



MEDWATCH CONSUMER REPORTING FORM 3500

Report a Problem With a Medical Product

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 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. Your name will not be given out to the public. 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
- 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 submit the report even if you do not have all the information requested.
- 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.

Who can I call if I have questions?

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

The public reporting burden for this collection of information has been estimated to average 36 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

*Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850*

*Please DO NOT
RETURN this form
to this address.*

*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
control number."*

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration**



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Report a Problem With a Medical Product

Section A – About the Problem

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

- Had an injury or bad side effect (including new or worsening symptoms)
- Used a product incorrectly which could have or led to unsafe use
- 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):

Date the problem occurred: _____

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
- 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 problems 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)**

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 (if you know it):

Expiration Date: _____ Lot # : _____ NDC # : _____

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: _____

Date the person stopped taking or using the product _____

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 the medical device: _____

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

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: _____

Date the implant was taken out (if relevant): _____

Go to Section D

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 (lbs or kg) | Race |
| _____ | | _____ | _____ | _____ |

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

Was 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/State:

Zip Code:

Telephone:

Email:

Today's Date:

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:

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)

Thank you for helping us protect the public health.