



## 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](http://www.fda.gov/reportinghelp)

To report online: [www.fda.gov/medwatch/report.htm](http://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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

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



# MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

## 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 describe below)*

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

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

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

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### **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)*

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 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)?*

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**

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

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**Section D – About the Person Who Had the Problem**

Person's Initials	Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	Age (at time the problem occurred) or Birth Date	Weight (Specify lbs or kg)	Race
List known medical conditions (such as diabetes, high blood pressure, cancer, heart disease, or others)				
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.				
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.				
 <b>Go to Section E</b>				

**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/Province	
Country		ZIP or Postal 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)? <input type="checkbox"/> Yes <input type="checkbox"/> No		May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product? <input type="checkbox"/> Yes <input type="checkbox"/> 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:

<b>Mail:</b> MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	<b>Fax:</b> 1-800-332-0178 (toll-free)
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**Thank you for helping us protect the public health.**

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

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**Continued Entries**

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

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

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

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