MEDWATCH CONSUMER REPORTING FORM 3500

Report a Problem Caused by a Medical Product

When do I use this form?

- You had a sudden or unsafe effect (including new or worsening symptoms) after taking a drug or using a device or product.
- Due to a confusing label or instructions, you used a drug, product, or device incorrectly, which could have or did cause harm.
- There is a problem with the quality of the drug, product or 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 (drugs being studied, not yet approved) – report problems to your doctor or to the contact person listed in the clinical trial
- Food – report problems to your local county department of health

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 so that we may contact them if we need more information. This information may be shared with the company that makes the product to help them evaluate 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 medications
- 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)
- Dietary supplements including vitamins and minerals, herbal remedies, infant formulas, medical foods, such as those labeled for people with a specific disease or condition
- Tobacco Products, including those to help you quit
- Cosmetics or Make-up Products

Are there specific instructions for filling out the form?

- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want talk with your health professional.
- Please do not send medical records, drugs, or other 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.

Who can I call if I have questions?

Call the FDA's MedWatch toll-free line: 800-332-1088.

FORM FDA 3500 **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

MEDWATCH CONSUMER REPORTING FORM 3500

Report a Problem Caused by a Medical Product

Section A – About the Problem

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

- ❑ Had a sudden or unsafe side effect (including new or worsening symptoms)
- ❑ Used a drug, product, or device incorrectly due to a confusing label or instructions
- ❑ Noticed a problem with the quality of the drug, product or device
- ❑ Had problems after switching from one drug or product maker to another maker

How bad was the problem? ***(Check all that apply)***

- ❑ Admitted to the hospital
- ❑ Required help to prevent permanent harm
- ❑ Caused long term serious disability or health problem
- ❑ Caused birth defect
- ❑ Life-threatening
- ❑ Caused death (mm/dd/yyyy):
- ❑ Other serious/important medical incident (please list):

_____

_____

Date the problem occurred (mm/dd/yyyy): _____

Tell us what happened (Include as many details as possible, such as how the person felt or what they noticed after taking or using the product, any signs and symptoms, and what happened as a result of the problem. (Please do not send medical records or the product to the FDA.):

_____

_____

_____

_____

_____

For problems caused by a product, including

- prescription or over-the-counter medicine
- dietary supplements, such as vitamins
- and minerals, herbal remedies, infant formulas, and medical foods
- tobacco products, including those to help you quit
- cosmetics or make-up products

Go to Section B

For problems caused by a device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits
- 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)

Section B – About the Product

Name of the product as it appears on the box, bottle, or package (include as many names as you see):

_____

Name of the company that makes the product (if you know it):

_____

What does the product look like (if it is a pill or capsule, list the color and any numbers or letters imprinted on it)?:

_____

Expiration Date (mm/dd/yyyy): _____

Strength (250 mg, 1g, etc)	**Quantity** (2 pills, 2 puffs, etc)	**Frequency** (twice daily, at bedtime, etc)	**How was it taken or used** (by mouth, injection, etc)
_____	_____	_____	_____

Date the person first started taking or using the product (mm/dd/yyyy): _____

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

Why was the person using the product (such as why it was prescribed)?

_____

_____

Did the problem stop after the person stopped taking or using the product? ❑ Yes ❑ No

If the person started taking or using the product again, did the problem return? ❑ Yes ❑ No ❑ Didn't restart

Go to Section D (skip section C)

Section C – About the Device

Name of the device: _____

Name of the company that makes the device (if you know it): _____

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

_____

Was someone operating the device: ❑ 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 devices ONLY (such as pacemakers, breast implants, etc.):

Date implant was put in: _____

Date implant was taken out (if relevant): _____

Go to Section D

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age		Birth Date (mm/dd/yyyy)	Weight lbs or kg
_____	❑ Female ❑ Male	_____	*or*	_____	_____

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

_____

List allergies (such as drugs, foods, pollen or others):

_____

List any other important information (such as smoking, pregnancy, alcohol use, etc):

_____

List all current prescription and over-the-counter medications, and any vitamins, minerals, and herbal remedies:

_____

Go to Section E

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information.

Last name: _____ First name: _____

Number/Street: _____ City/State: _____ Zip Code: _____

Telephone: _____ Email: _____

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

Did you report this problem to any of the following:

❑ Your doctor's office or pharmacy ❑ Company that makes the product

❑ Other, please list: _____

Date of this report (mm/dd/yyyy): _____

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 with the form. Mail or fax the form to:

Mail:
MedWatch
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852

Fax:
800-332-0178 (toll-free)

For more information:
Visit us at http://www.fda.gov/MedWatch
Call us at 800-332-1088 (toll-free)

How did you learn about this form? _____

Thank you for helping us protect the public health.