DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 6/30/2015
(See PRA Statement below)

MedWatch Consumer Voluntary Reporting (FORM FDA 3500B)

When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product, or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

Don't use this form to report:

- Vaccines – report problems to the Vaccine Adverse Event Reporting System (VAERS)
- Investigational drugs or medical devices (those being studied, not yet approved) – report problems to your doctor or to the contact person listed in the clinical trial

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern, so you should know:

- We ask only for the name and contact information of the person filling out the form in case we need more information. This information will not be given out to the public.
- Information about the problem may be shared with the company that makes the product to help them better understand the problem you are reporting, unless you request otherwise (see Section E).

What types of products should I use this form for?

- Drugs, including prescription or over-the-counter medicines, and biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- Medical devices, including any health-related kit, test, tool, or piece of equipment (such as breast implants, pacemakers, diabetes glucose-test kits, hearing aids, breast pumps, and many others)
- Nutrition products, including vitamins and minerals, herbal remedies, infant formulas, and medical foods, such as those labeled for people with a specific disease or condition
- Cosmetics or make-up products
- Foods (including beverages and ingredients added to foods)

Are there specific instructions for filling out the form?

- Fill in as much information as possible and send in the report even if you do not have all the information.
- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want to talk with your health professional.
- Feel free to include or attach an image. Please do not send the products to the FDA.

How will I know the FDA has received my form?

- You will receive a reply from the FDA after we receive your report. We will personally contact you only if we need additional information.
- Your report will become part of a database so that it can be reviewed and compared to other reports by an FDA safety evaluator who will determine what steps to take.

How can I contact the FDA if I have questions?

Toll-free line: 1-800-332-1088
www.fda.gov/reportinghelp
To report online: www.fda.gov/medwatch/report.htm

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 25 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the address to the right:

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 number."

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

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

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Section A – About the Problem

What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect *(including new or worsening symptoms)*
- ☒ Used a product incorrectly which could have or led to a problem
- ☐ Noticed a problem with the quality of the product
- ☐ Had problems after switching from one product maker to another maker

Date the problem occurred *(mm/dd/yyyy)*

09/2011

Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm *(for medical devices only)*
- ☐ Disability or health problem
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death *(Include date)*: _____
- ☒ Other serious/important medical incident *(Please describe below)*

The pharmacist made a mistake and dispensed the wrong medication for my child

Tell us what happened and how it happened. *(Include as many details as possible)*

My child, Timmy, has autism spectrum disorder and he is monitored by the school nurse practitioner, Karen, when he is in school. Last year, his episodes of agitation caused more disruptions in his classroom. Timmy's doctor was consulted and recommended a trial of XYZ Pharmaceuticals' ADHD medication, 1 mg tablet three times a day.

Continuation Page

List any relevant tests or laboratory data if you know them. *(Include dates)*

None

Continuation Page

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)

For more information, visit *http://www.fda.gov/MedWatch*

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

Section B – About the Products

Name of the product as it appears on the box, bottle, or package *(Include as many names as you see)*
ADHD medication

Name of the company that makes the product
XYZ Pharmaceutical

Expiration date *(mm/dd/yyyy)*	Lot number	NDC number

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, by injection, or on the skin)*?
1mg	1 tablet	Three times daily	By mouth

Date the person first started taking or using the product *(mm/dd/yyyy)*: 04/01/ 2011

Date the person stopped taking or using the product *(mm/dd/yyyy)*: _____

Why was the person using the product *(such as, what condition was it supposed to treat?)*
Autism spectrum disorder

Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☐ No

Did the problem return if the person started taking or using the product again?
☐ Yes ☐ No ☒ Didn't restart

Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)*
☐ Yes ☒ No

Go to Section D (Skip Section C)

Section C – About the Medical Device

Name of medical device

Name of the company that makes the medical device

Other identifying information *(The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)*

Was someone operating the medical device when the problem occurred?
☐ Yes
☐ No

If yes, who was using it?
☐ The person who had the problem
☐ A health professional *(such as a doctor, nurse, or aide)*
☐ Someone else *(Please explain who)*

For implanted medical devices ONLY *(such as pacemakers, breast implants, etc.)*

Date the implant was put in *(mm/dd/yyyy)*	Date the implant was taken out *(If relevant) (mm/dd/yyyy)*

Go to Section D

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age *(at time the problem occurred)* or Birth Date	Weight *(Specify lbs or kg)*	Race
TL	☐ Female ☒ Male	8 y.o.		

List known medical conditions *(such as diabetes, high blood pressure, cancer, heart disease, or others)*

Autism spectrum disorder

Please list all allergies *(such as to drugs, foods, pollen, or others)*.

List any other important information about the person *(such as smoking, pregnancy, alcohol use, etc.)*

List all current prescription medications and medical devices being used.

XYZ Pharmaceutical's ADHD medication

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List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Continuation Page

Go to Section E

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information. Your name will not be given out to the public.

Last name	First name
L	Jane

Number/Street	City and State/Province
111 Street	Columbia, MD

Country	ZIP or Postal code
USA	11111

Telephone number	Email address	Today's date *(mm/dd/yyyy)*
100-555-1212	Jane@xxxxx.net	12/12/2011

Did you report this problem to the company that makes the product (the manufacturer)?

☐ Yes ☒ No

May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product? ☐ Yes ☒ No

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA.
Mail or fax the form to:

Mail:	**Fax:**
MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	1-800-332-0178 (toll-free)

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*

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

Continued Entries

CONTINUED ENTRY FOR: Tell us what happened and how it happened. *(Include as many details as possible)*

Timmy's behavior improved. He experienced no major side effects from the medication that I observed.

Shortly after the new school year started in September, I called in a renewal of Timmy's prescription to E-Z Drug Store and I received it by mail. However, in December when I returned to E-Z Drug Store to get a new refill, I noticed the tablets looked different from the pill that Timmy had been taking since September. When I asked the pharmacist about this, I found out that the pharmacy had incorrectly filled the prescription in September, dispensing First Pharmaceutical's dopamine agonist medication, which has the same directions as XYZ Pharmaceutical's prescribed ADHD medication, both medications taken as a 1mg tablet, three times daily. The pharmacist apologized and explained that the two medications are stored side-by side on the same shelf in the pharmacy since they have similar sounding names and both begin with the letter, "R".

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CONTINUED ENTRY FOR: List any relevant tests or laboratory data if you know them. *(Include dates)*

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CONTINUED ENTRY FOR: List all current prescription medications and medical devices being used.

Back to Form

CONTINUED ENTRY FOR: List all over-the-counter medications and any vitamins, minerals, and herbal remedies being used.

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