The Small Print

How to report side effects, find drug information and engage with CDER

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Deputy Director, OCOMM Division of Drug Information

Division of Drug Information (DDI)

- DDI is CDERs focal point for public inquiries regarding human drug products
- The mission of DDI is to optimize CDER's educational and communication efforts to our global community
- We support the FDA mission to promote and protect public health

Reporting Side Effects

FDA MedWatch Program

Reports about problems with medical products come **IN** to MedWatch

Safety information about medical products goes **OUT** to health professionals, patients, and consumers

Why Report?

Pre-Marketing Clinical Trials are limited to:

- Size of the patient population studied
- Narrow population – often not providing sufficient data on special groups
- Narrow indications studied
- Short duration

Benefits of Post-Marketing Monitoring

The ability to study the following:

- Low frequency reactions (not identified in clinical trials)
- High risk groups
- Long-term effects
- Drug-drug / food interactions
- Increased severity and / or reporting frequency of known reactions

Who Should Report?

Anyone can report a serious problem.

Walla Walla, WA – Pharmacist
Sacramento, CA – Nurse
Houston, TX – Dentist
Tallahassee, FL – Consumer
Portland, ME – Physician Assistant

Make a Difference

One person can make a difference

What to Report

Any event that:

- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires / prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage
- Potential for harm / close calls (drugs or devices)


Medical Devices


Biologics


Combination Products

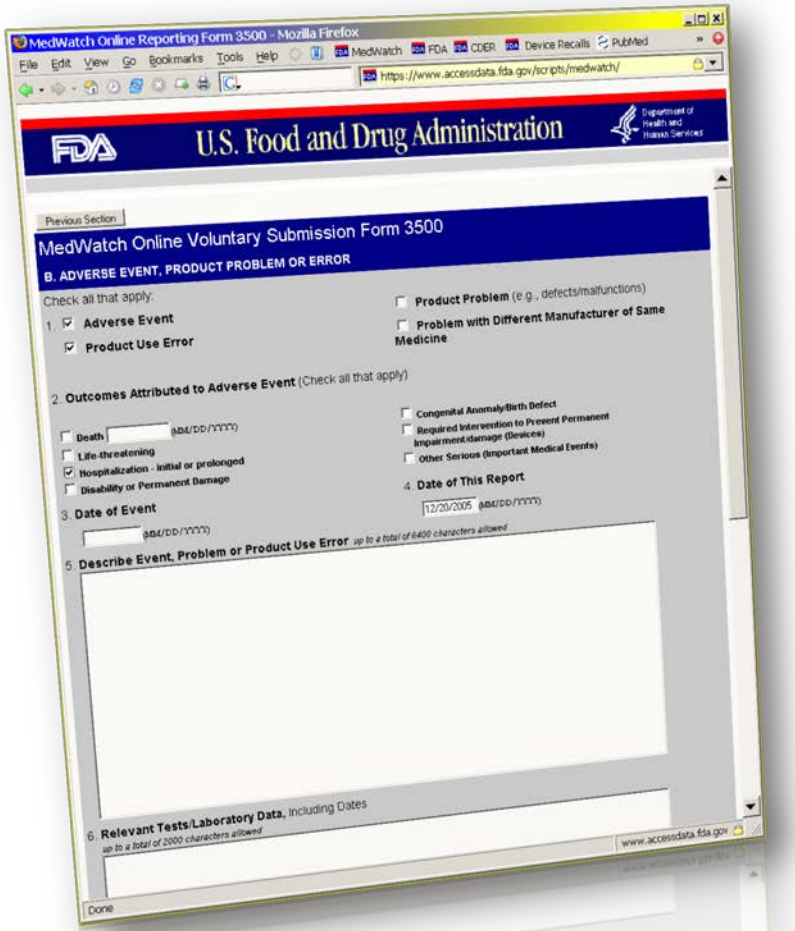

Special Nutritional Products


Drugs

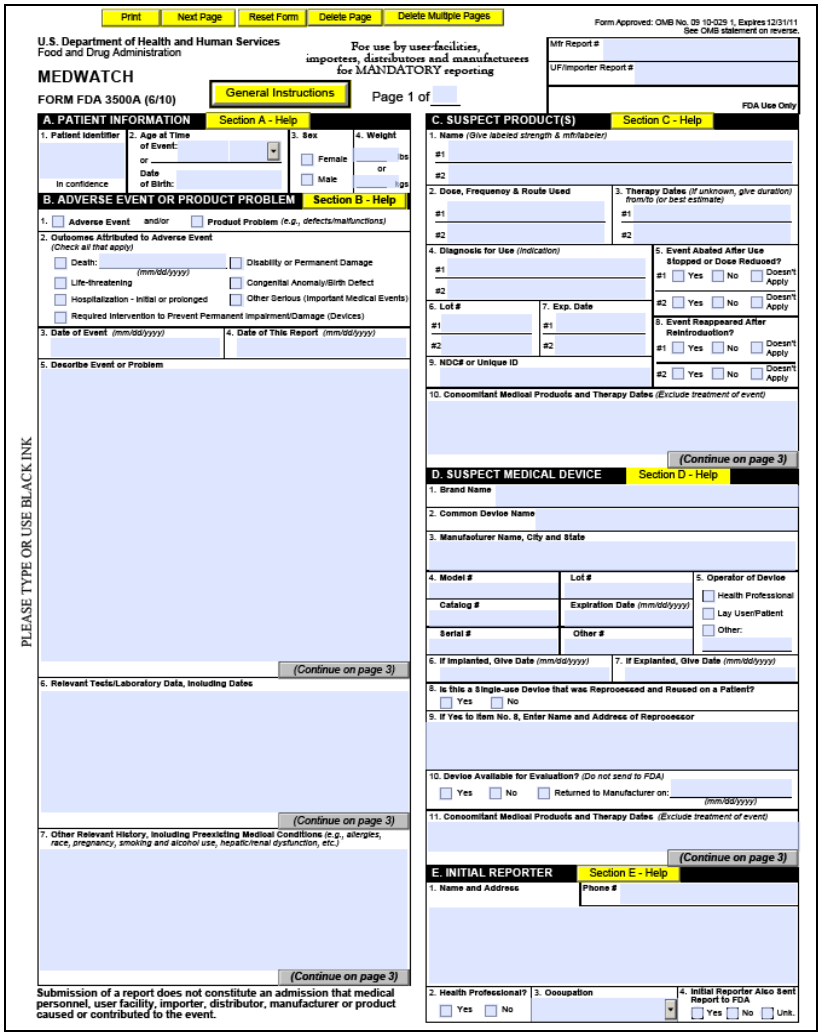
Food and Drug Administration
MEDWATCH

- How to Report:
  - Online (www.fda.gov/medwatch)
  - Download the form
    - Mail
    - Fax 1–800–332–0178
- For questions about the form:

  1–800–332–1088



MedWatch Form 3500A



Print | Next Page | Reset Form | Delete Page | Delete Multiple Pages

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11
See OMB statement on reverse.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (6/10)

For use by user facilities, importers, distributors and manufacturers for MANDATORY reporting

General Instructions

Page 1 of

Mfr Report #

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION — Section A - Help

1. Patient Identifier — In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex — Female / Male
4. Weight — lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM — Section B - Help

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
Death: (mm/dd/yyyy) — Disability or Permanent Damage
Life-threatening — Congenital Anomaly/Birth Defect
Hospitalization - initial or prolonged — Other Serious (Important Medical Events)
Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem
(Continue on page 3)
6. Relevant Tests/Laboratory Data, Including Dates
(Continue on page 3)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
(Continue on page 3)

C. SUSPECT PRODUCT(S) — Section C - Help

1. Name (Give labeled strength & mfr/labeler) #1 #2
2. Dose, Frequency & Route Used #1 #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate) #1 #2
4. Diagnosis for Use (Indication) #1 #2
5. Event Abated After Use Stopped or Dose Reduced? #1 #2 Yes No Doesn't Apply
6. Lot # #1 #2
7. Exp. Date #1 #2
8. Event Reappeared After Reintroduction? #1 #2 Yes No Doesn't Apply
9. NDC# or Unique ID
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
(Continue on page 3)

D. SUSPECT MEDICAL DEVICE — Section D - Help

1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # / Lot # / Catalog # / Expiration Date (mm/dd/yyyy) / Serial # / Other #
5. Operator of Device — Health Professional / Lay User/Patient / Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)
(Continue on page 3)

E. INITIAL REPORTER — Section E - Help

1. Name and Address
Phone #
2. Health Professional? Yes No
3. Occupation
4. Initial Reporter Also Sent Report to FDA Yes No Unk.

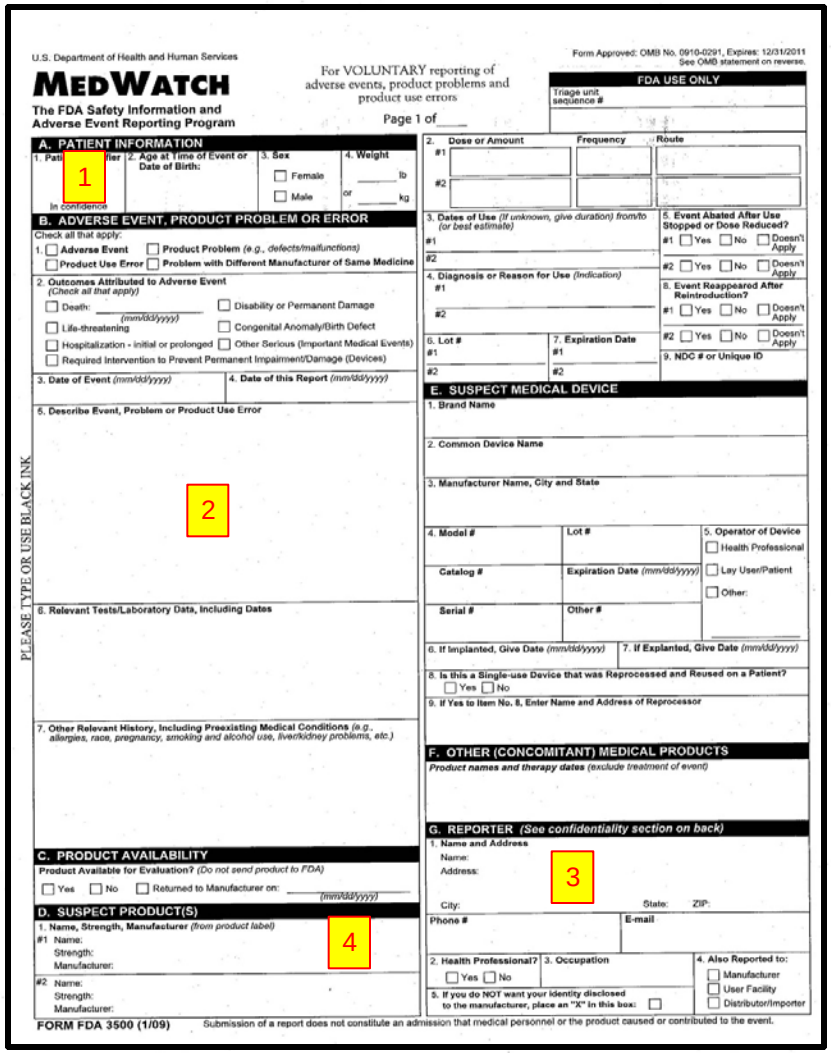
PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

MANDATORY Form 3500A

- User Facilities (medical devices)
- Manufacturers
  - Drugs
  - Biologics
  - Human Cell and Tissue Products
  - OTC Products
  - Medical Devices

MedWatch Form 3500



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of ____

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION
1. Patient Identifier (1) In confidence
2. Age at Time of Event or Date of Birth:
3. Sex ☐ Female ☐ Male
4. Weight ____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
Check all that apply:
1. ☐ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine
2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: ____ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy)
4. Date of this Report (mm/dd/yyyy)
5. Describe Event, Problem or Product Use Error (2)
6. Relevant Tests/Laboratory Data, Including Dates
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: ____ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label) (4)
#1 Name:
Strength:
Manufacturer:
#2 Name:
Strength:
Manufacturer:

2. Dose or Amount | Frequency | Route
#1
#2
3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1
#2
4. Diagnosis or Reason for Use (Indication)
#1
#2
5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot #
#1
#2
7. Expiration Date
#1
#2
8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # | Lot #
Catalog # | Expiration Date (mm/dd/yyyy)
Serial # | Other #
5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yyyy)
7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (exclude treatment of event)

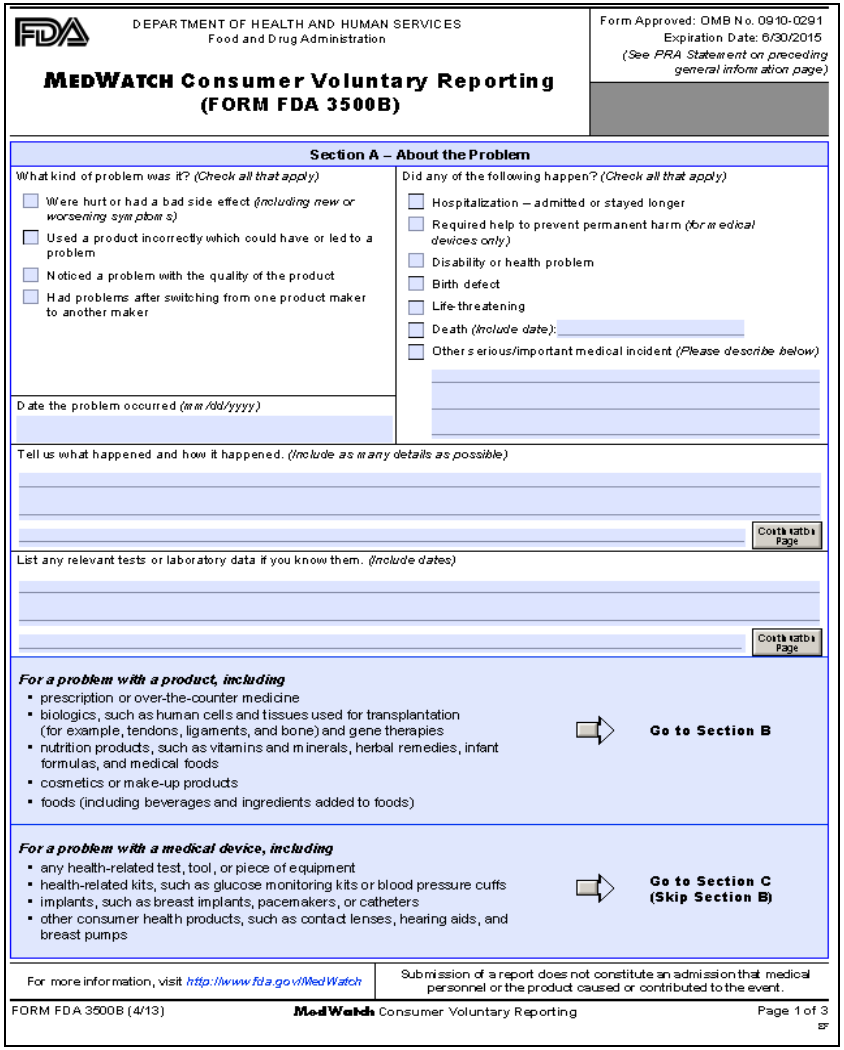
G. REPORTER (See confidentiality section on back)
1. Name and Address (3)
Name:
Address:
City: State: ZIP:
Phone # E-mail
2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

1. Patient Identifier
2. Event or Problem
3. Reporter
4. Product

MedWatch Form 3500B



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 6/30/2015
(See PRA Statement on preceding general information page.)

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)*

Continuation Page

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

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)

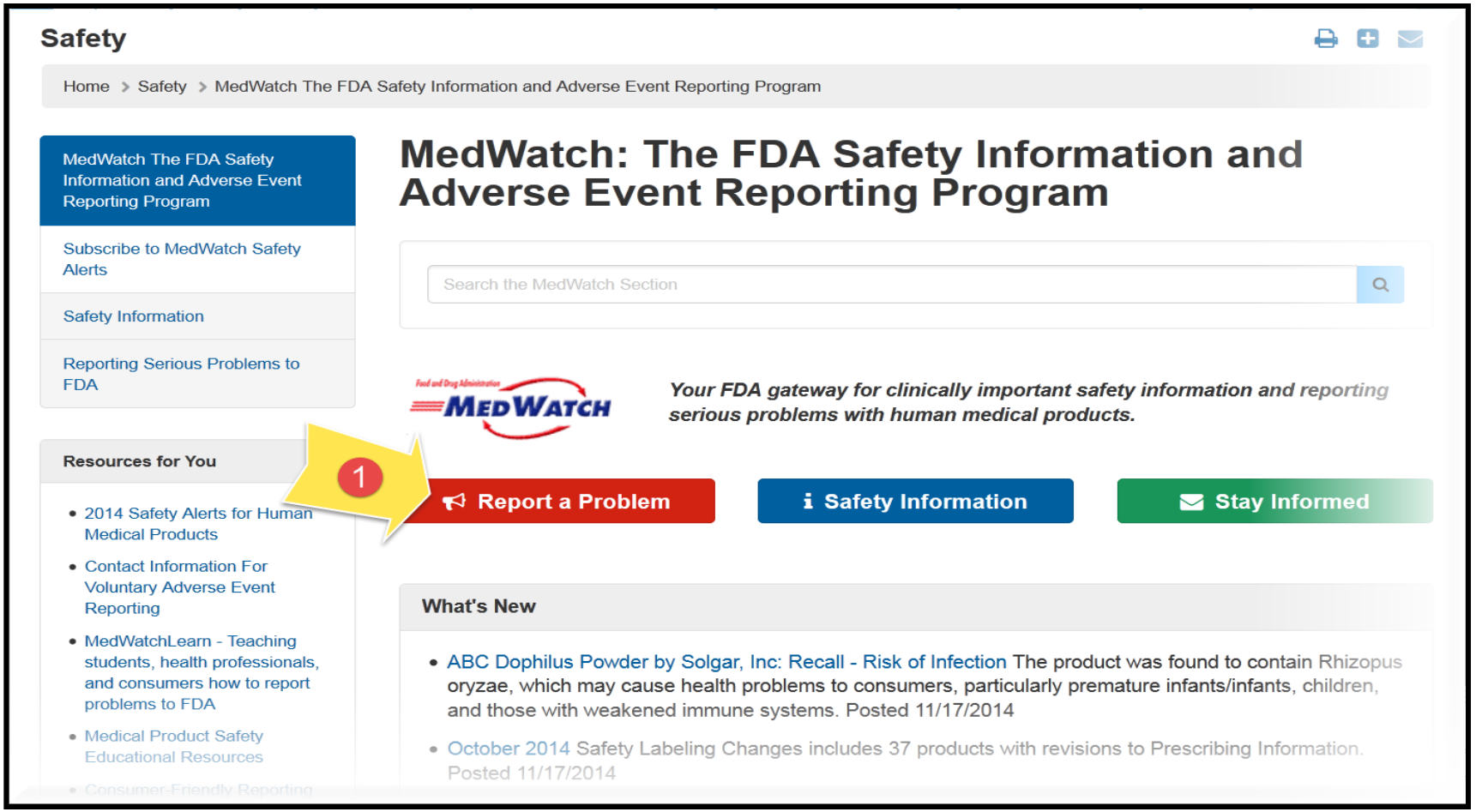
For more information, visit http://www.fda.gov/MedWatch

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

FORM FDA 3500B (4/13) **MedWatch** Consumer Voluntary Reporting Page 1 of 3

- Includes 4 primary components
  - Patient
  - Product
  - Event
  - Reporter
- User-friendly format for non-health care professionals

Reporting Online



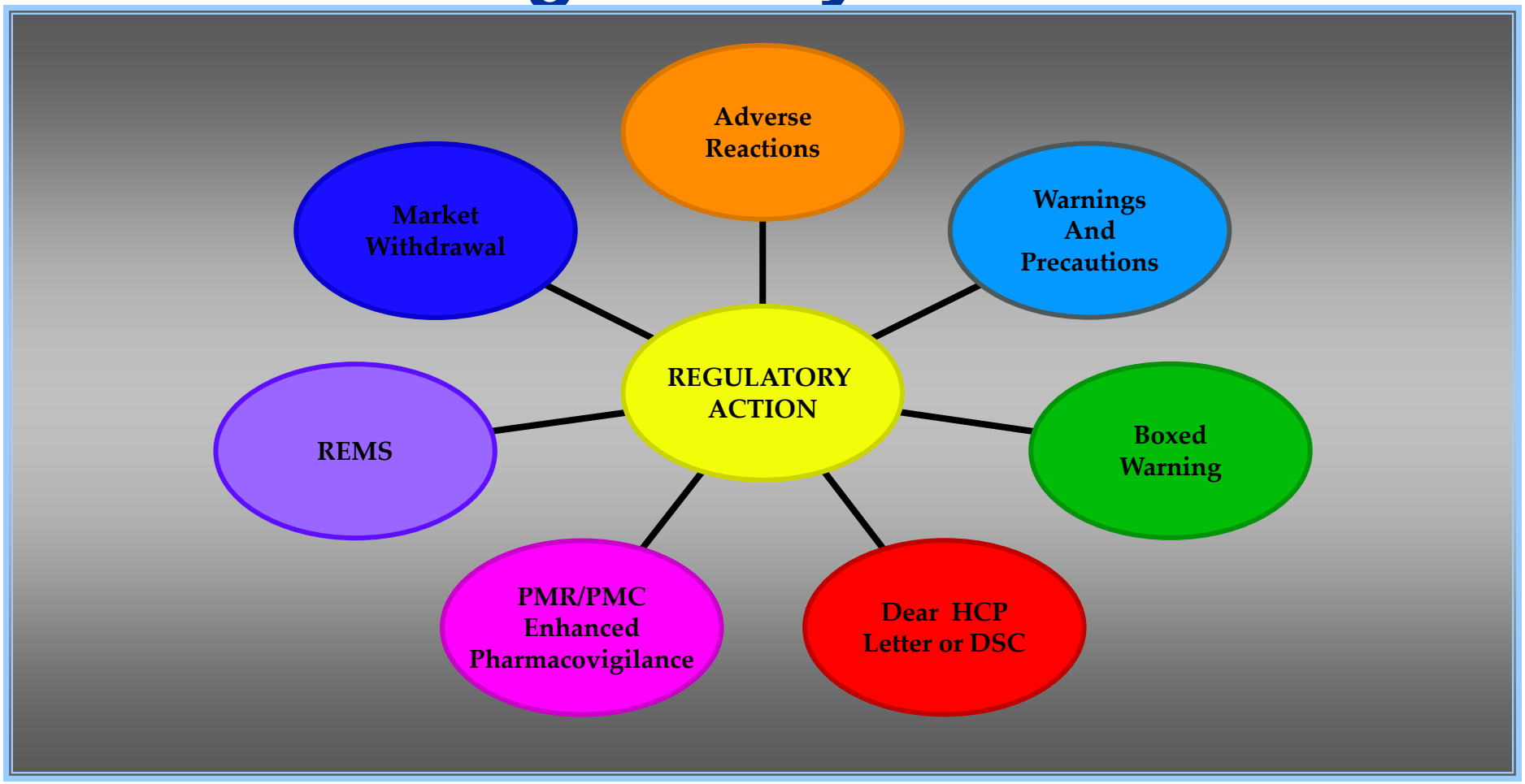
www.fda.gov/medwatch

www.fda.gov/medwatch/report

What Happens to Your MedWatch Report?

- Report is captured in a database.
- FDA safety evaluator reviews the report.
- FDA safety evaluator looks for similar reports.
- FDA review division may consult with manufacturer.
- FDA/manufacturer conducts further epidemiological studies or post-market clinical trials as needed.

How Can MedWatch Reports Result in Regulatory Action?



Find Drug Information

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Wallcur Practi-0.9‰ Sodium Chloride-IV Bags 50 mL, 250 mL, 500, mL, and 1000 mL Wallcur Practi-0.9‰ Sodium Chloride-IV Bag with Distilled Water 100 mL

Contact:
Consumer:
619-702-4333

FOR IMMEDIATE RELEASE — January 7, 2015 — San Diego, CA — This letter is to notify you of a product recall involving Wallcur's Practi-0.9‰ sodium chloride IV bags supplied in 50 mL, 250 mL, 500, mL, and 1000 mL sizes and the Practi-0.9‰ sodium chloride 100 mL IV solution bag with sterile distilled water.

As you know, all of Wallcur's products are intended for training, simulation, and educational purposes only. Recently some of Wallcur's training products were not used for their intended purpose. Specifically, despite the fact that the products are intended "for clinical simulation" only, we are aware of reports that these products have been used outside of their intended use and administered to patients. Because these products are not intended for human or animal administration, and are not sterile, administration of these products could result in adverse events.

We began shipping this product on May 22, 2014. Immediately examine your inventory, quarantine the products subject to recall, and return them to Wallcur. In addition, if you are a Wallcur distributor, or have further distributed or sold this product, please provide Wallcur with a list of your customers the products were distributed or sold to, and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter along with a copy of the enclosed product labels to make the products easily identifiable at the user level. Please also notify your customers that have purchased these products that the products are for demonstration, training, and educational purposes only, and not for human or animal use.

Your assistance is appreciated and necessary to prevent use of these products in humans or animals. Please complete and return the enclosed response form as soon as possible. If you have any questions call Carla Sanderson at 619-702-4333.

This recall is being carried out with the knowledge of the U.S. Food and Drug Administration.

In addition to the recall, as a precautionary measure, if you are a Wallcur distributor or reseller, we are requesting that you ensure your websites, catalogues, and other print materials advertising these products and any other Wallcur products prominently display the following language:

"THIS PRODUCT IS FOR TRAINING PURPOSES ONLY. NOT FOR HUMAN OR ANIMAL INJECTION."

Wallcur intends to add product enhancement labels containing similar language to the IV bags prior to future distribution.

Drug Safety and Availability
Drug Alerts and Statements
Medication Guides
Drug Safety Communications
Drug Shortages
Postmarket Drug Safety Information for Patients and Providers
Information by Drug Class
Medication Errors
Drug Safety Podcasts
Safe Use Initiative
Drug Recalls
Drug Supply Chain Integrity

FDA's investigation into patients being injected with simulated IV fluids continues

[Updated: 04/08/15] FDA's laboratory analysis of Wallcur's simulated Practi-0.9% sodium chloride IV is now complete. FDA sampled 11 of Wallcur's simulated saline solution bags and identified large amounts of endotoxin and significant bacterial contamination in the samples.

These include bacteria (e.g., *Bacillus spp., Brevundimonas sp., Pseudomonas spp., Rhizobium radiobacter, Sphingomonas koreensis, Sphingomonas trueperi, Sphingobium sp.*). It is possible that additional bacteria are present in other bags that were not included in this analysis.

Laboratory testing confirmed that samples of Wallcur's simulated Practi-0.9% sodium chloride IV solution products that FDA tested do **NOT** contain:

- yeast or mold;
- significant levels of lead, arsenic, cadmium, cobalt, chromium, nickel, selenium, thallium, or vanadium;
- drugs or poisons;
- dioctyl phthalate (plasticizer).

FDA is aware of more than 40 individuals who received infusions of the simulated Practi-0.9% sodium chloride IV products; 26 of whom reported adverse events that ranged from flu-like symptoms to sepsis, a potentially life-threatening complication of an infection. Of those 26 individuals, 2 deaths and 11 hospitalizations were reported.

FDA is reiterating its previous recommendations that ask health care professionals and consumers to do the following:

- Visually inspect all current IV solution bags. Ensure none of the bags are labeled "Wallcur," "Practi-0.9% sodium chloride," or "For clinical training purposes only";
- Consider reviewing clinic procedures and make sure there are procedures in place to visually inspect all future shipments of IV products to ensure they are appropriate for patient use;
- Seek medical attention if you were given a simulated Practi-0.9% sodium chloride product and you experience the symptoms described above;
- Report any suspected adverse events associated with accidental or intentional exposure to simulated products to FDA's MedWatch program online or at 1-800-332-1088.

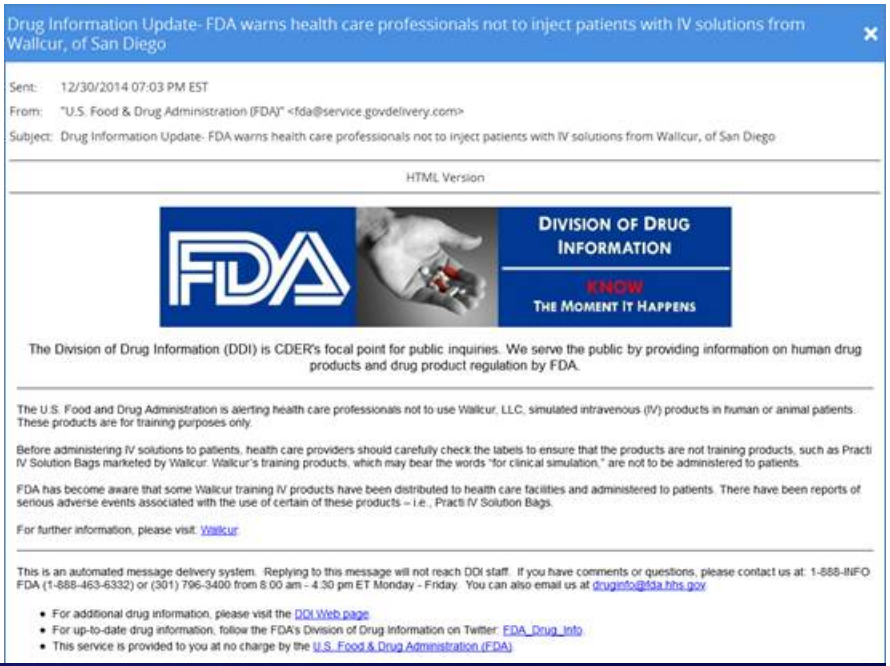

100 mL
NDC 5108-0954-75
PRACTI-0.9%
SODIUM CHLORIDE™
Contents: Sterile Distilled Water
1
2
3
4
WALLCUR®


TRAINING PRODUCT
100 mL
PRACTI-0.9%
SODIUM CHLORIDE™
simulates 0.9% sodium chloride
WARNING
NOT FOR HUMAN OR ANIMAL USE
Product harmful if injected or ingested
Product is non-sterile
FOR TRAINING PURPOSES ONLY
1
2
3
4
WALLCUR®

CDER Social Media

203,000 followers

Over 152,000 subscribers


Drug Information Update- FDA warns health care professionals not to inject patients with IV solutions from Wallcur, of San Diego

Sent: 12/30/2014 07:03 PM EST
From: "U.S. Food & Drug Administration (FDA)" <fda@service.govdelivery.com>
Subject: Drug Information Update- FDA warns health care professionals not to inject patients with IV solutions from Wallcur, of San Diego

HTML Version

DIVISION OF DRUG INFORMATION
KNOW THE MOMENT IT HAPPENS

The Division of Drug Information (DDI) is CDER's focal point for public inquiries. We serve the public by providing information on human drug products and drug product regulation by FDA.

The U.S. Food and Drug Administration is alerting health care professionals not to use Wallcur, LLC, simulated intravenous (IV) products in human or animal patients. These products are for training purposes only.

Before administering IV solutions to patients, health care providers should carefully check the labels to ensure that the products are not training products, such as Practi IV Solution Bags marketed by Wallcur. Wallcur's training products, which may bear the words "for clinical simulation," are not to be administered to patients.

FDA has become aware that some Wallcur training IV products have been distributed to health care facilities and administered to patients. There have been reports of serious adverse events associated with the use of certain of these products – i.e., Practi IV Solution Bags.

For further information, please visit: Wallcur

This is an automated message delivery system. Replying to this message will not reach DDI staff. If you have comments or questions, please contact us at: 1-888-INFO FDA (1-888-463-6332) or (301) 796-3400 from 8:00 am – 4:30 pm ET Monday – Friday. You can also email us at druginfo@fda.hhs.gov

- For additional drug information, please visit the DDI Web page
- For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter: FDA_Drug_Info
- This service is provided to you at no charge by the U.S. Food & Drug Administration (FDA)

DRUG SAFETY PODCASTS
Listen to Drug Safety Communications

Web Addresses:

- Drug Information Update Mailing List:
  - https://service.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_17
- MedWatch Mailing List:
  - https://service.govdelivery.com/accounts/USFDA/subscriber/new?topic_id=USFDA_46
- Twitter: Follow us:
  - @FDA_Drug_Info
- Drug Safety Podcasts:
  - http://www.fda.gov/DrugSafetyPodcasts
- Drug Safety Communications:
  - http://www.fda.gov/DrugSafetyCommunications

Engage with CDER

2015 Write-in Campaigns

- Duchenne Muscular Dystrophy – Drisapersen, Eteplirsen
- Amyotrophic Lateral Sclerosis – Genervon's GM604
- Clozapine REMS
- Country of Origin
- Vascepa
- Sayana Press
- Spinal Muscular Atrophy
- Move-On petition – Narcan

Talk to us

Division of Drug Information

Call: 855-543-3784

301-796-3400

Email: druginfo@fda.hhs.gov

Website: www.fda.gov/aboutDDI