DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. xxxx-xxxx
Expiration Date: xx/xx/201x
(See Burden Statement below)

MEDWATCH Consumer Reporting
MEDICAL PRODUCT PROBLEM REPORT
(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
- Food – report problems to your local 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 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, medical foods, such as those labeled for people with a specific disease or condition
- Tobacco and nicotine products, including those to help you quit
- Cosmetics or make-up products

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 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.

Who can I call if I have questions?

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

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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

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 list below)*

Designer note: Entry fields will be added after this visual layout proof is approved by FDA. At that time the form also will be made "508 compliant."

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

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

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

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
- tobacco and nicotine products, including those to help you quit
- cosmetics or make-up products

⇨ **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.

PSC Publishing Services (301) 443-6740 EF

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)*

Name of the company that makes the product

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

Strength *(For example, 250 mg per 500 ml or 1g)*	Quantity *(For example, 2 pills or 2 puffs, etc)*	Frequency *(For example, twice daily or at bedtime)*	How was it taken or used? *(For example, by mouth, injection, or on the skin)*

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 what condition was it supposed to treat)*

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
	☐ Female ☐ Male			

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

Is the person allergic to anything? *(Such as drugs, foods, pollen or others)*

Do you know any other important information about the person? *(Such as smoking, pregnancy, alcohol use, etc.)*

List all current prescription medications and medical devices being used.

List all 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. Your name will not be given out to the public.

Last name	First name	
Number/Street	City and State	ZIP code
Telephone number	Email address	Today's date *(mm/dd/yyyy)*

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:**	**For more information:**
MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20852	800-332-0178 (toll-free)	Visit us at *http://www.fda.gov/MedWatch* Call us at 800-332-1088 (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.