Next Page

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

PLEASE TYPE OR USE BLACK INK

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. **Patient Identifier**
JR
In Confidence

2. **Age** 6 ☐ Year(s) ☐ Month(s) ☒ Week(s) ☐ Days(s)
or Date of Birth *(e.g., 08 Feb 1925)*

3. **Sex** ☒ Female ☐ Male

4. **Weight** ☐ lb ☐ kg

5.a. **Ethnicity** *(Check single best answer)*
☐ Hispanic/Latino
☒ Not Hispanic/Latino

5.b. **Race** *(Check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native
☒ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

2. **Outcome Attributed to Adverse Event** *(Check all that apply)*
☐ Death *Include date (dd-mmm-yyyy):*
☒ Life-threatening ☐ Disability or Permanent Damage
☒ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(dd-mmm-yyyy)*

4. **Date of this Report** *(dd-mmm-yyyy)*

5. **Describe Event, Problem or Product Use Error**
6 week old newborn born after an uneventful pregnancy and delivery. At age 4 days, she was readmitted for treatment for wheezing and hypoxia and diagnosed with retrocardiac pneumonia.

At two weeks of age she was diagnosed with gastroesophageal reflux disease (GERD) and started on XYZ Pharmaceutical's thickening agent on 4/13. The

(Continue on page 2)

6. **Relevant Tests/Laboratory Data, Including Dates**
Not Available

(Continue on page 2)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
born at full-term; uneventful pregnancy and delivery

(Continue on page 2)

C. PRODUCT AVAILABILITY

2. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☒ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

D. SUSPECT PRODUCTS

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

#1 – Name and Strength	#1 – NDC # or Unique ID
Thickening agent 4 oz packet	
#1 – Manufacturer/Compounder	**#1 – Lot #**
XYZ Pharmaceutical	
#2 – Name and Strength	**#2 – NDC # or Unique ID**
#2 – Manufacturer/Compounder	**#2 – Lot #**

3.

	Dose or Amount	Frequency	Route
#1	4 oz packet	At every feeding	Oral
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1 13-Apr-YYYY - 04-May-YYYY
#2

5. **Diagnosis or Reason for Use** *(indication)*
#1
#2

6. **Is the Product Compounded?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

7. **Is the Product Over-the-Counter?**
#1 ☐ Yes ☐ No
#2 ☐ Yes ☐ No

8. **Expiration Date** *(dd-mmm-yyyy)*
#1 #2

9. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☒ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

10. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☒ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

2b. **Procode**

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

4. **Model #**

Lot #

Catalog #

Expiration Date *(dd-mmm-yyyy)*

Serial #

Unique Identifier (UDI) #

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

6. **If Implanted, Give Date** *(dd-mmm-yyyy)*

7. **If Explanted, Give Date** *(dd-mmm-yyyy)*

8. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

9. **If Yes to Item 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

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

(Continue on page 2)

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

1. **Name and Address**

Last Name: D
First Name: John
Address: ZZZ Clinic
City: New York
State/Province/Region:
Country:
ZIP/Postal Code: 11111
Phone #: 100-555-1212
Email:

2. **Health Professional?** ☒ Yes ☐ No

3. **Occupation** Physician Assistant

4. **Also Reported to:**
☒ Manufacturer/ Compounder
☐ User Facility
☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, please mark this box:** ☐

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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(CONTINUATION PAGE)

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program
FORM FDA 3500 (10/15) *(continued)*

For VOLUNTARY reporting of adverse events and product problems

B.5. **Describe Event or Problem** *(continued)*

On 5/9/2011, Patient was seen in the ER with bloody diarrhea and admitted after evaluation reveals signs of necrotizing enterocolitis.

Patient underwent a small bowel resection and the GI symptoms resolved completely over the next 10-14 days. She remains in good health after hospital discharge.

Back to Form

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

Back to Form

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

Back to Form

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

Back to Form