# Collaborating with FDA- Get Involved with the FDA MedWatch Adverse Event Reporting Program

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FDA Office of Health and Constituent Affairs

February 7, 2017

# Learning Objectives

- Introduce the FDA Office of Health and Constituent Affairs (OHCA)
- Share examples of ways to advance FDA messages and be involved in FDA processes
- Describe the FDA MedWatch Program
- Identify the types of adverse events and product problems that should be reported to FDA
- Explain how to submit a report to the FDA MedWatch Program
- Summarize how to obtain safety information from FDA MedWatch

# FDA Regulates $1 Trillion Worth of Products a Year

Every morning when you wake up and

brush your teeth
put in your contact lenses
microwave your breakfast
take your medicine
feed your pet
select a lipstick
go grocery shopping
get a flu shot or a mammogram….

You have been touched by the
U. S. Food and Drug Administration.

# Assessment question- Which is *Not* Regulated by the FDA

A) Aspirin

B) Anti-lice shampoo

C) Insect repellent

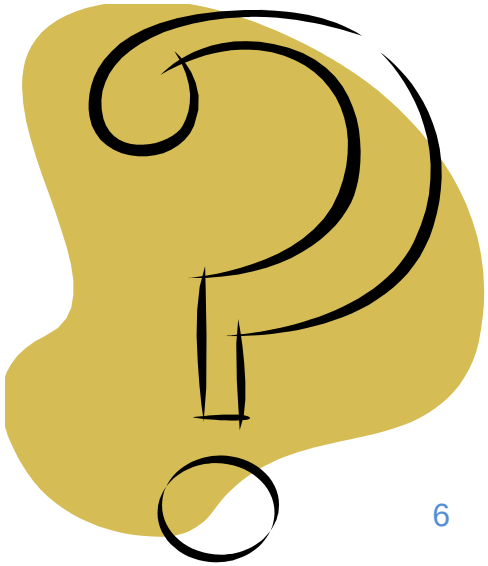
D) Lipstick

# Assessment question- Which is *Not* Regulated by the FDA

a. Spam
b. Puppy food
c. Chocolate covered cherries
d. Frozen spinach
e. Imported caviar

# Assessment question- Which is *Not* Regulated by the FDA

a. Illegal heroin use
b. Veterinary tetracycline
c. Barbiturates
d. Medical oxygen
e. Methadone

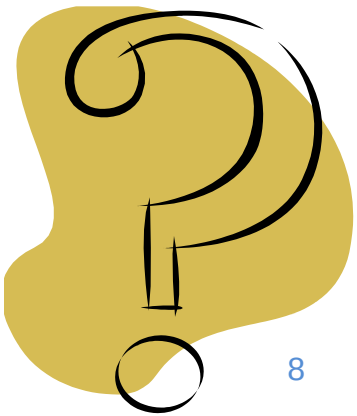


# Assessment question- Which is *Not* Regulated by the FDA

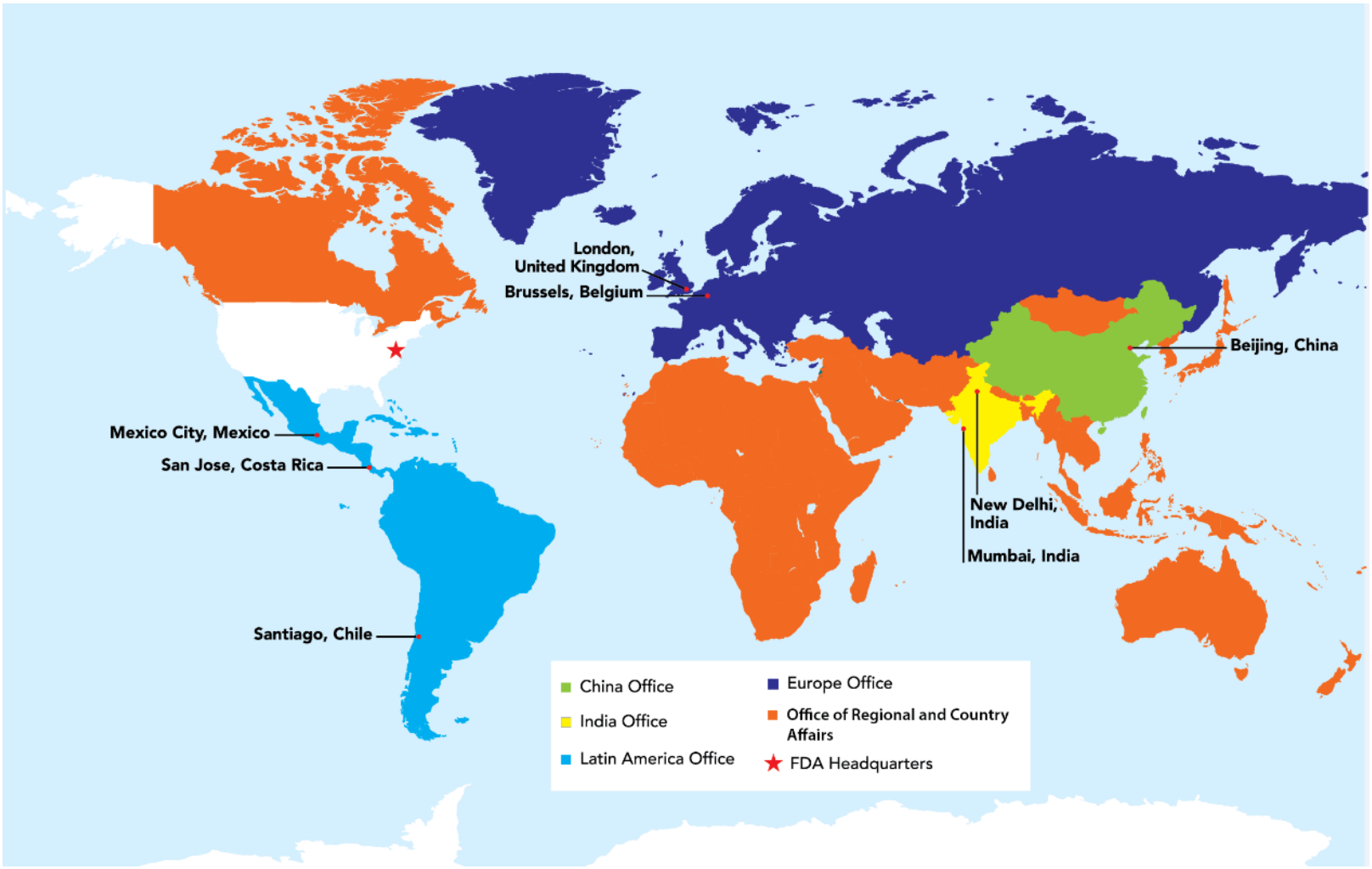
a. Kidney dialysis machine
b. Tongue depressor
c. Toothpaste
d. Fluoridated toothpaste
e. Hair dryer

# Assessment question- Which is *Not* Regulated by the FDA

a. Tamper-resistant packaging for over-the-counter (OTC) drugs
b. Child-proof packaging for OTC drugs
c. Plastic containers for soft drinks
d. Valentine heart box containing chocolates
e. Tube containing medical ointment




FDA In Your Neighborhood
FDA


London,
United Kingdom
Brussels, Belgium
Beijing, China
Mexico City, Mexico
San Jose, Costa Rica
New Delhi,
India
Mumbai, India
Santiago, Chile
China Office
India Office
Latin America Office
Europe Office
Office of Regional and Country Affairs
FDA Headquarters

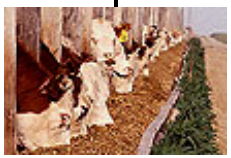
Office of the Commissioner

Office of Foods and Veterinary Medicine

Office of Medical Products & Tobacco

Office of Global Reg. Ops & Policy

**C**enter for **F**ood **S**afety & **A**pplied **N**utrition



**C**enter for **V**eterinary **M**edicine

**C**enter for **D**evices & **R**adiological **H**ealth

**C**enter for **B**iologics **E**valuation & **R**esearch

**C**enter for **D**rug **E**valuation & **R**esearch

**C**enter for **T**obacco **P**roducts

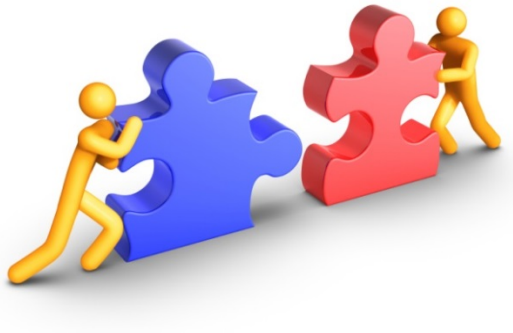
**O**ffice of **R**egulatory **A**ffairs

# Office of Health and Constituent Affairs

FDA's Office of Health and Constituent Affairs (OHCA) serves as the liaison between FDA and stakeholder organizations to educate constituents on FDA related issues and activities.

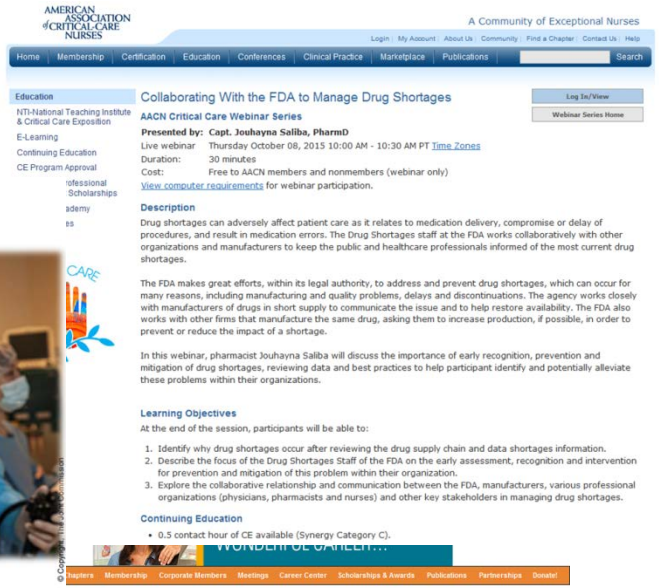
# Collaboration and Engagement Examples

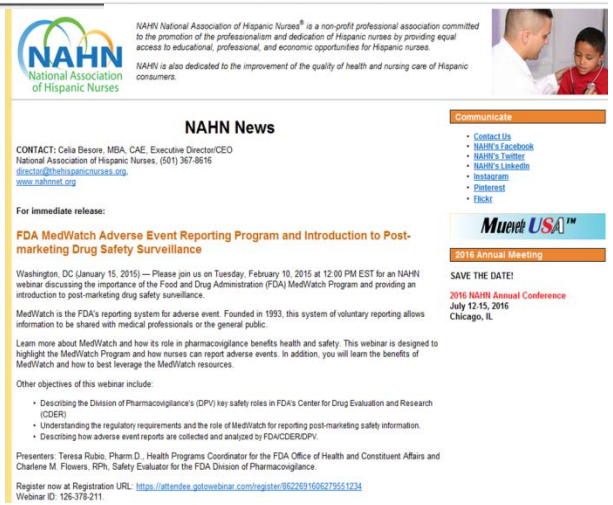
- Webinars
- Publishing
- Memorandum of Understanding
- MedWatch



# Advance our Reach *through* Webinars





# Advance our Reach *through* Publishing

drugsafety

## High doses of loperamide can cause serious cardiac events

BRENDA J. ROSE

FDA is warning that taking higher-than-recommended doses of the common OTC and prescription antidiarrheal medicine loperamide, including through abuse or misuse of the product, can cause serious cardiac events, including Torsades de pointes, cardiac arrest, ventricular tachycardia, syncope, and death. The risk of these serious cardiac events may also be increased when high doses of loperamide are taken with several kinds of medicines that interact with loperamide.

The majority of reported serious heart problems occurred in individuals who were intentionally misusing and abusing high doses of loperamide in attempts to self-treat opioid withdrawal symptoms or to achieve a feeling of euphoria.

### Background

Loperamide is approved to help control symptoms of diarrhea, including traveler's diarrhea. It is sold under the OTC brand name Imodium A-D, as store brands, and as generics.

It is important not to exceed the total daily dose that is recommended on the drug label. Loperamide is approved for use in single doses of 4 mg for the first dose, followed by 2 mg after each loose stool for adults. The maximum approved total daily dose is 8 mg per day for OTC use and 16 mg per day for prescription use. Dosing for children depends on the age of the child and is not recommended for use in children younger than 2 years.

Loperamide can interact with drugs that are cytochrome (CYP) 3A4 inhibitors (e.g., itraconazole, clarithromycin, omeprazole), CYP2C8 inhibitors (e.g., gemfibrozil), and *P*-glycoprotein inhibitors (e.g., quinidine).

### Safety data

In the 39 years between when loperamide was first approved in 1976 and 2015, FDA received reports of 48 cases of serious heart problems associated with use of loperamide. Thirty-one of these cases resulted in hospitalizations, and 10 patients died.

More than one-half of the 48 cases were reported after 2010.

In the majority of severe cases, individuals intentionally abused loperamide. Some patients also misused loperamide by taking higher-than-recommended doses to treat their diarrhea. In the most severe cases, individuals self-treated with doses ranging from 70 mg to 1,600 mg per day, which is 4 to 100 times the recommended dose. In several cases, individuals used concomitant drugs—CYP3A4 inhibitors, CYP2C8 inhibitors, and *P*-glycoprotein inhibitors—to increase gastrointestinal absorption, decrease loperamide metabolism, and increase blood–brain barrier penetration.

**In the majority of severe cases, individuals intentionally abused loperamide.**

In addition to reviewing the reports described above, FDA searched the medical literature and identified other cases of serious cardiac events with loperamide. Data from U.S. poison control call centers also indicate that since 2006, and particularly since 2010, calls have increased for intentional loperamide exposures, which include cases of intentional abuse, intentional misuse, suspected suicide attempt, and unknown intentional exposures.

### Counseling pearls

As the members of the health care team most often available at the point of purchase, pharmacists have an opportunity to help patients and caregivers select an appropriate OTC product. Pharmacists should provide the following information when counseling patients and caregivers seeking loperamide-containing products:

- Direct patients to take loperamide only at the dose directed by their primary care provider or according to the OTC Drug Facts label.
- Counsel patients about the cardiac risks of loperamide, and tell them not to use more than the recommended dose.
- Instruct patients to stop taking loperamide and contact their primary care provider if their diarrhea lasts more than 2 days, their symptoms get worse, or they have abdominal swelling or bulging.
- Warn patients that drug interactions with commonly used medications also increase the risk of serious cardiac adverse events.
- Refer patients with opioid use disorders for treatment. There are FDA-approved drugs to reduce opioid withdrawal symptoms.

Pharmacists are encouraged to report adverse events related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program, as follows:

- Complete and submit the report online at www.fda.gov/MedWatch/report.htm.
- Download the form or call 800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form, or submit by fax to 800-FDA-0178.

FDA will continue to evaluate this safety issue and will determine if additional FDA actions are needed.

**Brenda J. Rose, PharmD,** is a member of the Health Professional Liaison Program in FDA's Office of Health and Constituent Affairs. She acknowledges the help of subject matter experts in FDA's Center for Drug Evaluation and Research.



hospital pharmacy

NEWS

## Summaries of safety labeling changes approved by FDA—boxed warnings highlights, July–September 2016

As part of FDA's MedWatch program, changes to the boxed warnings in the labeling of drugs and therapeutic biologics are compiled quarterly. These and other labeling changes are searchable in the Drug Safety Labeling Changes (SLC) database,[1] where data are available to the public in downloadable and searchable formats. Boxed warnings are ordinarily used to highlight (1) an adverse reaction so serious in proportion to the potential benefit from the drug that it is essential that the reaction be considered in assessing the risks and benefits of using the drug, (2) serious adverse reactions that can be prevented or reduced in frequency or severity by appropriate use of the drug, and (3) situations in which FDA approved a drug with restrictions to ensure safe use because FDA concluded that the drug can be safely used only if distribution or use is restricted. The following changes to boxed warnings were identified in an October 10 search of the Drug Safety Labeling Changes (SLC) database over the date range July 1, 2016, through September 30, 2016.

**Class of Systemic Fluoroquinolone Antibacterial Drugs,** includes Avelox (moxifloxacin hydrochloride), Avelox in 0.8% sodium chloride solution for i.v. use (moxifloxacin hydrochloride), Cipro (ciprofloxacin; ciprofloxacin hydrochloride), Cipro IV in 5% dextrose injection (ciprofloxacin), Cipro XR (ciprofloxacin), Factive (gemifloxacin mesylate), Levaquin (levofloxacin), moxifloxacin hydrochloride, and Noroxin (norfloxacin); refer to www.accessdata.fda.gov/scripts/cder/safetylabelingchanges for specific new drug application

*Edited Boxed Warnings (class template)*

**Updated Quinolone Boxed Warning**

**WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS**

- Fluoroquinolones, including [Product], have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including:
  Tendinitis and tendon rupture
  Peripheral neuropathy
  Central nervous system effects
- Discontinue [Product] immediately and avoid the use of fluoroquinolones, including [Product], in patients who experience any of these serious adverse reactions. Fluoroquinolones, including [Product], may exacerbate muscle weakness in patients with myasthenia gravis. Avoid [Product] in patients with known history of myasthenia gravis.
- Because fluoroquinolones, including [Product], have been associated with serious adverse reactions, reserve [Product] for use in patients who have no alternative treatment options for the following indications:

*(for Avelox, Avelox in 0.8% sodium chloride solution for i.v. use, moxifloxacin hydrochloride, and Cipro IV)*
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis

*(for Cipro)*
- Acute exacerbation of chronic bronchitis
- Acute uncomplicated cystitis
- Acute sinusitis

*(for Cipro XR and Noroxin)*
- Uncomplicated urinary tract infections

*(for Factive)*
- Acute bacterial exacerbation of chronic bronchitis

*(for Levaquin)*
- Uncomplicated urinary tract infection
- Acute bacterial exacerbation of chronic bronchitis
- Acute bacterial sinusitis

**Krystexxa (pegloticase)**

*Added Section to Boxed Warning*

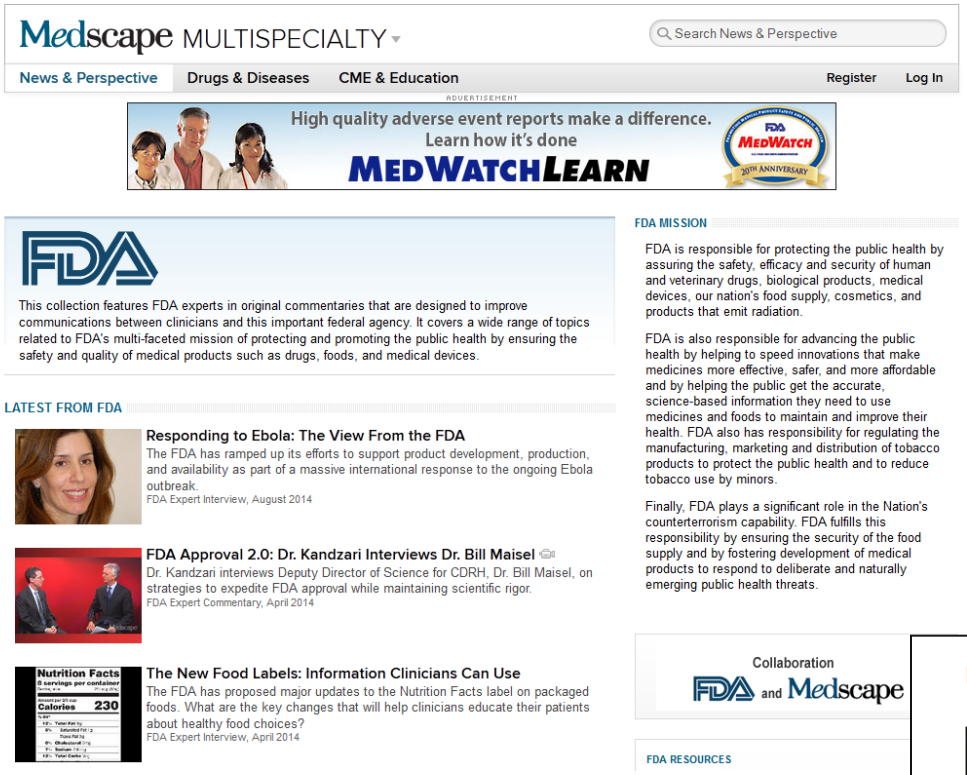
**Updated Krystexxa Boxed Warning**

**WARNING: ANAPHYLAXIS AND INFUSION REACTIONS; G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA** *(Title Updated)*

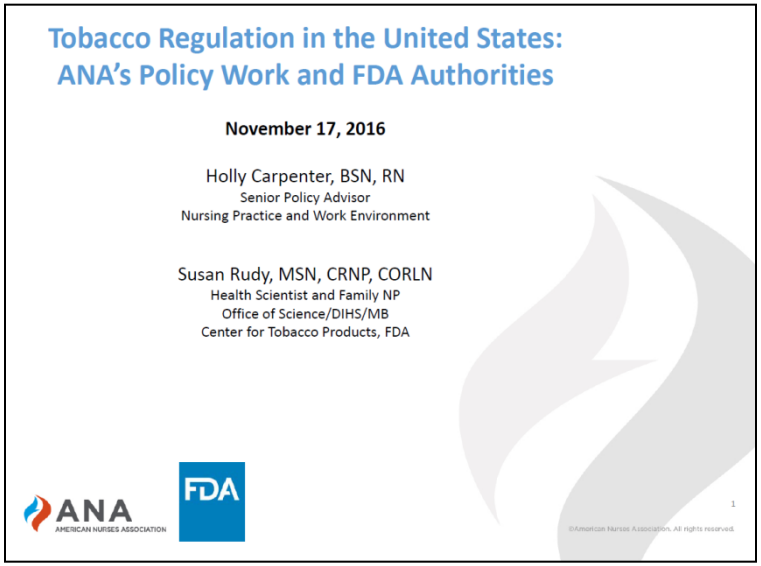
*Addition of:*

Screen patients at risk for G6PD deficiency prior to starting Krystexxa. Hemolysis and methemoglobinemia have been reported with Krystexxa in patients with G6PD deficiency. Do not administer Krystexxa to patients with G6PD deficiency.

# Advance our Reach *through* MOUs




http://www.medscape.com/partners/fda/public/fda




# MedWatch: a Vehicle to Engage with FDA

1. A way to send information *IN* to FDA
2. A way to get safety information *OUT* from FDA

**www.fda.gov/medwatch**

U.S. Food and Drug Administration

# Drug Approval Process

**What is a drug as defined by the FDA?**

A drug is any product that is intended for use in the diagnosis, cure mitigation, treatment , or prevention of disease; and that tis intended to affect the structure or any function of the body.

## PRE-CLINICAL

### Drug Sponsor's Discovery and Screening Phase

**Drug Developed**

Drug sponsor develops a new drug compound and seeks to have it approved by FDA for sale in the United States.

1

**Animals Tested**

Sponsor must test new drug on animals for toxicity. Multiple species are used to gather basic information on the safety and efficacy of the compound being investigated/researched.

2

**IND Application**

The sponsor submits an Investigational New Drug (IND) application to FDA based on the results from intial testing that include, the drug's composition and manufacturing, and develops a plan for testing the drug on humans.

**IND REVIEW**

FDA reviews the IND to assure that the proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. FDA also verifies that there are adequate informed consent and human subject protection.

**FDA's Center for Drug Evaluation and Research (CDER) evaluates new drugs before they can be sold.**

The center's evaluation not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely. CDER ensures that drugs, both brand-name and generic, are effective and their health benefits outweigh their known risks.

## CLINICAL

### Drug Sponsor's Clinical Studies/Trials

3

**PHASE 1**

**20-80**

**The typical number of healthy volunteers used in Phase 1; this phase emphasizes safety.** The goal here in this phase is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted.

4

**PHASE 2**

**100's**

**The typical number of patients used in Phase 2; this phase emphasizes effectiveness.** This goal is to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually a placebo, or a different drug. Safety continues to be evaluated, and short-term side effects are studied.


At the end of Phase 2, FDA and sponsors discuss how large-scale studies in Phase 3 will be done.

5

**PHASE 3**

**1000's**

**The typical number of patients used in Phase 3.** These studies gather more information about safety and effectiveness, study different populations and different dosages, and uses the drug in combination with other drugs.

FDA

## Who reviews new drug submissions?

A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists review the drug sponsor's data and proposed labeling of drugs.

## What other drug products are regulated by FDA?

Drugs include more than just medicines. For example, fluoride toothpastes, antiperspirants (not deodorant), dandruff shampoos, and sunscreens are all considered drugs.


# NDA REVIEW

## FDA's New Drug Application (NDA)Review

### 10 Drug Labeling

FDA reviews the drug's professional labeling and assures appropriate information is communicated to health care professionals and consumers.


### 8-9 Application Reviewed

After an NDA is received, FDA has 60 days to decide whether to file it so it can be reviewed. If FDA files the NDA, the FDA Review team is assigned to evaluate the sponsor's research on the drug's safety and effectiveness.

### 7 NDA Application

The drug sponsor formally asks FDA to approve a drug for marketing in the United States by submitting an NDA. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.


### 6 Review Meeting

FDA meets with a drug sponsor prior to submission of a New Drug Application.

### 11 Facility Inspection

FDA inspects the facilities where the drug will be manufactured.

### FASTER APPROVALS

The **Accelerated Approval** program allows earlier approval of drugs that treat serious diseases and that fill an unmet medical need. The approval is faster because FDA can base the drug's effectiveness on a "surrogate endpoint," such as a blood test or X-ray result, rather than waiting for results from a clinical trial.

The **Fast Track** program helps reduce the time for FDA's review of products that treat serious or life-threatening diseases and those that have the potential to address an unmet medical need. Drug sponsors can submit portions of an application as the information becomes available ("rolling submission") instead of having to wait until all information is available.

### 12 FDA Drug Approval

FDA reviewers will approve the application or issue a response letter.

# POST-MARKETING

## FDA's Post-Approval Risk Assessment Systems

**PHASE 4**

Because it's not possible to predict all of a drug's effects during clinical trials, monitoring safety issues after drugs get on the market is critical. The role of FDA's post-marketing safety system is to detect serious unexpected adverse events and take definitive action when needed.


Once FDA approves a drug, the post-marketing monitoring stage begins. The sponsor (typically the manufacturer) is required to submit periodic safety updates to FDA.

www.fda.gov/medwatch
(800) FDA-1088 (322-1088) phone
(800) FDA-0178 (322-0178) fax

MEDWATCH

FDA's MedWatch voluntary system makes it easier for physicians and consumers to report adverse events. Usually, when important new risks are uncovered, the risks are added to the drug's labeling and the public is informed of the new information through letters, public health advisories, and other education. In some cases, the use of the drug must be substantially limited. And in rare cases, the drug needs to be withdrawn from the market.

## PDUFA

Prescription Drug User Fee Act

**Since the PDUFA was passed in 1992, more than 1,000 drugs and biologics have come to the market, including new medicines to treat cancer, AIDS, cardiovascular disease, and life-threatening infections.**

PDUFA has enabled the Food and Drug Administration to bring access to new drugs as fast or faster than anywhere in the world, all while maintaining the same thorough review process. Under PDUFA, drug companies agree to pay fees that boost FDA resources, and FDA agrees to time frames for its review of new drug applications.

# Why Report?

"Every product that FDA approves carries some risk…Sometimes there are risks that only come to light after a medical product gets on the market and is used in a larger number of patients, for a longer period of time, and in patients whose health characteristics are different from those of the patients studied before approval."

- Norman Marks, M.D., retired MedWatch Medical Officer

# MedWatch - Reporting IN

**_Anyone_ can report a problem**

# MedWatch
# Reporting IN

- One person can make a difference.

# Assessment question

True or False. You must be a healthcare professional in order to submit a report to MedWatch.

**False**

# MedWatch - What to Report

- Serious events
- Medication errors
- Product quality problems
- Potential for error
- Non-serious events

Drugs

Medical Devices

Combination Products

Biologics

Special Nutritional Products

# Reporting IN – Serious events

- 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)


Drugs


Medical Devices

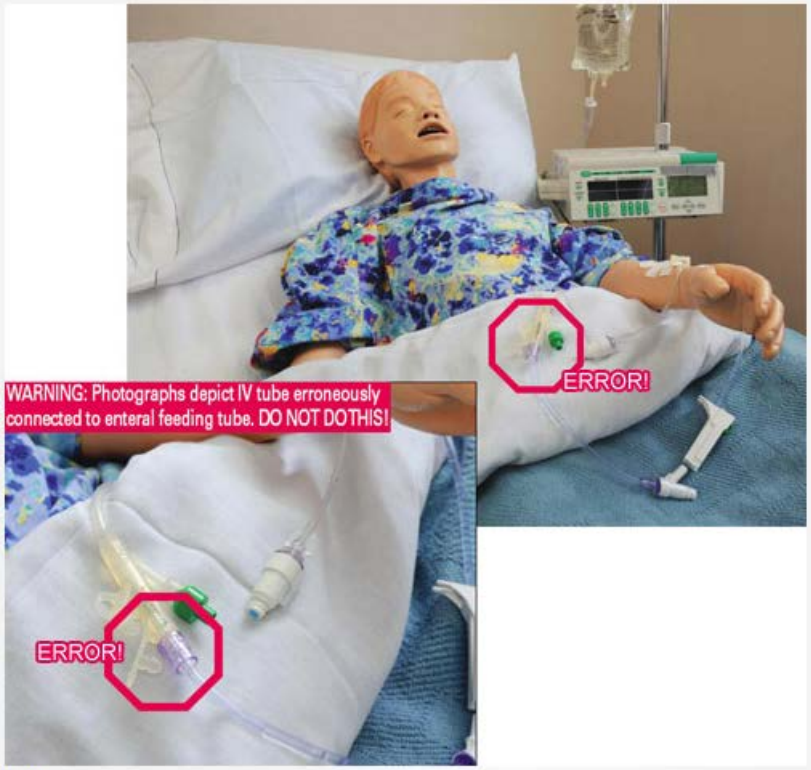

Biologics


Combination Products


Special Nutritional Products

# Reporting IN – Potential for Harm

**IV tubing erroneously connected to enteral feeding tube**




**CASE STUDY**

- A child had both a gastric feeding tube for nutrition and an IV for medicine and hydration
- When the child's gown was changed, a family member inadvertently attached the IV tubing to the gastric feeding tube
- The medicine was delivered through the feeding tube into the stomach
- There was no patient harm since the event was noted in a timely manner

**POTENTIAL FOR HARM:** Moderate

FDA is also interested in cases where the potential for harm exists

Such reports help FDA identify and better understand the risks associated with medical products

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/ucm313275.htm

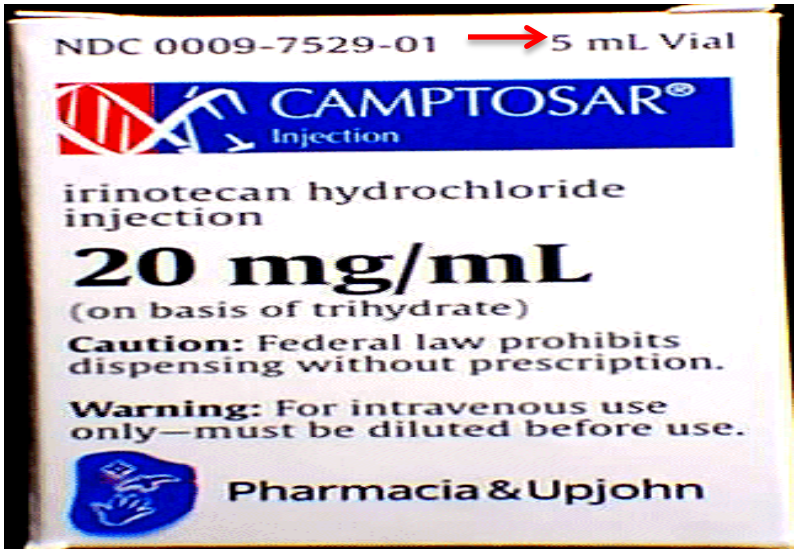
# *Potential* Errors

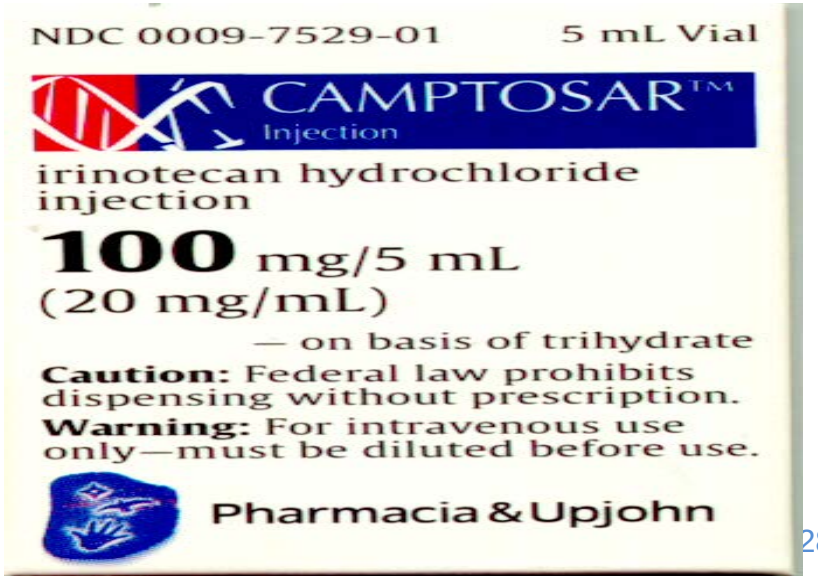
- Prescribing
  - handwriting, abbreviations

- Miscommunication of Orders/Nomenclature
  - sound alike, look alike

# *Potential* Errors

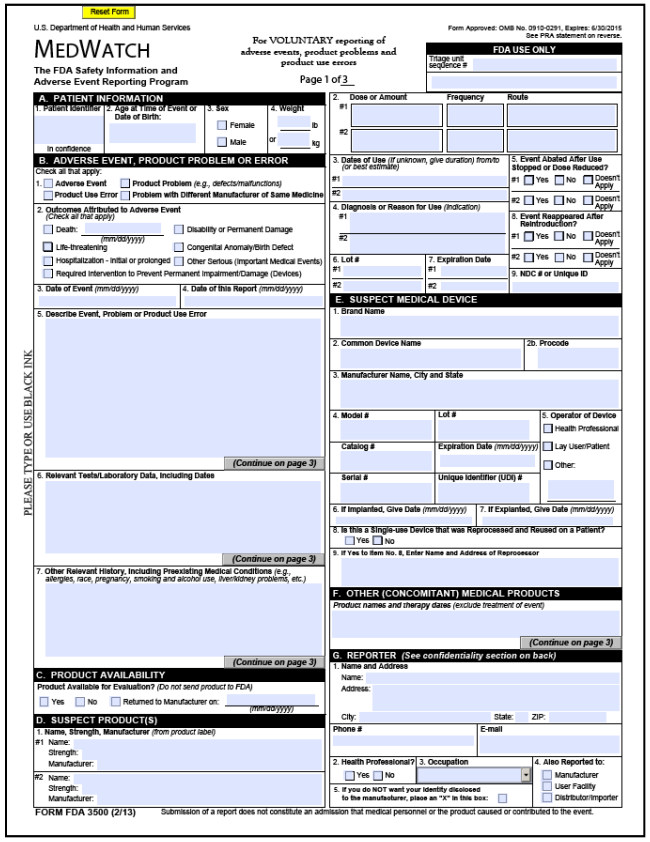
- Label/Packaging
  - placement of information
  - expression of strength/dose
  - readability of label
  - inappropriate labeling during repackaging



# MedWatch Reporting- VOLUNTARY

## Clinician Form 3500



Reset Form

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

Form Approved: OMB No. 0910-0291, Expires: 6/30/2016
See PRA statement on reverse.

Page 1 of 3

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier | 2. Age at time of Event or Date of Birth: | 3. Sex | 4. Weight

In confidence

Female / Male

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

(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, liver/kidney problems, etc.)

(Continue on page 3)

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)

#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 | 2b. Procode

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: Health Professional / Lay User/Patient / Other:

Catalog # | Expiration Date (mm/dd/yyyy)

Serial # | Unique Identifier (UDI) #

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)

(Continue on page 3)

G. REPORTER (See confidentiality section on back)

1. Name and Address

Name:

Address:

City: State: ZIP:

Phone # | E-mail

2. Health Professional? Yes / No | 3. Occupation | 4. Also Reported to: Manufacturer / User Facility / Distributor/Importer

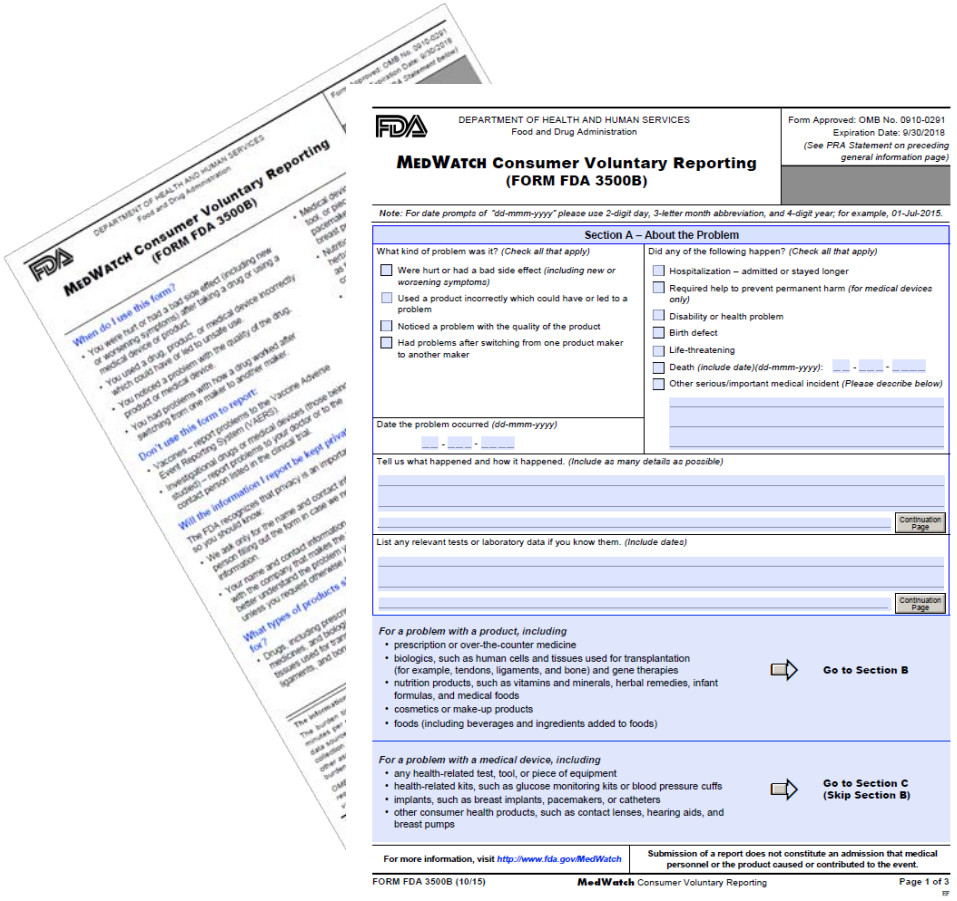
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (2/13)

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

## Consumer/Patient Form 3500B



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 9/30/2018
(See PRA Statement on preceding general information page)

MEDWATCH Consumer Voluntary Reporting
(FORM FDA 3500B)

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

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)(dd-mmm-yyyy): __ - ___ - ____
- Other serious/important medical incident (Please describe below)

Date the problem occurred (dd-mmm-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

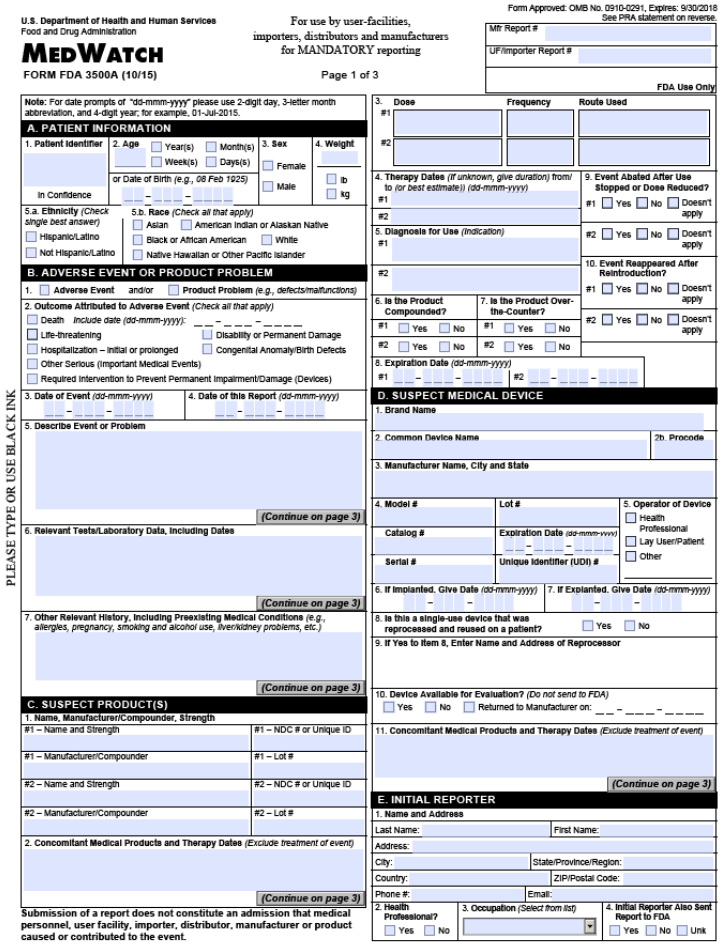
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FORM FDA 3500B (10/15) MedWatch Consumer Voluntary Reporting Page 1 of 3

# MedWatch Reporting- MANDATORY

**MANDATORY Form 3500A**

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



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

**MEDWATCH**
FORM FDA 3500A (10/15)

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

Page 1 of 3

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

Mfr Report #
UF/Importer Report #
FDA Use Only

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

**A. PATIENT INFORMATION**

1. Patient Identifier — In Confidence
2. Age — Year(s) Month(s) Week(s) Days(s) or Date of Birth (e.g., 08 Feb 1925)
3. Sex — Female Male
4. Weight — lb kg

5.a. Ethnicity (Check single best answer) — Hispanic/Latino; Not Hispanic/Latino
5.b. Race (Check all that apply) — Asian; American Indian or Alaskan Native; Black or African American; White; Native Hawaiian or Other Pacific Islander

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcome Attributed to Adverse Event (Check all that apply) — Death (Include date (dd-mmm-yyyy)); Life-threatening; Hospitalization – Initial or prolonged; Other Serious (Important Medical Events); Required Intervention to Prevent Permanent Impairment/Damage (Devices); Disability or Permanent Damage; Congenital Anomaly/Birth Defects
3. Date of Event (dd-mmm-yyyy)
4. Date of this Report (dd-mmm-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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) — (Continue on page 3)

**C. SUSPECT PRODUCT(S)**

1. Name, Manufacturer/Compounder, Strength
#1 – Name and Strength; #1 – NDC # or Unique ID
#1 – Manufacturer/Compounder; #1 – Lot #
#2 – Name and Strength; #2 – NDC # or Unique ID
#2 – Manufacturer/Compounder; #2 – Lot #
2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) — (Continue on page 3)

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.

3. Dose — Frequency — Route Used
4. Therapy Dates (If unknown, give duration) from/to (or best estimate)) (dd-mmm-yyyy)
5. Diagnosis for Use (Indication)
6. Is the Product Compounded? Yes No
7. Is the Product Over-the-Counter? Yes No
8. Expiration Date (dd-mmm-yyyy)
9. Event Abated After Use Stopped or Dose Reduced? Yes No Doesn't apply
10. Event Reappeared After Reintroduction? Yes No Doesn't apply

**D. SUSPECT MEDICAL DEVICE**

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

**E. INITIAL REPORTER**

1. Name and Address
Last Name: First Name:
Address:
City: State/Province/Region:
Country: ZIP/Postal Code:
Phone #: Email:
2. Health Professional? Yes No
3. Occupation (Select from list)
4. Initial Reporter Also Sent Report to FDA Yes No Unk

PLEASE TYPE OR USE BLACK INK

# Responsive Design

- First for FDA website
- Screen will adjust to device used to access web page: i.e. tablets, smart phone

# How do I report?

**Report**

**A**

**Problem**


**www.fda.gov/medwatch**

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

MedWatch Home | Help | OMB Paperwork Reduction Act | Your Privacy Statement

# MedWatch Online Voluntary Reporting Form

## Welcome

Frequently Asked Questions

**Begin report as a:**

Health Professional
(FDA Form 3500)

Consumer/Patient
(FDA Form 3500B)

### What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

### What Not to Report to FDA MedWatch:

- Tobacco: Tobacco product problems should be reported to the Safety Reporting Portal.
- Vaccines: Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/esub/index
- Investigational (study) drugs: Report investigational (study) drug adverse events as required in the study protocol and send to the address and contact person listed in the study protocol.
- Mandatory reporting by regulated industry:
  - Drugs and Biologics
  - Applicable Regulations
  - Devices
- Reporting on Dietary Supplements
- Reporting on Veterinary Medicine Products
- Reports FDA Does Not Handle (e.g. CPSC, FTC, State Health Departments) and Where to Send Them

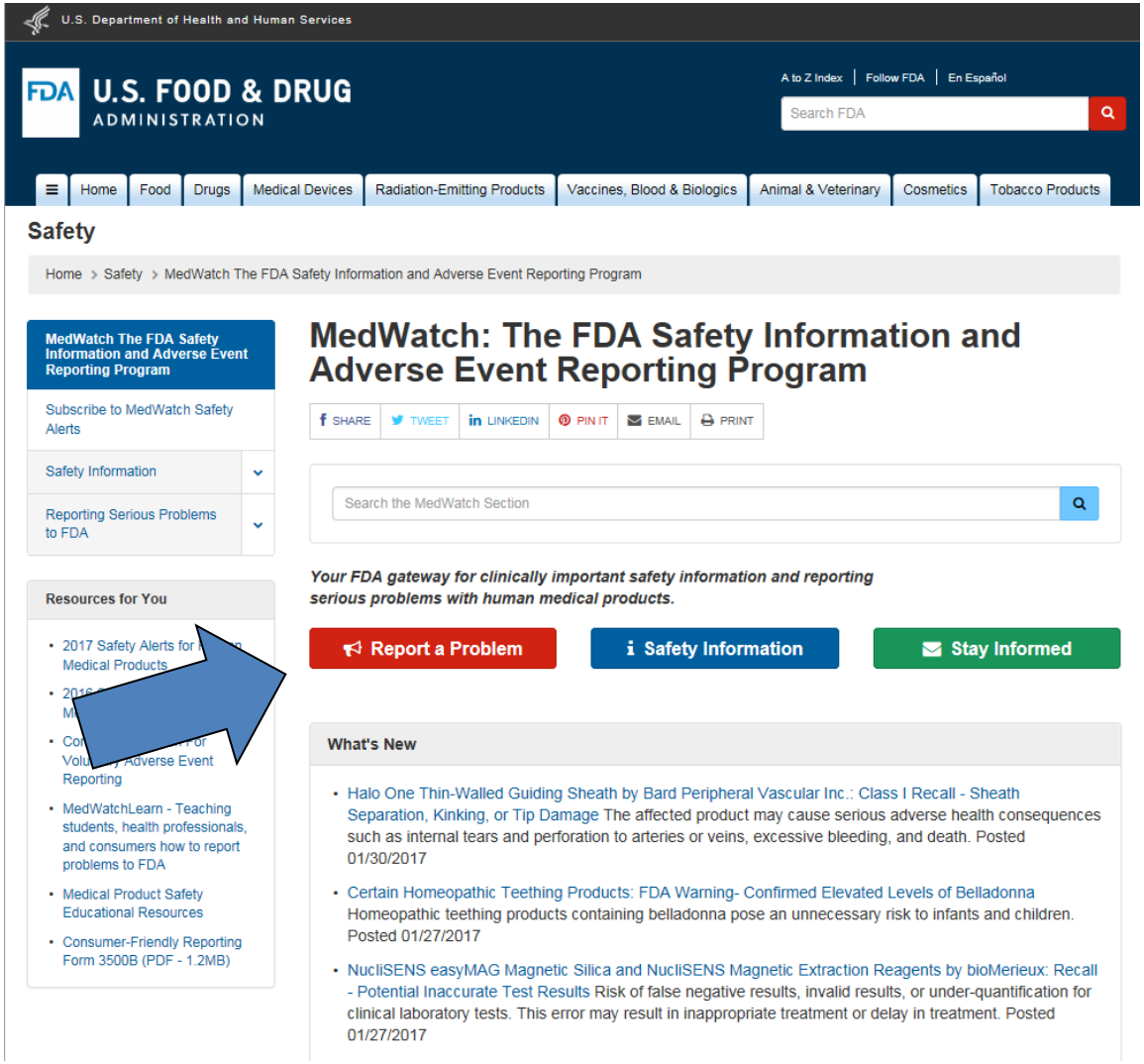
MedWatch Home | Safety Info | How to Report | Download Forms | Join E-list

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

# How do I report?

- Online
- Mail/Fax
- By Phone

*1-800-332-1088*



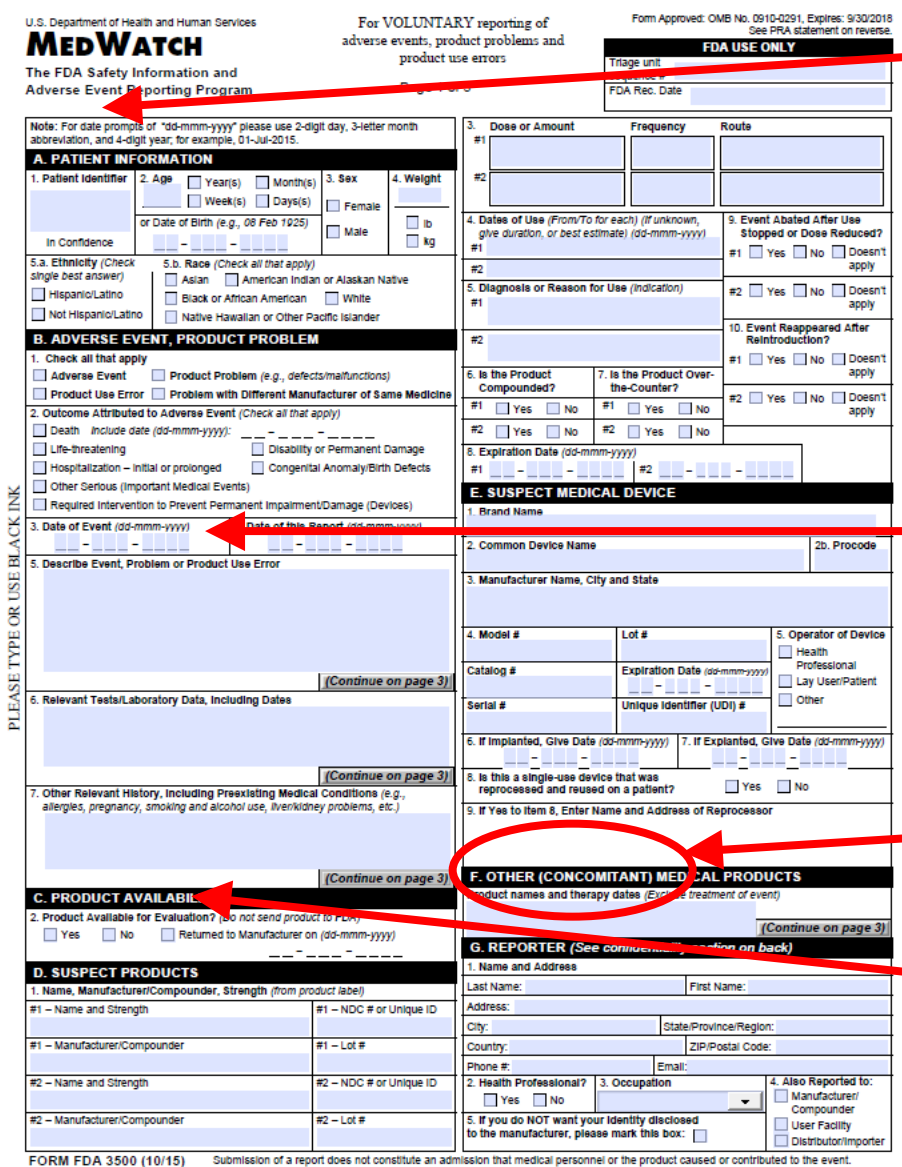

**www.fda.gov/medwatch**

# Assessment Question

The FDA will accept your adverse event report by which of the following methods?

A) Mail
B) Online submission
C) Fax
D) All of the Above

# Four Minimum Elements



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

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018
See PRA statement on reverse.

**FDA USE ONLY**

Triage unit

FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

**A. PATIENT INFORMATION**

1. Patient Identifier
In Confidence
2. Age ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)
or Date of Birth (e.g., 08 Feb 1925)
3. Sex ☐ Female ☐ Male
4. Weight ☐ lb ☐ kg
5.a. Ethnicity (Check single best answer) ☐ Hispanic/Latino ☐ Not Hispanic/Latino
5.b. Race (Check all that apply) ☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

**B. ADVERSE EVENT, PRODUCT PROBLEM**

1. Check all that apply
☐ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine
2. Outcome Attributed to Adverse Event (Check all that apply)
☐ Death Include date (dd-mmm-yyyy):
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects
☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (dd-mmm-yyyy)
Date of this Report (dd-mmm-yyyy)
5. Describe Event, Problem or Product Use Error
(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, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
(Continue on page 3)

**C. PRODUCT AVAILABIL**

2. Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on (dd-mmm-yyyy)

**D. SUSPECT PRODUCTS**

1. Name, Manufacturer/Compounder, Strength (from product label)

| | |
|---|---|
| #1 – Name and Strength | #1 – NDC # or Unique ID |
| #1 – Manufacturer/Compounder | #1 – Lot # |
| #2 – Name and Strength | #2 – NDC # or Unique ID |
| #2 – Manufacturer/Compounder | #2 – Lot # |

3. Dose or Amount | Frequency | Route
#1
#2
4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1
#2
5. Diagnosis or Reason for Use (Indication)
#1
#2
6. Is the Product Compounded? #1 ☐ Yes ☐ No #2 ☐ Yes ☐ No
7. Is the Product Over-the-Counter? #1 ☐ Yes ☐ No #2 ☐ Yes ☐ No
8. Expiration Date (dd-mmm-yyyy) #1 #2
9. Event Abated After Use Stopped or Dose Reduced? #1 ☐ Yes ☐ No ☐ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply
10. Event Reappeared After Reintroduction? #1 ☐ Yes ☐ No ☐ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name
2. Common Device Name
2b. Procode
3. Manufacturer Name, City and State
4. Model #
Lot #
5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other
Catalog #
Expiration Date (dd-mmm-yyyy)
Serial #
Unique Identifier (UDI) #
6. If Implanted, Give Date (dd-mmm-yyyy)
7. If Explanted, Give Date (dd-mmm-yyyy)
8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No
9. If Yes to Item 8, Enter Name and Address of Reprocessor

**F. OTHER (CONCOMITANT) MED CAL PRODUCTS**

Product names and therapy dates (Exclude treatment of event)
(Continue on page 3)

**G. REPORTER** (See confidentiality section on back)

1. Name and Address
Last Name: First Name:
Address:
City: State/Province/Region:
Country: ZIP/Postal Code:
Phone #: Email:
2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to: ☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK

FORM FDA 3500 (10/15) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

**Patient Identifier**

**Event or Problem**

**Reporter**

**Product**

# Assessment Question

**Case #1**

Health care worker ST reported male patient ABC123 started Drug X at 5 mg daily for type 2 diabetes on February 11, 2015.

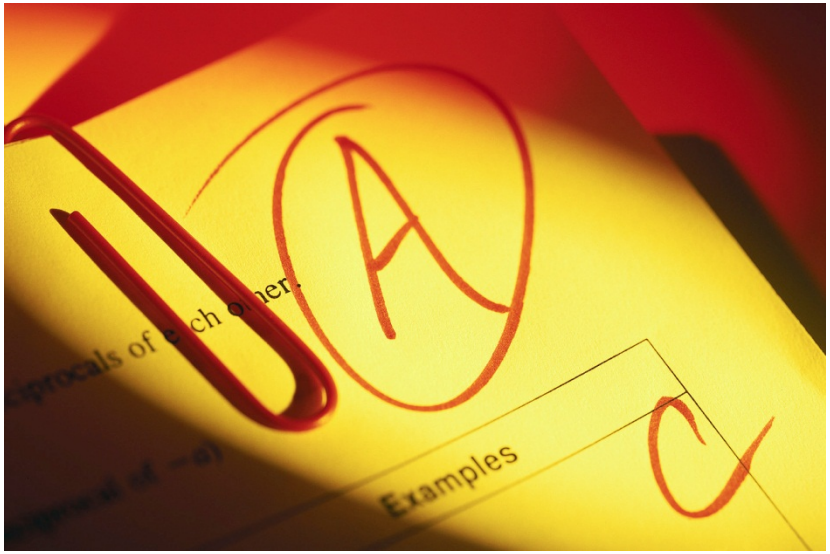
The patient developed liver failure.

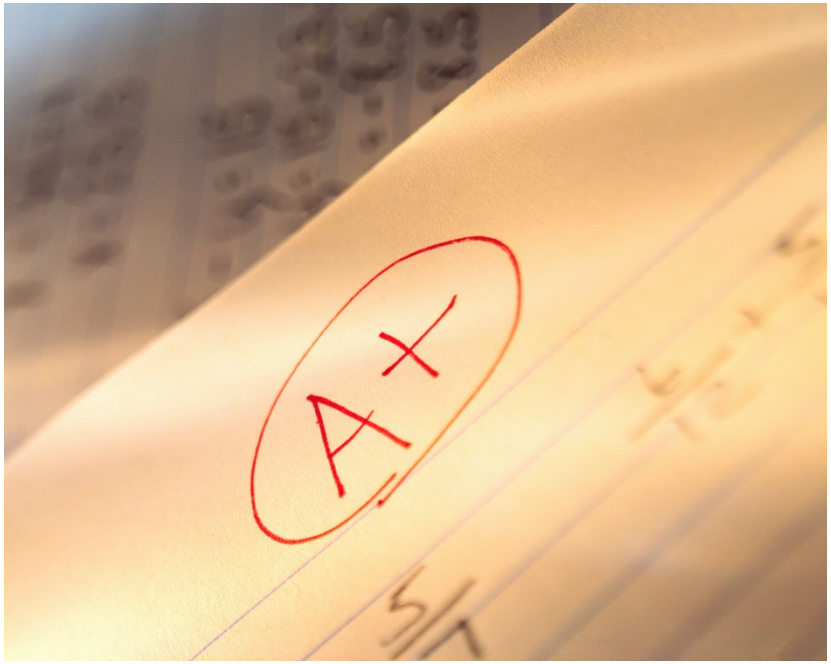
Question: Does Case #1 contain the four elements needed to file this report into the MedWatch database?

A Yes

B No

# What makes a good report a




*Great* report ?

# Quality is Key: Case #2

- 59-year-old male ABC123 with type 2 diabetes, hyperlipidemia, and hypertension. No history of liver disease.
- Started Drug X on February 11, 2015.
- Other medications: Drug Y and Drug Z.
- Labs drawn on Feb 11 revealed Liver enzymes, INR, creatinine, and bilirubin all within normal limits.
- No alcohol use.
- 8 weeks after starting Drug X patient presented to ER with 5 day history of jaundice, dark urine, and nausea/vomiting.
- He was admitted to ICU and subsequently diagnosed with acute liver failure.
- Drug X stopped upon admission.
- Viral hepatitis was ruled out.
- 7 days after stopping the medication, all lab values returned to normal.
- Reported by ST

# What Happens to Your MedWatch Report?

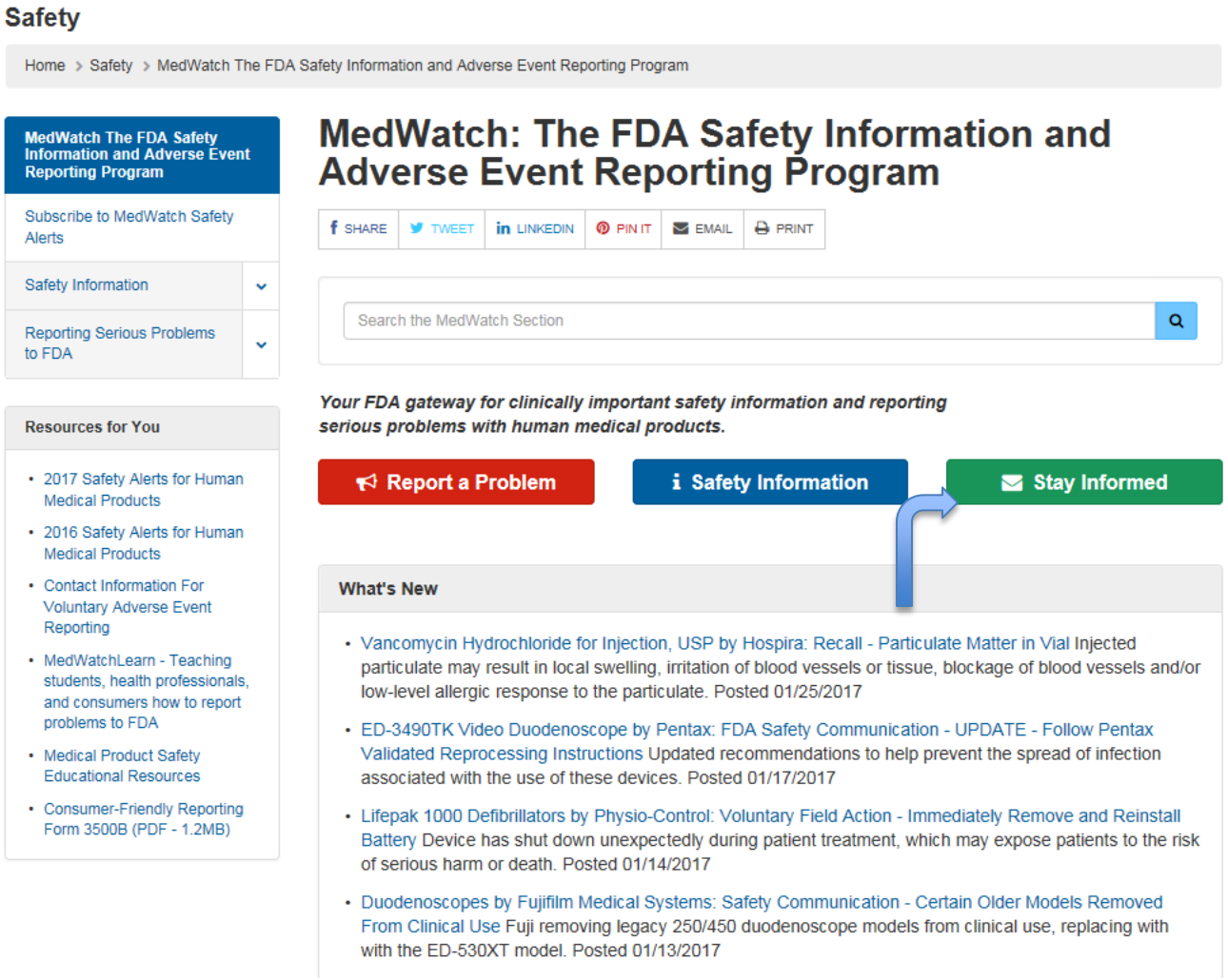
- Report is captured in a database
- FDA safety evaluator use a variety of methods to screen database

# How can MedWatch Reports Result in Product Changes?

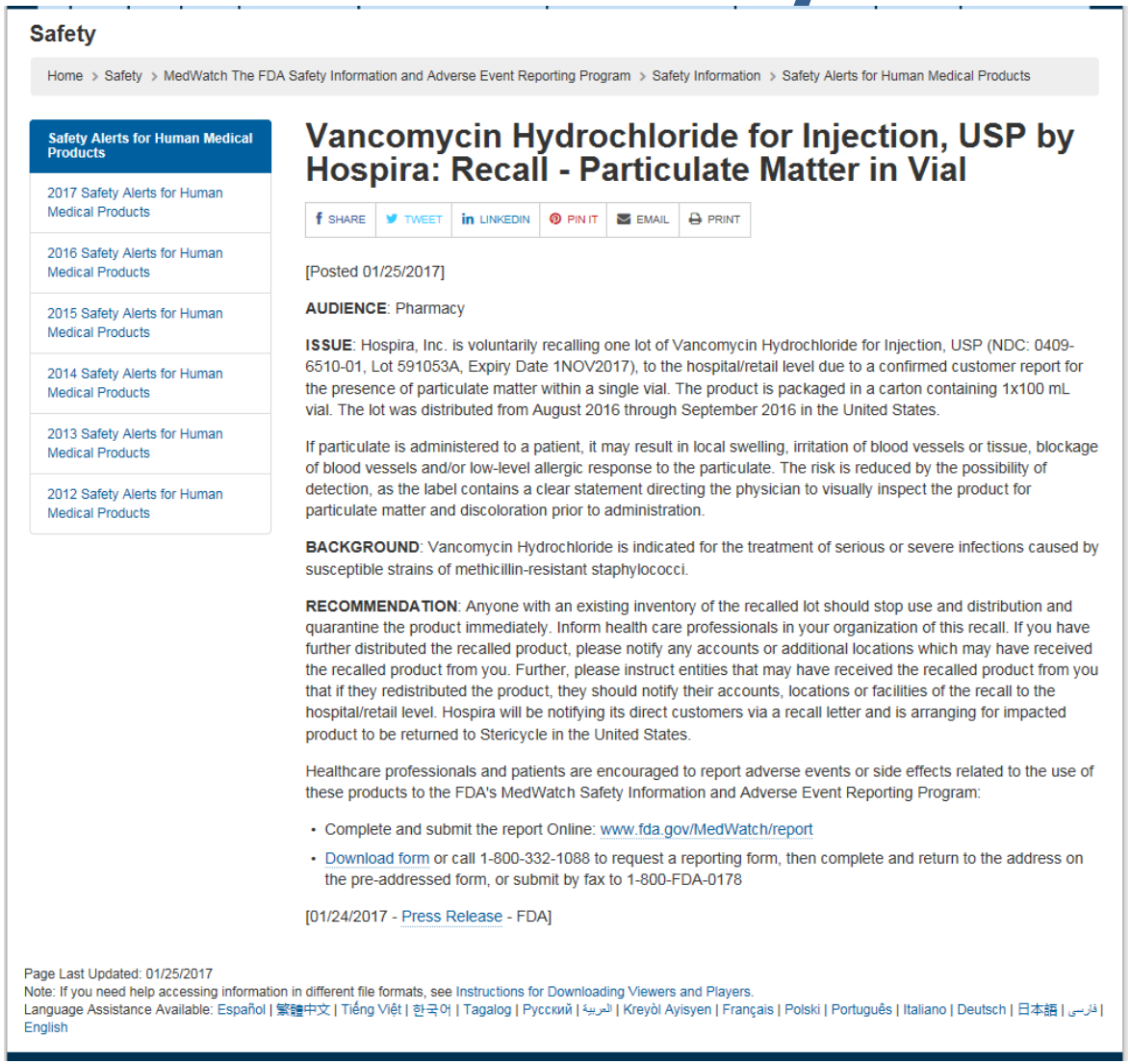
- Update the product label
- Request a change in the product's design, process, packaging, or distribution
- Request a product recall

# MedWatch-Safety OUT

- Subscribe to MedWatch
  - E-list
  - Twitter
  - RSS feeds



# MedWatch-Safety OUT



Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program > Safety Information > Safety Alerts for Human Medical Products

**Safety Alerts for Human Medical Products**

- 2017 Safety Alerts for Human Medical Products
- 2016 Safety Alerts for Human Medical Products
- 2015 Safety Alerts for Human Medical Products
- 2014 Safety Alerts for Human Medical Products
- 2013 Safety Alerts for Human Medical Products
- 2012 Safety Alerts for Human Medical Products

## Vancomycin Hydrochloride for Injection, USP by Hospira: Recall - Particulate Matter in Vial

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

[Posted 01/25/2017]

**AUDIENCE**: Pharmacy

**ISSUE**: Hospira, Inc. is voluntarily recalling one lot of Vancomycin Hydrochloride for Injection, USP (NDC: 0409-6510-01, Lot 591053A, Expiry Date 1NOV2017), to the hospital/retail level due to a confirmed customer report for the presence of particulate matter within a single vial. The product is packaged in a carton containing 1x100 mL vial. The lot was distributed from August 2016 through September 2016 in the United States.

If particulate is administered to a patient, it may result in local swelling, irritation of blood vessels or tissue, blockage of blood vessels and/or low-level allergic response to the particulate. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the physician to visually inspect the product for particulate matter and discoloration prior to administration.

**BACKGROUND**: Vancomycin Hydrochloride is indicated for the treatment of serious or severe infections caused by susceptible strains of methicillin-resistant staphylococci.

**RECOMMENDATION**: Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform health care professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital/retail level. Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[01/24/2017 - Press Release - FDA]

Page Last Updated: 01/25/2017
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

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# FDA Case Studies

U.S. FOOD & DRUG ADMINISTRATION

## FDA CASE STUDY

FDA MedWatch Adverse Event Reporting Curriculum Case Study

### DRUGS, DEVICES, & BIOLOGICS: Health professionals encounter adverse events with medical products and learn about reporting to FDA MedWatch

*This fictionalized case study is part of an educational series published by the U.S. Food and Drug Administration.*

#### A Patch of a Different Color

Dr. Jim Bean was excited as he reached examination room 4, where his last patient of the day was waiting for him. The family practice physician would be on a plane heading to Miami for a national medical conference later that evening. Old colleagues he hadn't seen since his residency, workshops and presentations on the latest advances in medicine and, most importantly, the remaining continuing education credits he needed for his licensure were a few short hours away. Pulling a chart out of the file holder on the wooden door, Jim knocked and let himself in after the voice on the other side said he could enter.

"Hello, Chris! How are you today?" Jim asked, shaking the young man's hand before sitting on a low stool in a corner of the room. Jim had joined the family practice of six physicians 2 years earlier. He had just finished his residency at the time, and Chris had become one of his first regular patients.

"I'm doing well, Dr. Bean," Chris smiled.

"That's what I like to hear," Jim said as he looked down at Chris' charts. The 24-year-old had been successfully treated for years with medication for Attention Deficit Hyperactivity Disorder (ADHD). In the 2 years that Jim had been treating Chris, he had switched his patient from oral ADHD medications to a patch worn on the skin. He noted the last prescription date in charts and said, "I'll need to refill your prescription. Let's get you checked out first and then I'll have the nurses send the prescription to your pharmacy before you leave."

After a routine checkup, Jim turned his attention to Chris' patch. Peeling it off, he noticed that some of Chris's skin at the application site was discolored. "Chris," he said, eyebrows pinched with concern. "I'm noticing some depigmentation underneath your patch that wasn't here the last time I saw you. Can you tell me when this first started happening?"

"I'm not sure," Chris replied. He took a few moments to think. "I noticed my skin was getting lighter there, but didn't think anything of it since I tend to put the patch in the same place and that area isn't exposed much to light."

"Well, discoloration like this is sometimes a sign of leukoderma, or loss of color pigment in the skin,

U.S. FOOD & DRUG ADMINISTRATION

## FDA MedWatch Adverse Event Reporting Curriculum Case Study: Instructor's Guide

**DRUGS, DEVICES, & BIOLOGICS: Health professionals encounter adverse events with medical products and learn about reporting to FDA MedWatch**

#### LEARNING OBJECTIVES

- Identify how to receive safety information from the FDA.
- Identify how to submit a quality medical product problem report to FDA.
- Explain how reports are used by FDA to investigate medical product problems and are translated into safety actions such as recalls or safety communications.
- Review the definitions of drug, device, and biologic.

#### TOPICS

Adverse event reporting; MedWatch; Forms 3500, 3500B, 3500A; Drugs; Devices; Biologics

#### ASSUMPTIONS

This case study is based on the assumption that the target audience is undergraduate students or health professionals who have little experience with adverse event reporting.

#### SUGGESTED APPROACH

1. Preparing Students: Students are expected to read the case study prior to the training session.

2. Engaging Students: The training session should consist of a discussion of the case study and completion of a MedWatch form.

3. Immersing Students: The training session should emphasize group discussion of the two examples in the case study. Students should be encouraged to review an additional case study on MedWatchLearn after class.

#### STUDENT ACTIVITIES

**Before Class**

Review the following materials before class:

1. MedWatch Homepage
http://www.fda.gov/Safety/MedWatch/default.htm

2. Print hard copies of Form 3500B and Form 3500 and bring them to class. http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

Answer the following questions before class:

1. How are reporting forms 3500, 3500B, and 3500A different?

Answer:

- Form FDA 3500, Voluntary Reporting: For use by health care professionals, consumers, and patients.
- Form FDA 3500B, Voluntary Reporting for Consumers: A consumer-friendly version of the 3500 reporting form.
- Form FDA 3500A Mandatory Reporting: For use by IND reporters, manufacturers, distributors, importers, and user facilities personnel.

2. True or False: Vaccine product problems should be reported to MedWatch.

Answer: **False.** Vaccine product problems should be reported to the Vaccine Adverse Event Reporting System (VAERS), not MedWatch. VAERS is a national vaccine safety surveillance program co-sponsored by FDA and the Centers for Disease Control and Prevention (CDC).

3. Good case reports include the following elements:

a. Description of the adverse events or disease experience, including time to the beginning of signs or symptoms
b. Clinical course of the event and patient outcomes (e.g., hospitalization or death)
c. Relevant therapeutic measures and laboratory data at baseline, during therapy, and subsequent to therapy, including blood levels, as appropriate
d. All of the above

Answer: **d.** All of the above

1

U.S. FOOD & DRUG ADMINISTRATION

## FDA CASE STUDY

FDA Drug Information Curriculum Case Study

### Useful FDA Drug Information for Clinicians: Practicing clinicians seek available information on a new drug before making a treatment decision

*This fictionalized case study is part of an educational series published by the U.S. Food and Drug Administration.*

#### A Rounding Team and One Patient

If they listened closely, the patients in the cardiology wing of Sun Valley hospital could hear them. Several pairs of rubber-soled shoes slapped the ground in quick patterns as they tried to keep up with the long stride of Dr. Michael Carosel, attending physician and director of the cardiology department. In his wake, the steady and practiced steps of his chief resident, Dr. Andrea Nash, barely made a sound as she followed with ease. Behind her, the newest crop of residents and interns beginning their four-week rotation program worked hard to keep pace in what many nurses at the community hospital jokingly called "Carosel's Running of the Interns."

However, no one complained. Dr. Carosel was well-respected in the California medical community. A practitioner of medicine for over 20 years, he had served as the Director of Cardiology at Sun Valley for the past 11 years. In that time, he had managed to employ Andrea, one fellow, and two residents. The four were among the brightest talents in cardiology in the country.

Quick sighs of relief once the march stopped at the central nurse's station were the only signs from the students that they had experienced any hardship. They took some time to

"Okay, everyone," Dr. Carosel began, "our patient of the day is named Simone, a 52-year-old female who was admitted two days ago after experiencing severe chest pain. This is not her first myocardial infarction (heart attack)," he continued. "She was admitted to Sun Valley at the age of 48 after she experienced severe chest pain and fell unconscious at her oldest son's graduation party. Since then, she

U.S. FOOD & DRUG ADMINISTRATION

## FDA Drug Information Curriculum Case Study: Instructor's Guide

**FDA Useful Drug Information for Clinicians: Practicing clinicians seek available information on a new drug before making a treatment decision**

#### LEARNING OBJECTIVES

- Identify an online resource for FDA's drug review materials found at: www.fda.gov.
- Determine if a drug or biologic marketed in the U.S. has been discussed at an FDA advisory committee meeting.
- Gain an understanding of the FDA advisory committee's evaluation of a product's benefits and risks.
- Explain the characteristics of a new molecular entity (NME).
- Gain an understanding of risk evaluation and mitigation strategies (REMS) and their role.

#### TOPICS

FDA Drug Information Resources; Drugs@FDA; Risk Evaluation and Mitigation Strategy (REMS); FDA CardioBeat; FDA Drug Shortages Program

#### ASSUMPTIONS

This case study is based on the assumption that the target audience is undergraduate students or health professionals who are unfamiliar with FDA drug information resources.

#### SUGGESTED APPROACH

1. Preparing Students: Students are expected to read the case study prior to the training session.

2. Engaging Students: The training session should consist of a discussion of the case study.

3. Immersing Students: The training session should emphasize group discussion of the case study. Students should be encouraged to use their mobile devices to access the drug resources apps mentioned in the case study and navigate to the FDA websites referenced in class.

#### STUDENT ACTIVITIES

**Before Class**

Review the following websites:

1. Drugs@FDA
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

2. FDA Advisory Committee http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/default.htm

3. REMS@FDA
http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm

4. Drug Shortages Program
http://www.fda.gov/Drugs/DrugSafety/DrugShortages/

Answer the following questions before class:

1. What is Drugs@FDA?

Answer: Drugs@FDA is a searchable database of drug product labels and approval-related documents, including reviews, approval letters, and current and archived labels.

2. True or False: Advisory Committee members are FDA employees.

Answer: **False**. Advisory committees are made up of outside experts that provide FDA with independent opinions and recommendations on applications to market new drugs and on FDA policies. The marketing applications they review include data about the safety and effectiveness of human drugs. The committees receive summary information about the drug applications and copies of FDA's review of the application documents. Based on this information, advisory

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**http://www.fda.gov/ForHealthProfessionals/LearningActivities/default.htm**

# Reporting Tutorial – MedWatch*Learn*

- Online practice portal
  - Students/Health Professionals
  - Consumers Section
  - Learn how to fill out a MedWatch Report


www.fda.gov/medwatchlearn

# Reporting Tutorial - MedWatch *Learn*

# Assessment Question

What is MedWatch?

- A A way to send information to FDA on problems with medical products
- B A way to receive safety information from FDA
- C Both A and B

# Thank You!
# Questions?

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