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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

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**
TL
In Confidence

2. **Age** 8 ☒ 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)*
Spring

4. **Date of this Report** *(dd-mmm-yyyy)*
12-Dec-2016

5. **Describe Event, Problem or Product Use Error**
The child was diagnosed with autism spectrum disorder in April and begun on XYZ Pharmaceutical's ADHD med 1 mg TID, with good control of his behavioral symptoms. The med was continued thru the summer and in Sept , a prescription for the same medication was called in to the pharmacy and delivered to mother by mail. Because of a pharmacy dispensing error, patient's mom was mailed an incorrect medication, a dopamine agonist

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

(Continue on page 2)

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

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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 Dopamine agonist 1mg	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder First Pharmaceutical	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

3.

	Dose or Amount	Frequency	Route
#1	1MG	TID	Oral
#2			

4. **Dates of Use** *(From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)*
#1
#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)*
none

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

1. **Name and Address**

Last Name: First Name: JJ
Address: ABC Elementary School health clinic
City: Boston State/Province/Region: MA
Country: ZIP/Postal Code: 11111
Phone #: 100-555-1212 Email:

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

3. **Occupation** Nurse Practitioner

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:** ☐

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.

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FORM FDA 3500 (10/15) *(continued)*

For VOLUNTARY reporting of adverse events and product problems

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

Patient took this medication for 3 months until child's mother went to refill prescription in December 2011 and reported to the pharmacist she that the medication looked different. The pharmacist apologized for the mistake and explained that the two medications with similar sounding names both beginning with the letter "R" are stored side-by-side on the same shelf in the pharmacy and also have the same dosing, 1 mg TID.

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

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

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