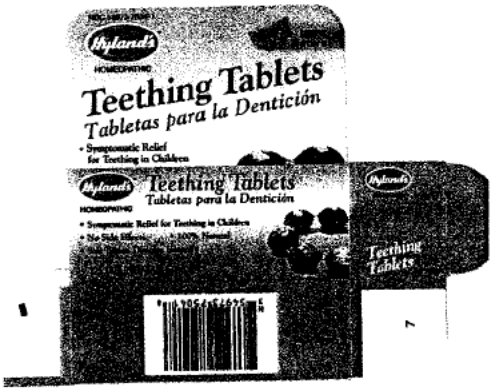
PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282761-02-00-04

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/19/10 DSS

BY: N/A DATE: APR 22 2013
QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE FORM SAE01

APR 19 2013

Individual Case Safety Report

9282767-03-00-01

For use by user-facilities, distributors and manufacturers MANDATORY reporting

Page 1 of 10

Form Approved: OMB No. 0910-0291 Expires: 10/31/08
See OMB statement on reverse

CaseID: 1282767

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 14 Months — or — Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☒ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 10/23/2010

4. Date of This Report *(mm/dd/yyyy)*: 11/03/2010

5. Describe Event or Problem

EYES ROLLING BACK IN THE HEAD AND CLENCHED JAW. THE BABY HAS BEEN USING TEETHING TABLETS FOR THE PAST YEAR (1-2 TIMES PER DAY). CHILD TAKEN TO PEDIATRICIAN AND WAS NOT ADMITTED TO HOSPITAL. DISCONTINUED USE OF PRODUCT. SYMPTOMS IMPROVED AND LESSENED IN FREQUENCY.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

RECEIVED
APR 19 2013
CDR

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 HYLAND'S TEETHING TABLETS
   - #2

2. Dose, Frequency & Route Used
   - #1 1 TAB 1-2 X PER DAY
   - #2

3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
   - #1
   - #2

4. Diagnosis for Use *(Indication)*
   - #1 TEETHING PAIN
   - #2

5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   - #1 107371
   - #2

7. Exp. Date
   - #1
   - #2

8. Event Reappeared After Reintroduction?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6) — CANADA
Phone #: (b) (6)

APR 19 2013

DSS
APR 22 2013

2. Health Professional? ☐ Yes ☒ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ☒ Unk.

Individual Case Safety Report

CaseID: 9282767

9282767-03-00-02

FDA USE ONLY

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | 5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* | 7. Type of Report ☐ Initial ☐ Follow-up # ____ | 8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device | 10. Event Problem Codes *(Refer to coding manual)* Patient Code ___ - ___ - ___ Device Code ___ - ___ - ___

11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/23/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☒ Follow-up # 2

9. Manufacturer Report Number: 54973 RAE102510SW-002

8. Adverse Event Term(s): EYES ROLLING BACK / CLENCHED JAW

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

APR 19 2013

Individual Case Safety Report

9282767-03-00-03

CaseID: 9282767

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

For use by user-facilities, distributors and manufacturers MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

Page 1 of 8

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 14 Months or Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - ☐ Death: ____ *(mm/dd/yyyy)*
   - ☒ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 10/23/2010

4. Date of This Report *(mm/dd/yyyy)*: 11/03/2010

5. Describe Event or Problem

EYES ROLLING BACK IN THE HEAD AND CLENCHED JAW. THE BABY HAS BEEN USING TEETHING TABLETS FOR THE PAST YEAR (1-2 TIMER PER DAY). CHILD TAKEN TO PEDIATRICIAN AND WAS NOT ADMITTED TO HOSPITAL. DISCONTINUED USE OF PRODUCT. SYMPTOMS IMPROVED AND LESSENED IN FREQUENCY.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 HYLAND'S TEETHING TABLETS
   - #2

2. Dose, Frequency & Route Used
   - #1 1 TAB 1-2 X PER DAY
   - #2

3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
   - #1
   - #2

4. Diagnosis for Use *(Indication)*
   - #1 TEETHING PAIN
   - #2

5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   - #1 107371
   - #2

7. Exp. Date
   - #1
   - #2

8. Event Reappeared After Reintroduction?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6) CANADA

Phone # (b) (6)

DSS

APR 22 2013

APR 19 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	FATHER	☐ Yes ☐ No ☒ Unk.

Individual Case Safety Report

CaseID: 9282767

9282767-03-00-04

FDA USE ONLY

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/23/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☒ Follow-up # 1

9. Manufacturer Report Number
54973

8. Adverse Event Term(s)
EYES ROLLING BACK / CLENCHED JAW

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

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APR 28 2013

APR 19 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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CaseID: 9282767

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD102510SW-002

TAKEN BY: (b) (6) DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS ITEM CODE: TEET

SIZE: 125 TABLETS LOT NO.: 107371

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: CANADA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: EYES ROLLING BACK IN THE HEAD AND CLENCHED JAW. THE BABY HAS BEEN USING TEETHING TABLETS FOR THE PAST YEAR (1-2 TIMES PER DAY). CHILD TAKEN TO PEDIATRICIAN AND WAS NOT ADMITTED TO HOSPITAL. DISCONTINUED USE OF PRODUCT. SYMPTOMS IMPROVED AND LESSENED IN FREQUENCY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282767-03-00-05

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS AE #: RAE102510SW-002

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10 BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

DSS APR 22 2013

BY: N/A DATE:

QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282767

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102510SW-002

COMPLAINT #: RVD102510SW-002

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: CANADA

ZIP CODE: (b) (6)

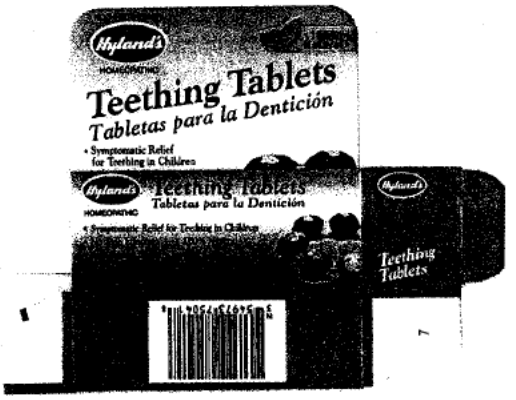
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282767-03-00-06

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

DSS
APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 19 2013

FORM SAE01

Individual Case Safety Report

9282767-03-00-07

CaseID: 9282767

Form Approved: OMB No. 0910-0291, Expires: 10/31/0
See OMB statement on revers

For use by user-facilities, ters, distributors and manufacturers for MANDATORY reporting

Mfr Report # 54973

UF/Importer Report #

FDA Use Onl

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	14 Months	☐ Female	____ lbs
In confidence	or ____	☒ Male	or
	Date of Birth:		____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/23/2010	11/03/2010

5. Describe Event or Problem

EYES ROLLING BACK IN THE HEAD AND CLENCHED JAW. THE BABY HAS BEEN USING TEETHING TABLETS FOR THE PAST YEAR (1-2 TIMES PER DAY). CHILD TAKEN TO PEDIATRICIAN AND WAS NOT ADMITTED TO HOSPITAL. DISCONTINUED USE OF PRODUCT. SYMPTOMS IMPROVED AND LESSENED IN FREQUENCY.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
#1 1 TAB 1-2 X PER DAY	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 107371	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)

Phone #: (b) (6)

(b) (6)

CANADA (b) (6)

APR 19 2013

DSS

APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	FATHER	☐ Yes ☐ No ☒ Unk.

PLEASE TYPE OR USE BLACK INK

FDA USE ONLY

...ly)

...ber

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | 5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)* | 7. Type of Report ☐ Initial ☐ Follow-up # ____ | 8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device | 10. Event Problem Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility
☐ Home ☐ Ambulatory Surgical Facility
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/23/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973

8. Adverse Event Term(s)
EYES ROLLING BACK / CLENCHED JAW

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 22 2013

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Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

APR 19 2013

CaseID: 9282767

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: COMPLAINT

COMPLAINT #: RVD102510SW-002

TAKEN BY: (b) (6)

DATE OF COMPLAINT: 10/25/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 107371

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: CANADA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: EYES ROLLING BACK IN THE HEAD AND CLENCHED JAW. THE BABY HAS BEEN USING TEETHING TABLETS FOR THE PAST YEAR (1-2 TIMES PER DAY). CHILD TAKEN TO PEDIATRICIAN AND WAS NOT ADMITTED TO HOSPITAL. DISCONTINUED USE OF PRODUCT. SYMPTOMS IMPROVED AND LESSENED IN FREQUENCY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282767-03-00-09

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION:

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/25/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: (b) (6)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102510SW-002

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/25/10

BY: (b) (6)

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

BY:

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

DSS
APR 22 2013

APR 19 2013

CaseID: 9282767

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102510SW-002

COMPLAINT #: RVD102510SW-002

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: CANADA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

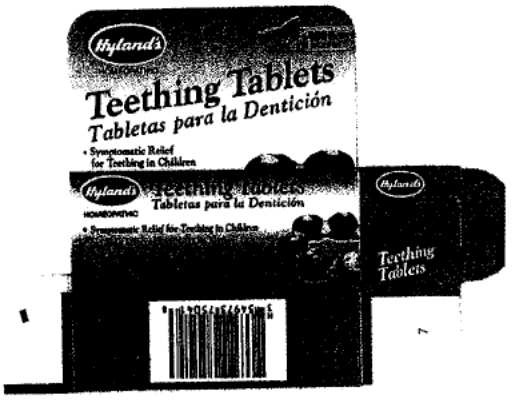
SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9282767-03-00-10

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE:

DSS
APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 19 2013

FORM SAE01

Individual Case Safety Report

9282776-02-00-01

MedWatch

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

CaseID: 9282776

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

FORM FDA 3500A (10/05)

Page 1 of 16

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	2 Months or	☒ Female ☐ Male	9 lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

- ☐ Death: _____ (mm/dd/yyyy)
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)
10/19/2010	11/11/2010

5. Describe Event or Problem

2 WEEKS AGO (APPROX. (b) (6) AVE 2 TEETHING TABLETS FOR THE FIRST TIME AND (b) (6) HOURS LATER CHILD STARTED COUGHING, CHOKING, AND TURNING PURPLE. WENT TO ER AND WERE TOLD THIS WAS A CHOKING EPISODE SECONDARY TO PHLEGM. NO TABLETS REMAINING IN THE MOUTH AS MOTHER CONFIRMED THAT SHE HELD THEM WITH HER FINGER UNDER THE BABIES TONGUE UNTIL THEY DISSOLVED. CHILD HAS A RUNNY NOSE AFTER THE EPISODE. CHILD TAKING VITAMINS. SYMPTOMS RESOLVED SPONTANEOUSLY SHORTLY AFTER ARRIVING AT ER.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1 2 TABS 3-4 HRS X 1 TIME	#1
#2	#2

4. Diagnosis for Use (Indication)	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 109673	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient
Serial #	Other #	☐ Other:

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS

APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☐ Yes ☐ No ☒ Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282776

9282776-02-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual)
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred
☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Ambulatory Surgical Facility ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source (Check all that apply)
☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer (mm/dd/yyyy): 10/19/2010
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply)
☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☒ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): CHOKING
9. Manufacturer Report Number: 54973

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type?
☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code: ____
4. Device Manufacture Date (mm/yyyy)
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual)
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification ☐ Repair ☐ Inspection ☐ Replace ☐ Patient Monitoring ☐ Relabeling ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device
☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Complaint # 9282776

Hylands

SECTION I: **COMPLAINT**

COMPLAINT #: RVD110210EF001

TAKEN BY: EDYTA FRACKIEWICZ DATE OF COMPLAINT: 11/02/10

PRODUCT: TEETHING TABLETS ITEM CODE: TEET

SIZE: 125 TABLETS LOT NO.: 109673

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: 2 WEEKS AGO (APPROX. (b) (6) AVE 2 TEETHING TABLETS FOR THE FIRST TIME AND (b) (6) HOURS LATER CHILD STARTED COUGHING, CHOKING, AND TURNING PURPLE. WENT TO ER AND WERE TOLD THIS WAS A CHOKING EPISODE SECONDARY TO PHLEGM. NO TABLETS REMAINING IN THE MOUTH AS MOTHER CONFIRMED THAT SHE HELD THEM WITH HER FINGER UNDER THE BABIES TONGUE UNTIL THEY DISSOLVED. CHILD HAS A RUNNY NOSE AFTER THE EPISODE. CHILD TAKING VITAMINS. SYMPTOMS RESOLVED SPONTANEOUSLY SHORTLY AFTER ARRIVING AT ER.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (CIRCLE ONE) N

PRODUCT BEING RETURNED FOR INSPECTION: Y (CIRCLE ONE) N

Individual Case Safety Report

9282776-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (CIRCLE ONE) N

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/02/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: RAE110210EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/02/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

DSS APR 22 2013

BY: N/A DATE:

QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282776

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE110210EF001 **COMPLAINT #:** RVD110210EF001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

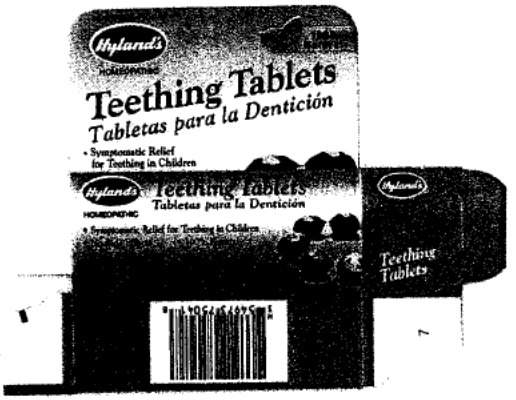
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282776-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

BY: N/A DATE:

QA / QC DIRECTOR

DSS
APR 22 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

9282791-02-00-01

CaseID: 9282791

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

CFTC

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Mfr Report #	54973
UF/Importer Report #	

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	20 Months	☒ Female	23 lbs
In confidence	or	☐ Male	or
	Date of Birth:		kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
06/08/2010	11/11/2010

5. Describe Event or Problem

CHILD HAS HAD 3 SEIZURES (GRANDMAL AND ABSENCE) SINCE 06/08/10 (JUNE, JULY, AUGUST). ATYPICAL SEIZURES BECAUSE DOCTOS DON'T KNOW WHAT IT'S DUE TO. VISITED DOCTOR AND PEDIATRIC NEUROLOGIST WHO SAY THEY'RE NOT FEBRIL SEIZURES. EEG IS NORMAL AND MRI SHOWS THAT WHITE MATTER HAS CHANGED. TAKING KEPPRA (SEIZURE MEDS) SINCE 08/25.

CHILD HAS TAKEN 1-3 TEETHING TABLET TABS BID EVERY OTHER DAY BETWEEN JULY OR SEPTEMBER 2009.

6. Relevant Tests/Laboratory Data, Including Dates

EEG IS NORMAL. MRI SHOWS THAT WHITE MATTER HAS CHANGED.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate)*
#1 1-3 TABS BID EVRYOTHRDY	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 106703	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional
Serial #	Other #	☐ Lay User/Patient
		☐ Other:

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

APR 19 2013

DSS

APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☐ Yes ☐ No ☒ Unk.

FDA USE ONLY

y)

1. Check One: ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report: ☐ Initial ☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*

Patient Code: ___ - ___ - ___

Device Code: ___ - ___ - ___

11. Report Sent to FDA?

☐ Yes _____ *(mm/dd/yyyy)*

☐ No

12. Location Where Event Occurred

☐ Hospital ☐ Outpatient Diagnostic Facility

☐ Home ☐ Ambulatory Surgical Facility

☐ Nursing Home

☐ Outpatient Treatment Facility

☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?

☐ Yes _____ *(mm/dd/yyyy)*

☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number

310-768-0700

3. Report Source *(Check all that apply)*

☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*

11/03/2010

5.

(A)NDA # _____

IND # _____

STN # _____

PMA/ 510(k) # _____

Combination Product ☐ Yes

Pre-1938 ☐ Yes

OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*

☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number

54973

8. Adverse Event Term(s)

SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event

☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?

☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?

☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?

☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*

Method ___ - ___ - ___ - ___

Results ___ - ___ - ___ - ___

Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type

☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/ Adjustment
☐ Other:

8. Usage of Device

☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 19 2013

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

C[illegible]282791

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: RAE110310EF001

TAKEN BY: EDYTA FRACKWICZ DATE OF COMPLAINT: 11/03/10

PRODUCT: TEETHING TABLETS ITEM CODE: TEET

SIZE: 125 TABLETS LOT NO.: 106703

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: CHILD HAS HAD 3 SEIZURES SINCE 06/08/10. JUNE, JULY, AUGUST. GRANDMAL AND ABSENCE SEIZURES. ATYPICAL SEIZURES BECAUSE DOCTORS DON'T KNOW WHAT IT'S DUE TO. CHILD WAS TAKING 1 TAB BID THEN WENT UP TO 2 TABS BID THEN 3 TABS BID EVERY OTHER DAY BETWEEN JULY OR SEPT. 2009. VISITED DOCTOR AND PEDIATRIC NEUROLOGIST WHO SAY THEY'RE NOT FEBRILE SEIZURES. EEG IS NORMAL AND MRI SHOWS THAT WHITE MATTER HAS CHANGED. TAKING KEPPRA (SEIZURE MEDS) SINCE 08/25.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

WANTS TO KEEP BOTTLE IN CASE OF A LAWSUIT.

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/03/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

Individual Case Safety Report

9282791-02-00-03

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: RAE110310EF001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/03/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

BY: N/A DATE:

QA / QC DIRECTOR

DSS

APR 22 2013

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

R

Case ID: 9282791

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE110310EF001 **COMPLAINT #:** RVD110310EF001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

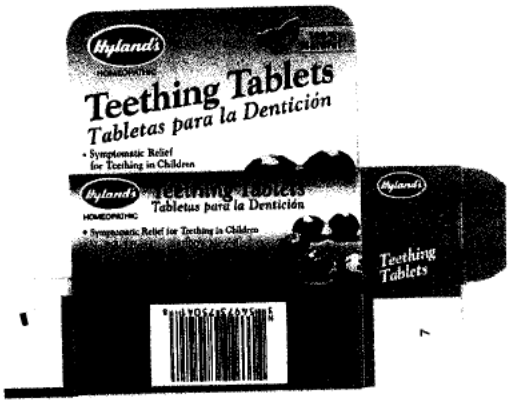
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282791-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/17/10

BY: N/A. DATE:

QA / QC DIRECTOR

DSS
APR 22 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE **FORM SAE01**

APR 19 2013

Individual Case Safety Report

9282797-02-00-01

OTC

For use by user-facilities, distributors and manufacturers MANDATORY reporting

CaseID: 9282797

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	17 Months or	[X] Female [ ] Male	29 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- [ ] Death: ____ *(mm/dd/yyyy)*
- [ ] Disability or Permanent Damage
- [ ] Life-threatening
- [ ] Congenital Anomaly/Birth Defect
- [X] Hospitalization - initial or prolonged
- [ ] Other Serious (Important Medical Events)
- [ ] Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/28/2010	11/10/2010

5. Describe Event or Problem

SLEEPY FOR NIGHT. WOKE WHILE SLEEPING, GIVEN 3 TABS AROUND 10 PM, WENT BACK TO BED. EXPERIENCED SEIZURE AROUND MIDNIGHT. CALLED '911'. CHILD TAKEN TO (b) (6) HOSPITAL VIA AMBULANCE.

DRS DIAGNOSIS IS UNCLEAR. GUESSED FEBRILE SEIZURES. LOTS OF TESTS, NO DIAGNOSIS.

USED TEETHING TABLETS FOR MONTHS. CHILD TAKING 3 TAB DOSE 1-3 TIMES PER DAY.

6. Relevant Tests/Laboratory Data, Including Dates

CAT SCAN, BLOOD TESTS, CHEST X-RAY, AND URINE / UTI TESTS ALL CAME BACK CLEAN.

EEG AND NEUROLOGIC TESTS SCHEDULED FOR (b) (6) OR (b) (6)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

NONE

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
#1 3 TABS X 1-3 X/DAY	#1 7 MONTHS
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 [ ] Yes [ ] No [ ] Doesn't Apply

#2 [ ] Yes [ ] No [ ] Doesn't Apply

6. Lot #	7. Exp. Date
#1 108486	#1
#2	#2

8. Event Reappeared After Reintroduction?

#1 [ ] Yes [ ] No [ ] Doesn't Apply

#2 [ ] Yes [ ] No [ ] Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

MOTRIN Q6H FOR SEVERAL DAYS & TYLENOL FOR FEVER SPIKE, BENADRYL AT NIGHT PRN PAST WEEK

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	[ ] Health Professional [ ] Lay User/Patient [ ] Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*

[ ] Yes [ ] No [ ] Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address

(b) (6)

Phone # (b) (6)

DSS

APR 19 2013

APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
[ ] Yes [X] No	MOTHER	[ ] Yes [ ] No [ ] Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9282797

9282797-02-00-02

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** — [ ] User Facility [ ] Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** — [ ] Initial [ ] Follow-up # ____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)* — Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. **Report Sent to FDA?** — [ ] Yes ____ *(mm/dd/yyyy)* [ ] No
12. **Location Where Event Occurred** — [ ] Hospital [ ] Home [ ] Nursing Home [ ] Outpatient Treatment Facility [ ] Outpatient Diagnostic Facility [ ] Ambulatory Surgical Facility [ ] Other: ____ *(Specify)*
13. **Report Sent to Manufacturer?** — [ ] Yes ____ *(mm/dd/yyyy)* [ ] No
14. **Manufacturer Name/Address**

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. **Phone Number** 310-768-0700

3. **Report Source** *(Check all that apply)*
- [ ] Foreign
- [ ] Study
- [ ] Literature
- [x] Consumer
- [ ] Health Professional
- [ ] User Facility
- [ ] Company Representative
- [ ] Distributor
- [ ] Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)* 10/31/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____
Combination Product [ ] Yes
Pre-1938 [ ] Yes
OTC Product [x] Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
- [ ] 5-day [ ] 30-day
- [ ] 7-day [ ] Periodic
- [ ] 10-day [x] Initial
- [x] 15-day [ ] Follow-up # ____

9. **Manufacturer Report Number** 54973

8. **Adverse Event Term(s)** SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event**
- [ ] Death
- [ ] Serious Injury
- [ ] Malfunction
- [ ] Other:

2. **If Follow-up, What Type?**
- [ ] Correction
- [ ] Additional Information
- [ ] Response to FDA Request
- [ ] Device Evaluation

3. **Device Evaluated by Manufacturer?**
- [ ] Not Returned to Manufacturer
- [ ] Yes [ ] Evaluation Summary Attached
- [ ] No *(Attach page to explain why not)* or provide code:

4. **Device Manufacture Date** *(mm/yyyy)*

5. **Labeled for Single Use?** — [ ] Yes [ ] No

6. **Evaluation Codes** *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. **If Remedial Action Initiated, Check Type**
- [ ] Recall
- [ ] Repair
- [ ] Replace
- [ ] Relabeling
- [ ] Notification
- [ ] Inspection
- [ ] Patient Monitoring
- [ ] Modification/Adjustment
- [ ] Other:

8. **Usage of Device**
- [ ] Initial Use of Device
- [ ] Reuse
- [ ] Unknown

9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**

10. [ ] **Additional Manufacturer Narrative** and / or 11. [ ] **Corrected Data**

DSS
APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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."

APR 9 2013

Please DO NOT RETURN this form to this address.

Case ID: 9282797

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

SECTION I: **COMPLAINT**

COMPLAINT #: RVD103110MP-001

TAKEN BY: MARK PHILLIPS

DATE OF COMPLAINT: 10/31/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 108486

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: SLEEPY FOR NIGHT. WOKE WHILE SLEEPING, GIVEN 3 TABS AROUND 10 PM, WENT BACK TO BED. EXPERIENCED SEIZURE AROUND MIDNIGHT. CALLED '911'. CHILD TAKEN TO (b) (6) HOSPITAL VIA AMBULANCE.

DRS DIAGNOSIS IS UNCLEAR. GUESSED FEBRILE SEIZURES. LOTS OF TESTS, NO DIAGNOSIS.

USED TEETHING TABLETS FOR MONTHS. CHILD TAKING 3 TAB DOSE 1-3 TIMES PER DAY.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282797-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/31/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: MARK PHILLIPS

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE103110MP-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/31/10

BY: MARK PHILLIPS

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/10/10

BY: N/A
QA / QC DIRECTOR

DATE:

DQS APR 22 2013

cc: QA / QC, Packaging, Production, Shipping / Receiving

Form # VD1

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE103110MP-001

COMPLAINT #: RVD103110MP-001

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

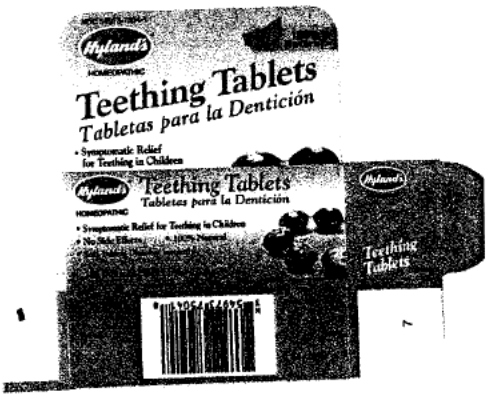
PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)



Individual Case Safety Report

9282797-02-00-04

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/19/16

BY: N/A
QA / QC DIRECTOR

DATE:

DSS
APR 22 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

CaseID: 9282809

9282809-02-00-01

MedWatch

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05) Page 1 of 4

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 17 Months — or — Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: 30 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
   - ☐ Death: ____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☒ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 03/01/2009

4. Date of This Report *(mm/dd/yyyy)*: 10/26/2010

5. Describe Event or Problem

SON WENT LETHARGIC, NEUROLOGICAL SYMPTOMS. BECAME LETHARGIC, LIMP, TWITCHING, ALTERNATING FLUSHED AND WHITE FACE, WOBBLY GAIT BUMPING INTO WALLS.

DOCTOR DIAGNOSED PROBLEM AS VIRAL.

6. Relevant Tests/Laboratory Data, Including Dates

BLLOD TESTS AND X-RAYS. ALL CAME BACK NEGATIVE.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
   - #1 TEETHING TABLETS
   - #2

2. Dose, Frequency & Route Used
   - #1
   - #2

3. Therapy Dates *(If unknown, give duration from/to (or best estimate))*
   - #1
   - #2

4. Diagnosis for Use *(Indication)*
   - #1 TEETHING PAIN
   - #2

5. Event Abated After Use Stopped or Dose Reduced?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
   - #1 101986
   - #2

7. Exp. Date
   - #1
   - #2

8. Event Reappeared After Reintroduction?
   - #1 ☐ Yes ☐ No ☐ Doesn't Apply
   - #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-2

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address: (b) (6)

Phone #: (b) (6)

DSS

APR 19 2013

APR 22 2013

2. Health Professional? ☐ Yes ☒ No

3. Occupation: MOTHER

4. Initial Reporter Also Sent Report to FDA: ☒ Yes ☐ No ☐ Unk.

FDA USE ONLY

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:

2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation

3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:

4. Device Manufacture Date (mm/yyyy)

5. Labeled for Single Use? ☐ Yes ☐ No

6. Evaluation Codes (Refer to coding manual)

Method ___ - ___ - ___ - ___

Results ___ - ___ - ___ - ___

Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment ☐ Other:

8. Usage of Device ☐ Initial Use of Device ☐ Reuse ☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

1. Check One ☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)

7. Type of Report ☐ Initial ☐ Follow-up # ___

8. Date of This Report (mm/dd/yyyy)

9. Approximate Age of Device

10. Event Problem Codes (Refer to coding manual)

Patient Code ___ - ___ - ___

Device Code ___ - ___ - ___

11. Report Sent to FDA? ☐ Yes ___ (mm/dd/yyyy) ☐ No

12. Location Where Event Occurred ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ___ (Specify)

13. Report Sent to Manufacturer? ☐ Yes ___ (mm/dd/yyyy) ☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply) ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 10/26/2010

5. (A)NDA # ___ IND # ___ STN # ___ PMA/ 510(k) # ___ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report (Check all that apply) ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☒ 15-day ☐ Follow-up # ___

8. Adverse Event Term(s): LETHARGIC

9. Manufacturer Report Number: 54973

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

Ca[illegible]9282809

SECTION I: COMPLAINT

COMPLAINT #: RVD102610TG-001

TAKEN BY: TUTTI GOULD DATE OF COMPLAINT: 10/26/10

PRODUCT: TEETHING TABLETS ITEM CODE: TEET

SIZE: 250 LOT NO.: 101986

REPORTER: (b) (6)

ADDRESS: (b) (6)

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT:

SON WENT LETHARGIC, NEUROLOGICAL SYMPTOMS. EVENT OCCURRED IN (b) (6) AND CONTINUED FOR SEVERAL DAYS. CALLED 911. SON TRANSFERRED FROM ER TO CHILDREN'S HOSPITAL; STAYED 4 DAYS. EXAMINED BY CARDIOLOGY, NEUROLOGY, AND RADIOLOGY. BLOOD TESTS & X-RAYS CAME BACK NEGATIVE. RELEASED FROM HOSPITAL AFTER 4 DAYS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: (Y) N (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

Individual Case Safety Report

9282809-02-00-03

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 10/26/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: 10/26/10

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102610TG-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/26/10 BY: TUTTI GOULD

DSS

APR 22 2013

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 4/17/13

BY: N/A DATE:

QA / QC DIRECTOR

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

CaseID: 9282809

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE102610TG-001

COMPLAINT #: RVD102610TG-001

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

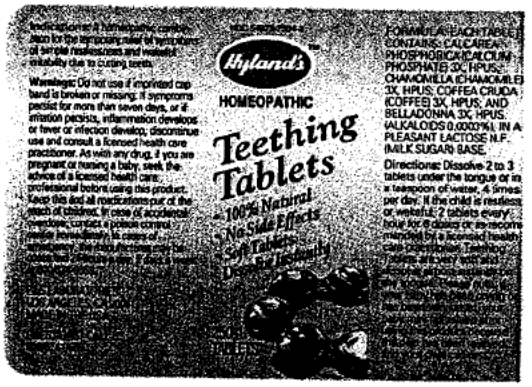
ZIP CODE:

PHONE: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

Individual Case Safety Report

9282809-02-00-04

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/23/10

DSS

APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

CaseID: 9282818

9282818-02-00-01

Form Approved: OMB No. 0910-0291 Expires: 03/31/08
See OMB statement on reverse.

For use by user facilities, importers, distributors and manufacturers MANDATORY reporting

JETC

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

FORM FDA 3500A (10/05)

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) In confidence
2. Age at Time of Event: 17 Months or Date of Birth:
3. Sex: ☐ Female ☒ Male
4. Weight: 29 lbs or 13 kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)
- ☐ Death: _____ (mm/dd/yyyy)
- ☒ Life-threatening
- ☒ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy): 11/11/2010

4. Date of This Report (mm/dd/yyyy): 11/23/2010

5. Describe Event or Problem

AFTER ADMINISTERING TWO TEETHING TABLETS TO (b) (6) EARLIER IN THE EVENING, MOM OBSERVED BABY EXHIBITING 'WEIRD NIGHT TERRORS'. HE WAS SCREAMING WHILE SOUND ASLEEP. IT TOOK HER 10 - 15 MINS. TO WAKE HIM. WHEN AWAKENED, HE COULDN'T FOCUS ON ANYTHING. HE WAS SHAKING, TREMBLING, HAD DIALATED PUPILS AND WAS HOT AND SWEATY. THE PARENTS CALLED 911. THE BABY WAS TAKEN TO (b) (6) HOSPITAL IN (b) (6) ((b) (6) (b) (6)). HE WAS HOSPITALIZED FOR APPROX. 8 HOURS. PARENTS THOUGHT THE CHILD WAS EXHIBITING SEIZURE DISORDER AS SEIZURES RUN IN THE MOM'S FAMILY. HOWEVER, PER MOM, ALL THE TEST RESULTS FOR SEIZURE DISORDER WERE NEGATIVE (EFF AND BLOOD WORK) AND THE BABY WAS DISCHARGED. AS A RESULT, THE FAMILY HAS INCURRED NUMEROUS HOSPITAL BILLS. BACK AT HOME, THE DAY AFTER THESE EVENTS, THE MOM REPORTS THAT BABY'S NEXT BM WAS EITHER DIARRHEA OR CONSTIPATION. MOM CLAIMS THE BABY EXHIBITED SIMILAR (BUT NOT NEARLY AS ACUTE) SYMPTOMS FOLLOWING THE PRN ADMINISTRATION OF TEETHING TABLETS SUBSEQUENT TO HOSPITALIZATION. THE FAMILY CONTINUES TO WONDER WHAT CAUSED THE BABY'S SYMPTOMS.

PLEASE TYPE OR USE BLACK INK

6. Relevant Tests/Laboratory Data, Including Dates

ALL TESTS WERE NEGATIVE -- EEG AND BLOOD WORK

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

SEIZURES RUN IN MOM'S FAMILY

RECEIVED
APR 19 2013
CDR

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used
#1 2 TABS @ HS OR 2 BID
#2

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for Use (Indication)
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
#1 N/A
#2

7. Exp. Date
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone #: (b) (6)

DSS
APR 22 2013

2. Health Professional? ☐ Yes ☒ No
3. Occupation: MOTHER
4. Initial Reporter Also Sent Report to FDA: ☒ Yes ☐ No ☐ Unk.

APR 19 2013

Individual Case Safety Report

CaseID: 9282818

9282818-02-00-02

FDA USE ONLY

G. ALL MANUFACTURERS

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number:
3. User Facility or Importer Name/Address:
4. Contact Person:
5. Phone Number:
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy):
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report (mm/dd/yyyy):
9. Approximate Age of Device:
10. Event Problem Codes (Refer to coding manual): Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ (mm/dd/yyyy) ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ (Specify)
13. Report Sent to Manufacturer? ☐ Yes ____ (mm/dd/yyyy) ☐ No
14. Manufacturer Name/Address:

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices):

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700

3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:

4. Date Received by Manufacturer (mm/dd/yyyy): 11/22/2010

5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☒ Yes

6. If IND, Give Protocol #:

7. Type of Report (Check all that apply): ☐ 5-day ☐ 7-day ☐ 10-day ☐ 15-day ☐ 30-day ☐ Periodic ☐ Initial ☐ Follow-up # 1

8. Adverse Event Term(s): NIGHT TERRORS / SEIZURES

9. Manufacturer Report Number: 54973 RAE112210CMD001

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No (Attach page to explain why not) or provide code:
4. Device Manufacture Date (mm/yyyy):
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes (Refer to coding manual): Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other:
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

APR 19 2013

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

CUSTOMER COMPLAINT RECORD

Hyland's

9282818

SECTION I: **COMPLAINT**

COMPLAINT #: RVD112210CMD001

TAKEN BY: CATHERINE DOW

DATE OF COMPLAINT: 11/22/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: NOT AVAILABLE SINCE MOM RIPPED OFF LABEL AS CHILD WAS CHEWING ON PKG.

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: AFTER ADMINISTERING TWO TEETHING TABLETS TO (b) (6) EARLIER IN THE EVENING, MOM OBSERVED BABY EXHIBITING 'WEIRD NIGHT TERRORS'. HE WAS SCREAMING WHILE SOUND ASLEEP. IT TOOK HER 10 – 15 MINS. TO WAKE HIM. WHEN HE AWAKENED, HE COULDN'T FOCUS ON ANYTHING. HE WAS SHAKING, TREMBLING, HAD DILATED PUPILS AND WAS HOT AND SWEATY. THE PARENTS CALLED 911. THE BABY WAS TAKEN TO (b) (6) HOSPITAL IN (b) (6) (b) (6). HE WAS HOSPITALIZED FOR APPROX. 8 HOURS. PARENTS THOUGHT THE CHILD WAS EXHIBITING SEIZURE DISORDER WERE NEGATIVE (EEG AND BLOOD WORK) AND THE BABY WAS DISCHARGED. AS A RESULT, THE FAMILY HAS INCURRED NUMEROUS HOSPITAL BILLS. BACK AT HOME, THE DAY AFTER THESE EVENTS, THE MOM REPORTS THE BABY'S NEXT BM WAS EITHER DIARRHEA OR CONSTIPATION. MOM CLAIMS THE BABY EXHIBITED SIMILAR (BUT NOT NEARLY AS ACUTE) SYMPTOMS FOLLOWING THE PRN ADMINISTRATION OF TEETHING TABLETS SUBSEQUENT TO HOSPITALIZATION. THE FAMILY CONTINUES TO WONDER WHAT CAUSED THE BABY'S SYMPTOMS.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

Individual Case Safety Report

9282818-02-00-03

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 11/22/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: CATHERINE DOW

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE112210CMD001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/22/10

BY: CATHERINE DOW

DSS

APR 22 2013

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE:

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

APR 19 2013

RVD1

STANDARD HOMEOPATHIC
MADE IN THE USA SINCE 1903

Hyland's

SERIOUS ADVERSE EVENT DATA FORM

AE #: RAE112210CMD001 COMPLAINT #: RVD112210CMD001

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE: (b) (6)

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

Individual Case Safety Report

9282818-02-00-04

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 12/1/10

DSS
APR 22 2013

BY: N/A DATE:
QA / QC DIRECTOR

APR 19 2013

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

Individual Case Safety Report

9410071-01-00-01

Form Approved: OMB No. 0910-0291 Expires: 10/31/08
See OMB statement on reverse.

Case 1:21-cv-24107-J...

...er facilities, ...or and manufacturers ...TORY reporting

1 of 2

Mfr Report # 54973

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	9 Months or	☐ Female ☒ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☒ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/09/2010	11/11/2010

5. Describe Event or Problem

SEIZURES. CHILD TENSES BODY AND THEN STOPS BREATHING, AND CONVULSES FOR 1-2 MINUTES. THE PARENTS ADMINISTERED CPR AFTER THE SEIZURE. THE CHILD HAD TAKEN TEETHING TABLETS FOR THE PAST 7 MONTHS WITHOUT EVENT, MOTHER NOTICED THEY HELPED HIM STOP CRYING FROM THE PAIN OF TEETHING. BY 3:40 PM ONE DAY, CHILD HAD THE FIRST OF 5 SEIZURES THAT DAY, WITH NO FEVER. HE WAS HOSPITALIZED. SEIZURES CONTINUED EVERY 3 DAYS OR SO. THERE HAVE BEEN NONE SINCE OCT. 31ST. DISCONTINUED USE OF TEETHING TABLETS AROUND OCT. 25. MOM NOTICED SEIZURE ACTIVITY GRADUALLY LESSENED AFTER SHE STOPPED THE TABLETS. THE CHILD HAS BEEN ON ANTI-CONVULSIVE MEDICATION SINCE THE EVENT. SHE HAS GIVEN THE CHILD TYLENOL ON PREVIOUS TEETHIING TIMES.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

RECEIVED
APR 19 2013
CDR

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
#1 HYLAND'S TEETHING TABLETS
#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration) from/to (or best estimate)*
#1 2 TABS 2-3 X DAY	#1
#2	#2

4. Diagnosis for Use *(Indication)*
#1 TEETHING PAIN
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 N/A	#1
#2	#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID
54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address
(b) (6)

Phone # (b) (6)

DSS
APR 19 2013 APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☐ Yes ☒ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9410071

9410071-01-00-02

FDA USE ONLY

of 2

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # _____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ___ - ___ - ___
Device Code ___ - ___ - ___

11. Report Sent to FDA?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: _____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes _____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
11/09/2010

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☒ Follow-up # 1

9. Manufacturer Report Number
54973 RAE110910TG001

8. Adverse Event Term(s)
SEIZURES

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ___ - ___ - ___ - ___
Results ___ - ___ - ___ - ___
Conclusions ___ - ___ - ___ - ___

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

APR 19 2013

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this form to this address.

Individual Case Safety Report

CaseID: 9410124

9410124-01-00-01

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

...acilities, ...d manufacturers ...MANDATORY reporting

Mfr Report # 54973
UF/Importer Report #
FDA Use Only

MEDWATCH

FORM FDA 3500A (10/05)

Page 1 of 4

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event:	3. Sex	4. Weight
(b) (6)	16 Months or	☒ Female ☐ Male	____ lbs or ____ kgs
In confidence	Date of Birth: (b) (6)		

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
10/27/2010	11/01/2010

5. Describe Event or Problem

THE BABY HAS BEEN USING THE TABLETS FOR SEVERAL WEEKS AND TYPICALLY CONSUMED 2 TABLETS AT A TIME. AROUND 10/16/10 THE CONSUMER HAD A LOW GRADE FEVER. ON 10/26/10 SHE CONSUMED 2 TABLETS IN THE EARLY AFTERNOON AND TWO TABLETS AROUND 8:00 PM. THE CONSUMER'S MOTHER REPORTED THAT AT APPROX. 1:30 THIS MORNING (10/27/10) THE CONSUMER FELT HOT WITH FEVER. THEN, BETWEEN 3:300 - 3:45 AM, THE CONSUMER EXPERIENCED A SEIZURE. THE CONSUMER'S MOTHER FIRST NOTICED A NOISE OVER THE BABY MONITOR AND UPON CHECKING ON THE CONSUMER SHE OBSERVED THAT THE CONSUMER WAS LYING FLAT ON HER BACK AND AT INTERVALS OF APPROXIMATELY TEN SECONDS SHE WOULD TWITCH AND GRUNT. THIS BEHAVIOR LASTED FOR APPROXIMATELY TEN MINUTES. DURING THAT TIME THE CONSUMER'S FATHER CALLED AN AFTER-HOURS NURSE FOR ADVISE. WHEN THE CONSUMER WOKE UP A FEW MINUTES LATER SHE WAS REPORTED TO BE LETHARGIC AND UNRESPONSIVE. CONSUMER'S PARENTS DECIDED NOT TO TAKE HER TO THE EMERGENCY ROOM BECAUSE THE SEIZURE STOPPED AND THE CONSUMER FELL BACK TO SLEEP. WHEN THE CONSUMER WOKE UP THIS MORNING AT APPROX. 7:30 AM, SHE WAS REPORTED TO HAVE HAD NO SYMPTOMS. THE CONSUMER WAS TAKEN TO THE DOCTOR THIS MORNING AS A FOLLOW-UP TO THE EVENTS OF FEVER, SEIZURE, AND LETHARGY. HYLAND'S TEETHING TABLETS HAVE BEEN DISCONTINUED AND THE EVENTS OF SEIZURE, FEVER, AND LETHARGY HAVE RESOLVED.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

ALLERGY TO NKA

PLEASE TYPE OR USE BLACK INK

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1 2 TABS EA TIME/SVL WKS	#1
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1 TEETHING PAIN	#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1 109090	#1	#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 109352	#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS

APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☐ Yes ☐ No ☒ Unk.

APR 19 2013

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Individual Case Safety Report

CaseID: 9410124

9410124-01-00-02

FDA USE ONLY

FORM FDA 3500A (10/09) (continued) Page ___ of 4

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. Check One: ☐ User Facility ☐ Importer
2. UF/Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*
7. Type of Report: ☐ Initial ☐ Follow-up # ____
8. Date of This Report *(mm/dd/yyyy)*
9. Approximate Age of Device
10. Event Problem Codes *(Refer to coding manual)*: Patient Code ____ - ____ - ____ Device Code ____ - ____ - ____
11. Report Sent to FDA? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
12. Location Where Event Occurred: ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: ____ *(Specify)*
13. Report Sent to Manufacturer? ☐ Yes ____ *(mm/dd/yyyy)* ☐ No
14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

LESLIE WORTHEY
EXPERT RECALL
c/o HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number: 310-768-0700
3. Report Source *(Check all that apply)*: ☐ Foreign ☐ Study ☐ Literature ☒ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other:
4. Date Received by Manufacturer *(mm/dd/yyyy)*: 10/27/2010
5. (A)NDA # ____ IND # ____ STN # ____ PMA/510(k) # ____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☒ Yes
6. If IND, Give Protocol #
7. Type of Report *(Check all that apply)*: ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☒ 15-day ☐ Follow-up # ____
8. Adverse Event Term(s): SEIZURE, FEVER, LETHARGY
9. Manufacturer Report Number: 54973 RSAE102710 LW-dcl

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☐ Serious Injury ☐ Malfunction ☐ Other: ____
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: ____
4. Device Manufacture Date *(mm/yyyy)*
5. Labeled for Single Use? ☐ Yes ☐ No
6. Evaluation Codes *(Refer to coding manual)*: Method ____ - ____ - ____ - ____ Results ____ - ____ - ____ - ____ Conclusions ____ - ____ - ____ - ____
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: ____
8. Usage of Device: ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS

APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

Please DO NOT RETURN this form to this address.

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

APR 19 2013

Individual Case Safety Report

CaseID: 9410124

9410124-01-00-03

NT RECORD

COMPLAINT #: RVD102710LW-001

TAKEN BY: LESLEY WORTHEY

DATE OF COMPLAINT: 10/27/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 109090 & 109352

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY:

ZIP CODE: (b) (6)

PHONE #:

E-MAIL:

NATURE OF COMPLAINT: CHILD TOOK TEETHING TABLETS FOR SEVERAL WEEKS. AROUND 10/16/10 CHILD HAS A LOW GRADE FEVER. ON 10/17/10 CHILD FELT HOT WITH FEVER. CHILD EXPERIENCED SEIZURE BETWEEN 3:30 – 3:45 AM ON 10/27/10. CHILD IS 16 MONTHS OLD. CHILD NOT TAKEN TO ER. SYMPTOMS PASSED BY 7:30 AM. CHILD TAKEN TO DR FOR F/U. DISCONTINUED PRODUCT AND EVENTS HAVE RESOLVED. ALLERGY TO NKA.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/27/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: LESLIE WORTHEY

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102710LW-001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 10/27/10

BY: LESLIE WORTHEY

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/23/10

DSS

APR 22 2013

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC
Packaging
Production
Shipping / Receiving

Form # VD1

APR 19 2013

Individual Case Safety Report

CaseID: 9410124

9410124-01-00-04

Hyland's®

EVENT DATA FORM

AE #: RAE102710LW-001 **COMPLAINT #:** RVD102710LW-001

SECTION I: **PATIENT INFORMATION** ***(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6) STATE: (b) (6)

COUNTRY: ZIP CODE:

PHONE #:

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/23/10

DSS

APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAER

APR 19 2013

Individual Case Safety Report

CaseID: 9410139

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

9410139-01-00-01

facilities,
nd manufacturers
Y reporting

Mfr Report #	54973
UF/Importer Report #	
	FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
(b) (6) In confidence	11 Months	☐ Female ☒ Male	25 lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: ____ *(mm/dd/yyyy)*
- ☒ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
08/05/2010	11/23/2010

5. Describe Event or Problem

WHEEZING: 'WHISTLE FROM CHEST, RETRACTED STOMACH AREA DUE TO DIFFICULTY BREATHING'. CHILD STARTED TEETHING TABLETS, 1 TABLET, JUNE 1, 2010 FOR MILD TEETHING SYMPTOMS. THE SYMPTOMS INTENSIFIED IN AUGUST AND WHEEZING STARTED AUGUST 5TH. HE SAW THE DOCTOR SEVERAL TIMES THAT MONTH FOR THE WHEEZING. ALLERGIST WAS CONSULTED AND RULED OUT ALLERGIES. CHILD WAS PUT ON MEDICATION: ZOBINEX FOR THE WHEEZING. THEY STOPPED GIVING THE TEETHING TABLETS AT THE TIME OF THE RECALL (OCT. 25). THE WHEEZING SYMPTOMS STOPPED AT AROUND THE SAME TIME.

6. Relevant Tests/Laboratory Data, Including Dates

TESTED FOR ALLERGIES.

RECEIVED
APR 19 2013
CDR

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

MOTHER HAS A HISTORY OF ASTHMA AS A CHILD.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*

#1 HYLAND'S TEETHING TABLETS

#2

2. Dose, Frequency & Route Used	3. Therapy Dates *(If unknown, give duration from/to (or best estimate)*
#1 1-3TABS 2-3XDAY X 4 MO.	#1
#2	#2

4. Diagnosis for Use *(Indication)*

#1 TEETHING PAIN

#2

5. Event Abated After Use Stopped or Dose Reduced?

#1 ☐ Yes ☐ No ☒ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date
#1 109439	#1
#2 108018	#2

8. Event Reappeared After Reintroduction?

#1 ☐ Yes ☐ No ☒ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

54973-7504-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
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

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone #
(b) (6)	(b) (6)

DSS
APR 19 2013 APR 22 2013

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☒ No	MOTHER	☐ Yes ☐ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

Individual Case Safety Report

CaseID: 9410139

9410139-01-00-02

FDA USE ONLY

of 6

1. Check One
☐ User Facility ☐ Importer

2. Of/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
11/15/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☐ Initial
☐ 15-day ☐ Follow-up # 1

9. Manufacturer Report Number
54973 RAE111510TG001

8. Adverse Event Term(s)
WHEEZING

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

DSS
APR 22 2013

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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OMB Statement:
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APR 19 2013

Individual Case Safety Report

9410139-01-00-03

Article # 7008 1830 0000 8628 8788

Case 1:13-cv-00139

12/1/10

T RECORD

Hylands®

COMPLAINT #: RVD111510TG001

TAKEN BY: TUTTI GOULD

DATE OF COMPLAINT: 11/15/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS

LOT NO.: 109439 / 108018

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: WHEEZING: "WHISTLE FROM CHEST, RETRACTED STOMACH AREA DUE TO DIFFICULTY BREATHING". CHILD STARTED TEETHING TABLETS, 1 TABLET, JUNE 1, 2010 FOR MILD TEETHING SYMPTOMS. THE SYMPTOMS INTENSIFIED IN AUGUST AND WHEEZING STARTED AUGUST 5TH. HE SAW THE DOCTOR SEVERAL TIMES THAT MONTH FOR THE WHEEZING. ALLERGIST WAS CONSULTED AND RULED OUT ALLERGIES. CHILD WAS PUT ON MEDICATION: ZOBINEX FOR THE WHEEZING. THEY STOPPED GIVING THE TEETHING TABLETS AT THE TIME OF THE RECALL (OCT. 25). THE WHEEZING SYMPTOMS STOPPED AT AROUND THE SAME TIME. MOTHER HAS A HISTORY OF ASTHMA AS A CHILD.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 11/15/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: TUTTI GOULD

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY:

DATE:

SECTION IV: **ADVERSE EVENT REPORTS**

AE #: RAE1115510TG001

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 11/15/10 BY: TUTTI GOULD

SECTION V:

REVIEWED BY MANAGEMENT BY:

DATE: 11/30/10

DSS

APR 22 2013

BY: N/A

QA / QC DIRECTOR

DATE:

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

APR 19 2013

Individual Case Safety Report

CaseID: 9410139

9410139-01-00-04

EVENT DATA FORM

AE #: RAE111510TG001

COMPLAINT #: RVD111510TG001

SECTION I: PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)*

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: PACKAGING INFORMATION:

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 11/30/10

DSS

APR 22 2013

BY: N/A DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Individual Case Safety Report

CaseID: 9410150

Form Approved: OMB No. 09-10-0029, Expires 12/31/11
See OMB statement on reverse.

9410150-01-00-01

ser-facilities,
rs and manufacturers
ORY reporting

of 5

Mfr Report # 54973-...

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6) — In confidence
2. Age at Time of Event: 4 Months — or Date of Birth:
3. Sex: ☐ Female ☑ Male
4. Weight: ____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: ____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☑ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other Serious (Important Medical Events)

3. Date of Event *(mm/dd/yyyy)*: 04/01/2013

4. Date of This Report *(mm/dd/yyyy)*: 04/03/2013

5. Describe Event or Problem

INFANT RECEIVED 2 TABLETS X 1 DOSE AT 21:00 ON 04/01/13 AND AROUND 23:00 CHILD STARTED HAVING DIFFICULTY BREATHING, IRRITABILITY AND SLEEPINESS. ON (b) (6) THEY TOOK THE CHILD TO THE HOSPITAL BECAUSE OF THE BREATHING DIFFICULTY AND CHILD WAS ADMITTED AND RELEASED (b) (6) IN THE EVENING. IN THE HOSPITAL CHILD'S BREATHING WAS MONITORED AND BLOOD WORK AND X-RAYS WERE NORMAL. CHILD CONTINUES TO HAVE SOME PROBLEMS BREATHING AND IS SLEEPING A LOT.

6. Relevant Tests/Laboratory Data, Including Dates

BLOOD WORK AND X-RAYS. ALL WERE NORMAL. BREATHING MONITORED.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

CHILD WAS BORN 1 MONTH PREMATURE WITH LUNG PROBLEMS.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name *(Give labeled strength & mfr/labeler)*
- #1 HYLAND'S BABY TEETHING TABLETS 135 COUNT
- #2

2. Dose, Frequency & Route Used
- #1 2 TABS 4/1 & 2 TABS PREV
- #2

3. Therapy Dates *(If unknown, give duration)* from/to *(or best estimate)*
- #1
- #2

4. Diagnosis for Use *(Indication)*
- #1 TEETHING PAIN
- #2

5. Event Abated After Use Stopped or Dose Reduced?
- #1 ☐ Yes ☐ No ☐ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #
- #1
- #2

7. Exp. Date
- #1
- #2

8. Event Reappeared After Reintroduction?
- #1 ☐ Yes ☐ No ☐ Doesn't Apply
- #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID: 54973-3127-1

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date *(mm/dd/yyyy)* / Serial # / Other #
5. Operator of Device: ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date *(mm/dd/yyyy)*
7. If Explanted, Give Date *(mm/dd/yyyy)*
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? *(Do not send to FDA)* ☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ *(mm/dd/yyyy)*
11. Concomitant Medical Products and Therapy Dates *(Exclude treatment...*

DSS
APR 19 2013

E. INITIAL REPORTER

1. Name and Address: (b) (6)
Phone # (b) (6)

(b) (6)

3 2013 USA

2. Health Professional? ☐ Yes ☑ No
3. Occupation
4. Initial Reporter Also Sent Report to FDA ☐ Yes ☐ No ◉ Unk.

Individual Case Safety Report

CaseID: 9410150

9410150-01-00-02

1 of 5

FDA USE ONLY

1. Check One
☐ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ - ____ - ____
Device Code ____ - ____ - ____

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address *(and Manufacturing Site for Devices)*

EDYTA FRACKIEWICZ
HYLAND'S, INC.
154 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☑ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
04/03/2013

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☑ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☑ Initial
☑ 15-day ☐ Follow-up # ____

8. Adverse Event Term(s)
IRRITABILITY, SLEEPINESS, DIFFICULTY BREATHING

9. Manufacturer Report Number
54973 AE # 1337

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other: ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code: ____

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ____ - ____ - ____ - ____
Results ____ - ____ - ____ - ____
Conclusions ____ - ____ - ____ - ____

7. If Remedial Action Initiated, Check Type
☐ Recall ☐ Notification
☐ Repair ☐ Inspection
☐ Replace ☐ Patient Monitoring
☐ Relabeling ☐ Modification/Adjustment
☐ Other: ____

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ Additional Manufacturer Narrative and / or 11. ☐ Corrected Data

DSS
APR 18 2013
APR 19 2013

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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B.5. **Describe Event or Problem** *(continued)*

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

B.7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)*

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks

DSS
APR 19 2013

APR 18 2013

Individual Case Safety Report

CaseID: 9410150

LAINT RECORD

9410150-01-00-04

COMPLAINT #: 2259

DATE OF COMPLAINT: 04/03/13

PRODUCT: HYLAND'S BABY TEETHING TABLETS

ITEM CODE: BTET----T135

SIZE: 135 TABLETS

LOT NO.: DOCTOR HAS BOTTLE. BOUGHT 1 WEEK AGO AT WALMART

REPORTER: (b) (6)

ADDRESS: (b) (6)

RECEIVED
APR 18 2013
CDR

CITY: (b) (6) STATE: (b) (6)

COUNTRY: USA ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: GAVE 2 TABLETS X 1 DOSE ON 4/1/13 AT 9 AM AND 11 PM. CHILD STARTED HAVING DIFFICULTY BREATHING, IRRITATION, SLEEPINESS. PRIOR TO THAT HAD GIVEN A COUPLE OF DOSES AND CHILD WAS SLEEPY. WENT TO THE HOSPITAL (b) (6) CHILD WAS ADMITTED AND CAME HOME IN THE EVENING ON (b) (6) MONITORED HIS BREATHING IN THE HOSPITAL. DOCTORS SAID HE WAS HAVING DIFFICULTY BREATHING BECAUSE OF BELLADONNA IN TEETHING TABLETS. BLOODWORK AND X-RAYS NORMAL. CHILD STILL HAVING SOME PROBLEMS BREATHING AND SLEEPING A LOT. CHILD HAS A FOLLOW-UP VISIT ON FRIDAY. I TOLD THE CUSTOMER THAT IF SYMPTOMS ARE CONTINUING OR WORSENING, TO SEEK MEDICAL ATTENTION ASAP. I OFFERED A REFUND AND CUSTOMER DECLINED AND STATED THAT HE DID NOT WANT A REFUND. NO KNOWN ALLERGIES. 1 MONTH PREMATURE WITH SOME LUNG PROBLEMS. BOTTLEFED.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: **INVESTIGATION**

4-15-13

INVESTIGATION: NO LOT NUMBER. PROCEDURES ARE IN PLACE TO ENSURE SAFE PRODUCTS FOR CUSTOMERS. EVERY LOT OF BABY TEETHING TABLETS IS TESTED FOR BELLADONNA ALKALOIDS AND MICRO BEFORE RELEASING TO ENSURE SAFETY.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **ON**: 04/03/13

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION **BY**: EDYTA FRACKIEWICZ

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: **ADVERSE EVENT REPORTS** AE #: 1337

ADVERSE EVENT SERIOUS: (Y) / N

ADVERSE EVENT REPORTED ON: 04/03/13 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 04-16-13

DSS
APR 19 2013

BY: QA / QC DIRECTOR DATE: 04-10-13

cc: QA / QC, Packaging, Production, Shipping / Receiving

APR 18 2013

Form # VD1

Individual Case Safety Report

CaseID: 9410150

9410150-01-00-05

VENT DATA FORM

AE #: 1337

COMPLAINT #: 2256

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

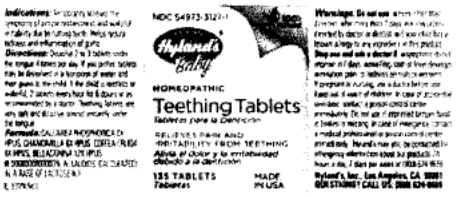
ZIP CODE:

PHONE: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE



AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: RWult DATE: 04-10-13

DSS APR 10 2013

BY: QA / QC DIRECTOR DATE: 04-10-13

DISTRIBUTION: FDA ADVERSE EVENT FILE

APR 18 2013

Individual Case Safety Report

CaseID: 9410155

9410155-01-00-02

FDA USE ONLY

of 4

☐ User Facility ☐ Importer

3. User Facility or Importer Name/Address

4. Contact Person | **5. Phone Number**

6. Date User Facility or Importer Became Aware of Event *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up # ____

8. Date of This Report *(mm/dd/yyyy)*

9. Approximate Age of Device

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ☐ - ☐ - ☐
Device Code ☐ - ☐ - ☐

11. Report Sent to FDA?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Home
☐ Outpatient Treatment Facility
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility
☐ Other: ____ *(Specify)*

13. Report Sent to Manufacturer?
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. Contact Office - Name/Address ***(and Manufacturing Site for Devices)***

HYLAND'S, INC.
210 W. 131ST STREET
LOS ANGELES, CA 90061

2. Phone Number
310-768-0700

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☒ Consumer
☐ Health Professional
☐ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. Date Received by Manufacturer *(mm/dd/yyyy)*
10/28/2010

5.
(A)NDA # ____
IND # ____
STN # ____
PMA/510(k) # ____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☒ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☐ 5-day ☐ 30-day
☐ 7-day ☐ Periodic
☐ 10-day ☒ Initial
☒ 15-day ☐ Follow-up # ____

9. Manufacturer Report Number
54973 RSAE102810EF-003

8. Adverse Event Term(s)
DIFFICULTY BREATHING & RASH

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other:

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code:

4. Device Manufacture Date *(mm/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Codes *(Refer to coding manual)*
Method ☐ - ☐ - ☐ - ☐
Results ☐ - ☐ - ☐ - ☐
Conclusions ☐ - ☐ - ☐ - ☐

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment
☐ Other:

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and / or **11.** ☐ **Corrected Data**

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APR 19 2013 APR 22 2013

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Department of Health and Human Services
Food and Drug Administration - MedWatch
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

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Individual Case Safety Report

CaseID: 9410155

INT RECORD

9410155-01-00-03

COMPLAINT #: RVD102810EF-003

DATE OF COMPLAINT: 10/28/10

PRODUCT: TEETHING TABLETS

ITEM CODE: TEET

SIZE: 125 TABLETS (PK OF 4 THROUGH AMAZON)

LOT NO.: THREW AWAY THE BOTTLE

REPORTER: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

NATURE OF COMPLAINT: TOOK ¼ OF THE BOTTLE ON 9/25 AND THEN ON (b) (6) WENT TO ER WITH DIFFICULTY BREATHING. RASH ON HIPS THAT STARTED AROUND THE SAME NIGHT AND IS STILL CONTINUING.

FOR ADDITIONAL SPACE PLEASE USE REVERSE OR ATTACH A SEPARATE SHEET

PRODUCT RECEIVED FOR INSPECTION: Y (N) (CIRCLE ONE)

PRODUCT BEING RETURNED FOR INSPECTION: Y (N) (CIRCLE ONE)

DATE REQUESTED PRODUCT BE RETURNED:

UPS CALL TAG ISSUED: Y (N) (CIRCLE ONE)

DATE PRODUCT RECEIVED:

SECTION II: INVESTIGATION

INVESTIGATION: THIS COMPLAINT WAS TAKEN DURING THE TEET RECALL AS A SERVICE RELATED CONCERN AND FORWARDED DIRECTLY TO THE PHARMACIST AND MEDICAL DIRECTOR FOR TIMELY AE DATA CAPTURE AND EVALUATION.

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION ON: 10/28/10

ADVERSE EVENT FORWARDED TO PHARMACIST / NURSE FOR EVALUATION BY: EDYTA FRACKIEWICZ

SECTION III: CORRECTIVE ACTION:

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV: ADVERSE EVENT REPORTS

AE #: RAE102810EF-003

ADVERSE EVENT SERIOUS: Y / (N)

ADVERSE EVENT REPORTED ON: 10/28/10 BY: EDYTA FRACKIEWICZ

SECTION V:

REVIEWED BY MANAGEMENT BY: DATE: 11/23/10

DSS APR 22 2013

BY: N/A
QA / QC DIRECTOR

DATE:

cc: QA / QC Production
Packaging Shipping / Receiving

Form # VD1

APR 19 2013

Individual Case Safety Report

9410155-01-00-04

CaseID: 9410155

Hyland's

ENT DATA FORM

AE #: RAE102810EF-003

COMPLAINT #: RVD102810EF-003

SECTION I: **PATIENT INFORMATION *(IF DIFFERENT FROM REPORTER ON FORM VD1)***

NAME: (b) (6)

ADDRESS:

CITY: (b) (6)

STATE: (b) (6)

COUNTRY: USA

ZIP CODE:

PHONE #: (b) (6)

E-MAIL:

SECTION II: **PACKAGING INFORMATION:**

AFFIX PACKAGING LABEL HERE

AFFIX COPY OF OUTER CARTON HERE
(INCLUDE DRUG FACTS AND PRINCIPAL DISPLAY PANELS)

SECTION III: **CORRECTIVE ACTION:**

CORRECTIVE ACTION(S) COMPLETED BY: DATE:

SECTION IV:

REVIEWED BY MANAGEMENT BY: DATE: 10/23/10

DSS

APR 22 2013

BY: DATE:

QA / QC DIRECTOR

DISTRIBUTION: FDA ADVERSE EVENT FILE

FORM SAE01

APR 19 2013

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 04-Nov-2016 08:03 AM
Total Number of Cases: 4
Total Number of Pages: 39
Print Job Number: 12978

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Reversible cerebral vasoconstriction syndrome in a patient taking citalopram and Hydroxycut: a case report

Journal of Medical Case Reports 2011, **5**:548 doi:10.1186/1752-1947-5-548

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ISSN 1752-1947

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Article URL http://www.jmedicalcasereports.com/content/5/1/548

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