

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



[Teresa Rubio, Pharm.D.](#)

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

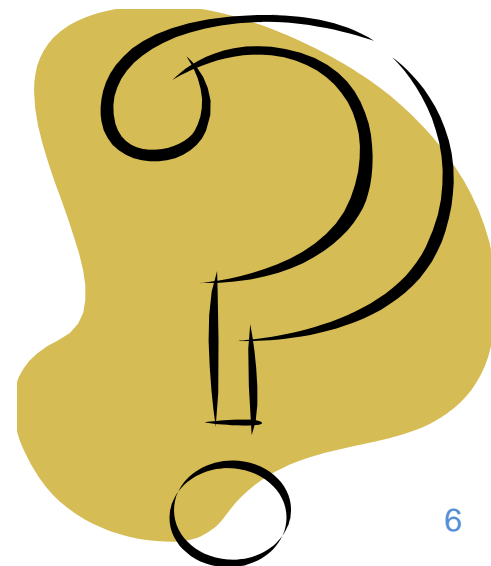
- a. Spam
- b. Puppy food
- c. Chocolate covered cherries
- d. Frozen spinach
- e. Imported caviar



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

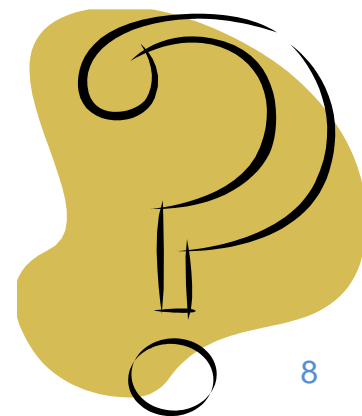
- a. Kidney dialysis machine
- b. Tongue depressor
- c. Toothpaste
- d. Fluoridated toothpaste
- e. Hair dryer



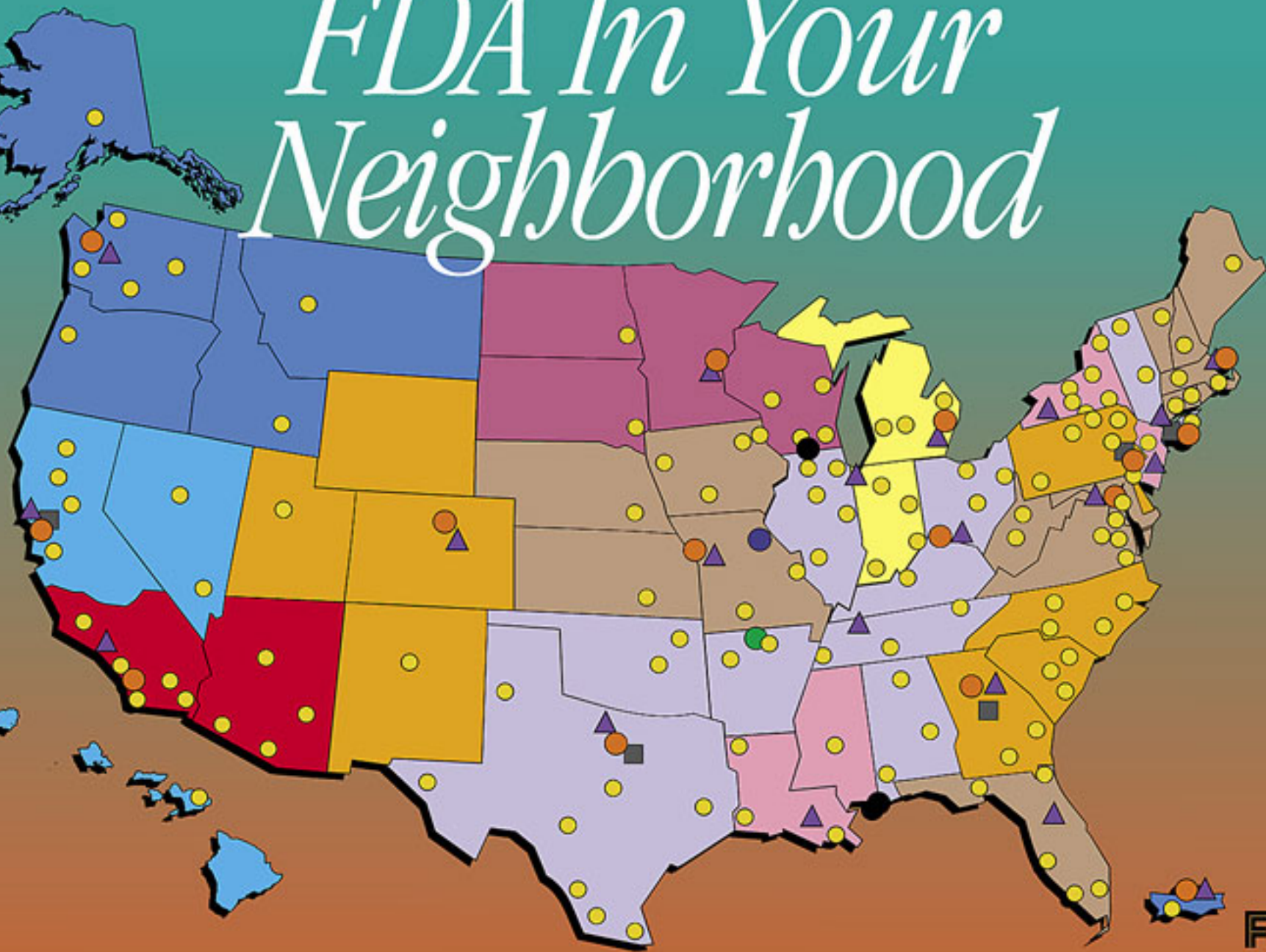
Assessment question-

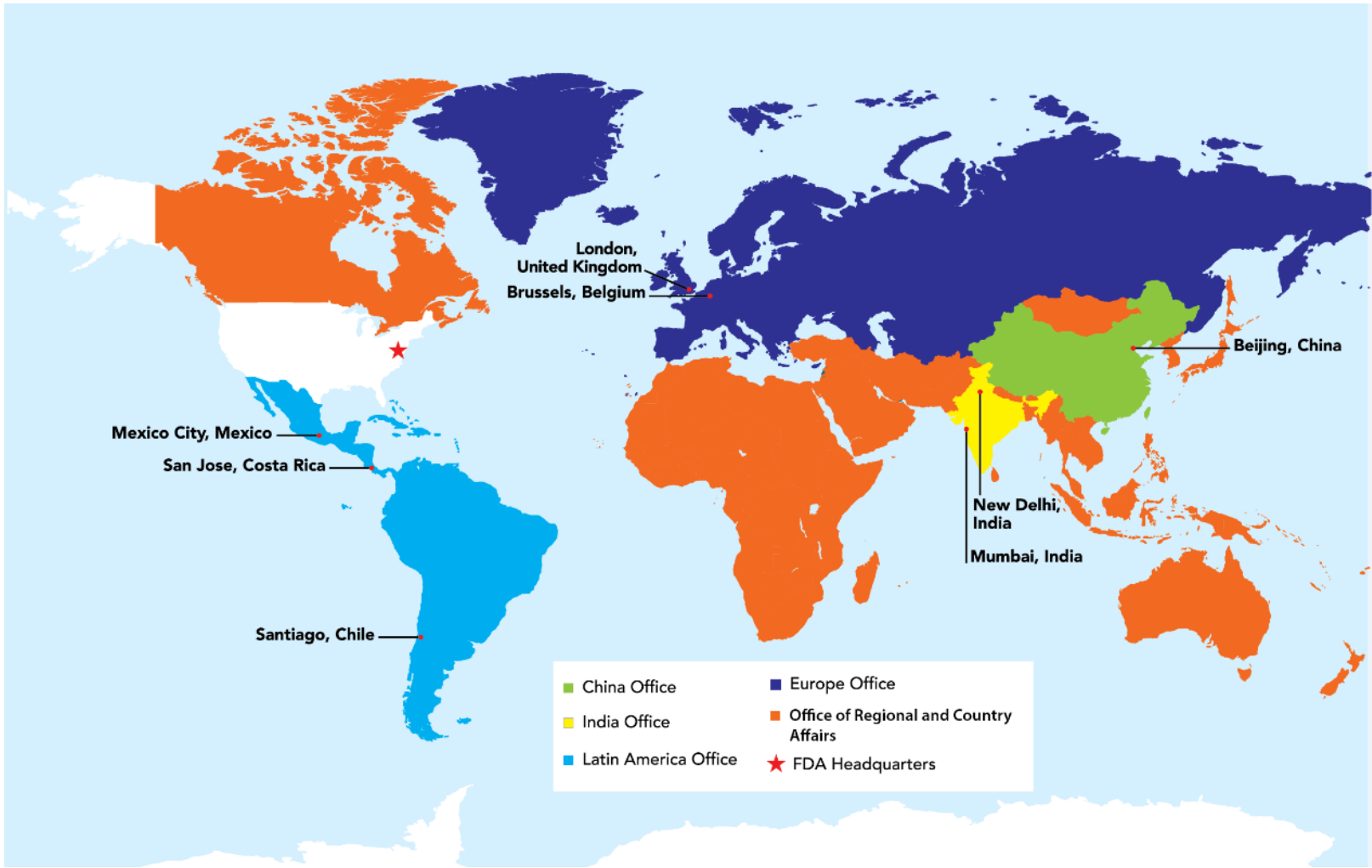
Which is Not Regulated by the FDA

- 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







Office of the
Commissioner

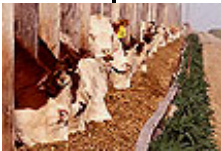
Office of Foods and
Veterinary Medicine

Office of Medical Products
& Tobacco

Office of Global
Reg. Ops &
Policy



Center for
Food
Safety &
Applied
Nutrition



Center for
Veterinary
Medicine



Center for
Devices &
Radiological
Health



Center for
Biologics
Evaluation
&
Research



Center for
Drug
Evaluation
&
Research



Center for
Tobacco
Products



Office of
Regulatory
Affairs

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

FREE WEBINAR NOV. 19, 2015 • NOON ET

THE AMERICAN NURSES ASSOCIATION AND THE U.S. FOOD AND DRUG ADMINISTRATION PRESENT:

FDA'S MENU LABELING REQUIREMENTS WHAT NURSES NEED TO KNOW

NOV. 19, 2015 • NOON ET

The United States is suffering from an unprecedented overweight/obesity epidemic and from the chronic diseases that overweight and obesity exacerbate. Registered nurses (RNs) suffer from these conditions as well. RNs need to know the status of their own nutritional health. They need to know how to make the most informed, healthful menu choices when eating out at restaurants, not only for themselves but also so they can educate their patients.

By knowing the state of one's own health and the caloric count and sodium/sugar/carbohydrate content of menu choices, RNs can truly be role models, advocates and educators of healthier lifestyles.

There are several resources, including the FDA's upcoming regulations, that will provide menu and menu board labeling, to assist consumers in making their most healthful choices when eating out at restaurants.

This continuing nursing education activity was approved by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

FOLLOWING THIS WEBINAR, NURSES WILL BE ABLE TO:

- 1 Identify types of establishments that will have to display calories on menus and menu boards
- 2 Identify what type of information will be available on menus and menu boards
- 3 Analyze current research on RN nutritional status and intake
- 4 Describe methods for nurses to promote and utilize menu labeling and nutritional facts to increase their own and their patients' health and wellness

Register Today!

CLICK HERE

For more information regarding contact hours, please call
Holly Carpenter at 301-628-5105



ANFFAR1709 E-LIT



A Joint Commission/FDA Webinar on Reprocessing of Scopes



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Education Collaborating With the FDA to Manage Drug Shortages Log In/View
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NTI-National Teaching Institute & Critical Care Exposition
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is

Presented by: Capt. Jouhanna Saliba, PharmD
Live webinar: Thursday October 08, 2015 10:00 AM - 10:30 AM PT [Time Zones](#)
Duration: 30 minutes
Cost: Free to AACN members and nonmembers (webinar only)
[View computer requirements](#) for webinar participation.

Description
Drug shortages can adversely affect patient care as it relates to medication delivery, compromise or delay of procedures, and result in medication errors. The Drug Shortages staff at the FDA works collaboratively with other organizations and manufacturers to keep the public and healthcare professionals informed of the most current drug shortages.

The FDA makes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays and discontinuations. The agency works closely with manufacturers of drugs in short supply to communicate the issue and to help restore availability. The FDA also works with other firms that manufacture the same drug, asking them to increase production, if possible, in order to prevent or reduce the impact of a shortage.

In this webinar, pharmacist Jouhanna Saliba will discuss the importance of early recognition, prevention and mitigation of drug shortages, reviewing data and best practices to help participant identify and potentially alleviate these problems within their organizations.

Learning Objectives
At the end of the session, participants will be able to:

1. Identify why drug shortages occur after reviewing the drug supply chain and data shortages information.
2. Describe the focus of the Drug Shortages Staff of the FDA on the early assessment, recognition and intervention for prevention and mitigation of this problem within their organization.
3. Explore the collaborative relationship and communication between the FDA, manufacturers, various professional organizations (physicians, pharmacists and nurses) and other key stakeholders in managing drug shortages.

Continuing Education
• 0.5 contact hour of CE available (Synergy Category C).

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NAHN National Association of Hispanic Nurses
National Association of Hispanic Nurses
NAHN is also dedicated to the improvement of the quality of health and nursing care of Hispanic consumers.

CONTACT: Celia Besore, MBA, CAE, Executive Director/CEO
National Association of Hispanic Nurses, (501) 367-8615
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Mueve! USA™
2016 Annual Meeting

SAVE THE DATE!
2016 NAHN Annual Conference
July 12-15, 2016
Chicago, IL

Washington, DC (January 15, 2015) — Please join us on Tuesday, February 10, 2016 at 12:00 PM EST for an NAHN webinar discussing the importance of the Food and Drug Administration (FDA) MedWatch Program and providing an introduction to post-marketing drug safety surveillance.

MedWatch is the FDA's reporting system for adverse event. Founded in 1993, this system of voluntary reporting allows information to be shared with medical professionals or the general public.

Learn more about MedWatch and how its role in pharmacovigilance benefits health and safety. This webinar is designed to highlight the MedWatch Program and how nurses can report adverse events. In addition, you will learn the benefits of MedWatch and how to best leverage the MedWatch resources.

Other objectives of this webinar include:

- Describing the Division of Pharmacovigilance's (DPV) key safety roles in FDA's Center for Drug Evaluation and Research (CDER)
- Understanding the regulatory requirements and the role of MedWatch for reporting post-marketing safety information.
- Describing how adverse event reports are collected by FDA/CDER/DPV.

Presenters: Tereza Ruble, Pharm.D., Health Programs Coordinator for the FDA Office of Health and Constituent Affairs and Charlene M. Flowers, RPh, Safety Evaluator for the FDA Division of Pharmacovigilance.

Register now at Registration URL: <https://attendee.gotowebinar.com/register/8622691506279551724>
Webinar ID: 126-378-211

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 anti-diarrheal 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

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

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 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 attempts, 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.

www.pharmacytoday.org

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 Avelex (moxifloxacin hydrochloride), Avelex in 0.8% sodium chloride solution for i.v. use (moxifloxacin hydrochloride), Cipro (ciprofloxacin; ciprofloxacin hydrochloride), Cipro XR 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:

<ul style="list-style-type: none"> (for Avelex, Avelex in 0.8% sodium chloride solution for i.v. use, moxifloxacin hydrochloride, and Cipro IV) • Acute bacterial sinusitis • Acute bacterial exacerbation of chronic bronchitis 	<ul style="list-style-type: none"> (for Cipro XR and Noroxin) • Uncomplicated urinary tract infections
<ul style="list-style-type: none"> (for Factive) • Acute bacterial exacerbation of chronic bronchitis 	<ul style="list-style-type: none"> (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.

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High quality adverse event reports make a difference. Learn how it's done

MEDWATCH LEARN




This collection features FDA experts in original commentaries that are designed to improve communications between clinicians and this important federal agency. It covers a wide range of topics related to FDA's multi-faceted mission of protecting and promoting the public health by ensuring the safety and quality of medical products such as drugs, foods, and medical devices.

FDA MISSION

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

LATEST FROM FDA



Responding to Ebola: The View From the FDA

The FDA has ramped up its efforts to support product development, production, and availability as part of a massive international response to the ongoing Ebola outbreak.

FDA Expert Interview, August 2014



FDA Approval 2.0: Dr. Kandzari Interviews Dr. Bill Maisel

Dr. Kandzari interviews Deputy Director of Science for CDRH, Dr. Bill Maisel, on strategies to expedite FDA approval while maintaining scientific rigor.

FDA Expert Commentary, April 2014



The New Food Labels: Information Clinicians Can Use

The FDA has proposed major updates to the Nutrition Facts label on packaged foods. What are the key changes that will help clinicians educate their patients about healthy food choices?

FDA Expert Interview, April 2014



FDA RESOURCES

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

Tobacco Regulation in the United States: ANA's Policy Work and FDA Authorities

November 17, 2016

Holly Carpenter, BSN, RN
Senior Policy Advisor
Nursing Practice and Work Environment

Susan Rudy, MSN, CRNP, CORLN
Health Scientist and Family NP
Office of Science/DIHS/MB
Center for Tobacco Products, FDA



Interviews



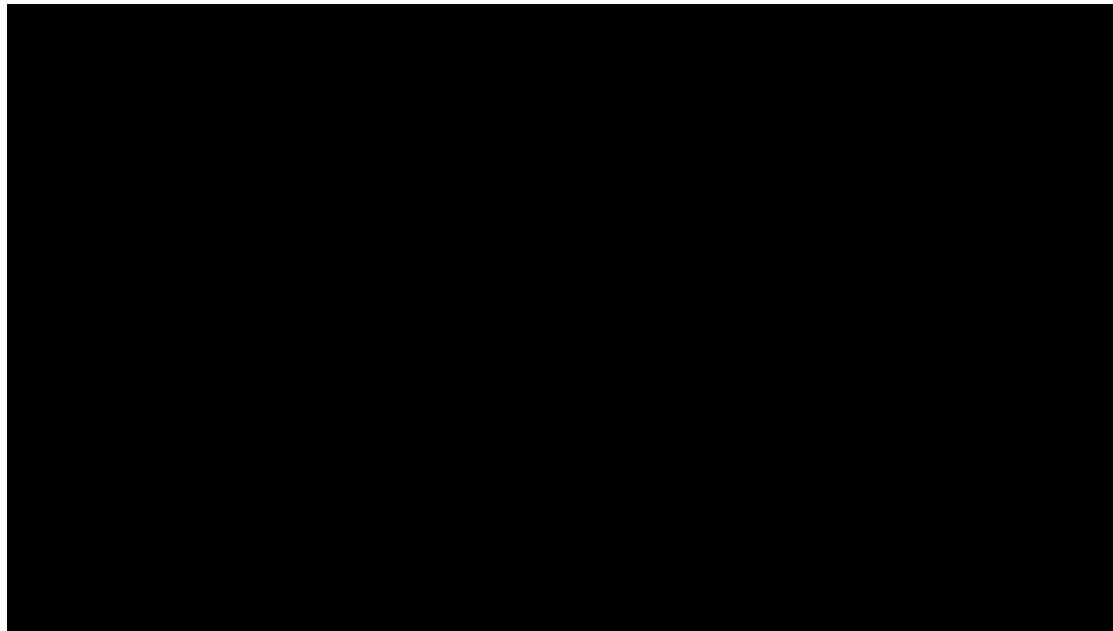
Does Your Patient Need Both an Opioid and Benzodiazepine?

<http://www.medscape.com/viewarticle/871284>

Featuring Dr. John Whyte, Director of Professional Affairs and Stakeholder Engagement, FDA Center for Drug Evaluation and Research, November 2016

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 is 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.



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.



IND Application

The sponsor submits an Investigational New Drug (IND) application to FDA based on the results from initial 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.

CLINICAL

Drug Sponsor's Clinical Studies/Trials



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.



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.



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'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.

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

POST-MARKETING

FDA's Post-Approval Risk Assessment Systems

Drug Labeling

10

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



Application Reviewed

8-9

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.



NDA Application

7

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.



Review Meeting

6

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.

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



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



Biologics



Combination Products



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



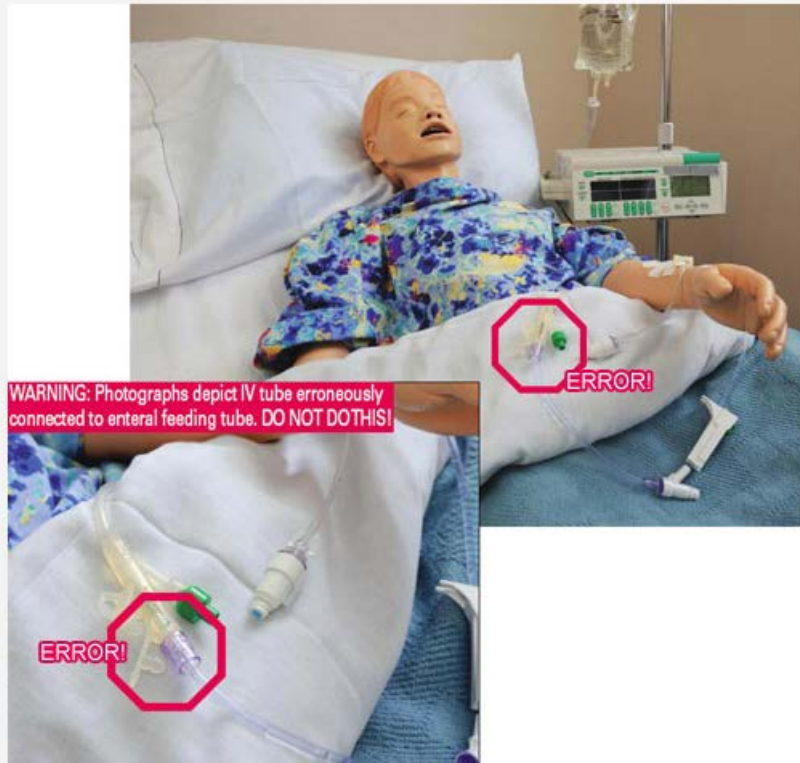
Combination Products



Special Nutritional Products

Reporting IN – Potential for Harm

IV tubing erroneously connected to enteral feeding tube



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

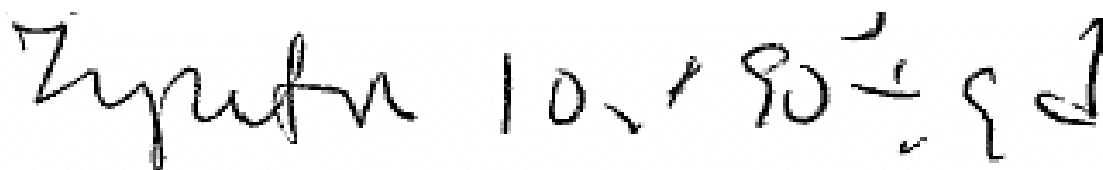
CASE STUDY

- 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

Potential Errors

- Prescribing
 - handwriting, abbreviations

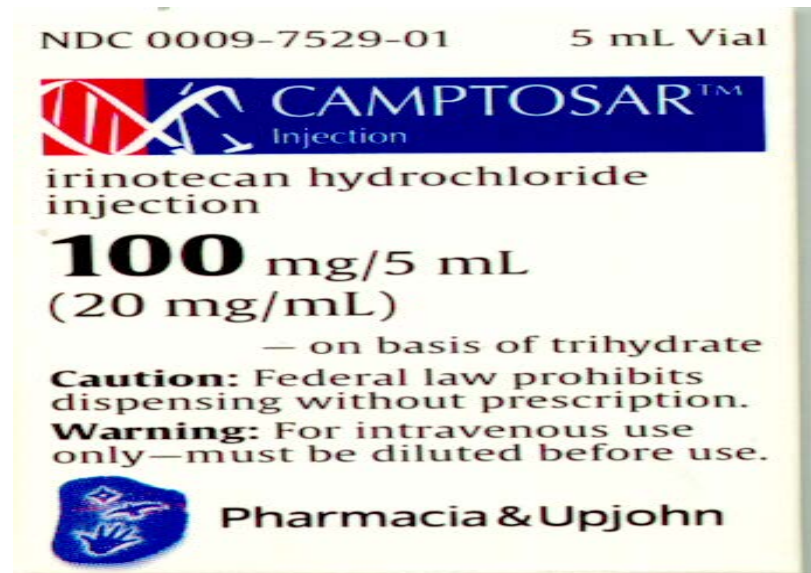


Handwritten prescription: Zyrtec 10mg/90mg qd

- 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

Consumer/Patient Form 3500B

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 3

Form Approved: OMB No. 0910-0291, Expires 6/30/2018
 See FRA statement on reverse.

FDA USE ONLY
 Usage unit sequence #

A. PATIENT INFORMATION

1. Patient's name: a. Age at time of event or Date of Birth: b. Sex: Male Female Other c. Weight: lb kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
 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 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

C. SUSPECT MEDICAL DEVICE

1. Brand Name
 2. Common Device Name
 3. Manufacturer Name, City and State
 4. Model # Lot # 5. Operator of Device Health Professional
 Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient
 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

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

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

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, please so "X" in this box:

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

Form Approved: OMB No. 0910-0291, Expires 6/30/2018
 See FRA statement on reverse.

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, or medical device incorrectly which could have led to or made use of the drug or medical device.
- You noticed a problem with the quality of the drug or medical device.
- You had problems with how a drug worked after waiting from one make to another make.
- You noticed a problem with how a drug worked after waiting from one make to another make.
- Vaccines - report problems to the Vaccine Adverse Event Reporting System (VAERS).
- Investigational drugs or medical devices (those being studied) - report problems to your doctor or to the sponsor of the study in the clinical trial.

Don't use this form to report:

- Events that are not related to the drug or medical device.
- Events that are not reported in the clinical trial.
- Events that are not reported in the clinical trial.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern because it makes the form a case as to you only.

We are strict and correct information so you should be able to make the form as private as possible.

- Your name and correct information will be shared with the manufacturer that makes the product and the FDA to help us investigate the problem.
- Your name and correct information will be shared with the manufacturer that makes the product and the FDA to help us investigate the problem.

What types of products do I report?

- Drugs, including prescription medicines, and over-the-counter medicines, and body supplements.
- Medical devices, including implants, contact lenses, hearing aids, and breast pumps.
- 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).

The manufacturer will be notified by the FDA and you will receive a letter from the FDA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

Form Approved: OMB No. 0910-0291, Expires 6/30/2018
 See FRA Statement on preceding general information page.

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
- 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)

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

For a problem with a product, including:

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

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 B

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

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

Form Approved OMB No. 0910-0291, Expires: 9/30/2016
See PRA statement on reverse.

MEDWATCH
FORM FDA 3500A (10/15)

Page 1 of 3

MR 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 _____

2. Age Year(s) Month(s) 3. Sex Male Female

4. Weight lb kg

5.a. Ethnicity (Check single best answer) Hispanic/Latino Black or African American White 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/manufacture)

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) _____

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)

D. SUSPECT MEDICAL DEVICE

1. Brand Name _____

2. Common Device Name _____ 2b. Procedure _____

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 Expanted, 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

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.

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



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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

Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Subscribe to MedWatch Safety Alerts

Safety Information

Reporting Serious Problems to FDA

Resources for You

- 2017 Safety Alerts for Human Medical Products
- 2016 Safety Alerts for Human Medical Products
- Contact Information For Voluntary Adverse Event Reporting
- MedWatchLearn - Teaching students, health professionals, and consumers how to report problems to FDA
- Medical Product Safety Educational Resources
- Consumer-Friendly Reporting Form 3500B (PDF - 1.2MB)

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

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Search the MedWatch Section

Your FDA gateway for clinically important safety information and reporting serious problems with human medical products.

Report a Problem | **Safety Information** | **Stay Informed**

What's New

- Vancomycin Hydrochloride for Injection, USP by Hospira: Recall - Particulate Matter in Vial Injected particulate may result in local swelling, irritation of blood vessels or tissue, blockage of blood vessels and/or low-level allergic response to the particulate. Posted 01/25/2017
- ED-3490TK Video Duodenoscope by Pentax: FDA Safety Communication - UPDATE - Follow Pentax Validated Reprocessing Instructions Updated recommendations to help prevent the spread of infection associated with the use of these devices. Posted 01/17/2017
- Lifepak 1000 Defibrillators by Physio-Control: Voluntary Field Action - Immediately Remove and Reinstall Battery Device has shut down unexpectedly during patient treatment, which may expose patients to the risk of serious harm or death. Posted 01/14/2017
- Duodenoscopes by Fujifilm Medical Systems: Safety Communication - Certain Older Models Removed From Clinical Use Fuji removing legacy 250/450 duodenoscope models from clinical use, replacing with with the ED-530XT model. Posted 01/13/2017

www.fda.gov/medwatch



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

How do I report?

- Online
 - Mail/Fax
 - By Phone
- 1-800-332-1088**

The screenshot shows the FDA MedWatch website. At the top, it says "U.S. Department of Health and Human Services" and "U.S. FOOD & DRUG ADMINISTRATION". There is a search bar and navigation tabs for various product categories. The main heading is "Safety" with a breadcrumb trail: "Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program".

On the left, there is a sidebar with a blue box titled "MedWatch The FDA Safety Information and Adverse Event Reporting Program". Below it are links to "Subscribe to MedWatch Safety Alerts", "Safety Information", and "Reporting Serious Problems to FDA". A blue arrow points from the "Reporting Serious Problems to FDA" link to the "Report a Problem" button in the main content area.

The main content area has a title "MedWatch: The FDA Safety Information and Adverse Event Reporting Program" and social media sharing options (SHARE, TWEET, LINKEDIN, PIN IT, EMAIL, PRINT). Below that is a search bar for the MedWatch section. A tagline reads: "Your FDA gateway for clinically important safety information and reporting serious problems with human medical products." Three buttons are visible: "Report a Problem" (red), "Safety Information" (blue), and "Stay Informed" (green).

At the bottom, there is a "Resources for You" section with links to safety alerts, teaching resources, and reporting forms. A "What's New" section lists recent recalls, including Halo One Thin-Walled Guiding Sheath, certain homeopathic teething products, and NucliSENS easyMAG and NucliSENS Magnetic Extraction Reagents.

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



Patient Identifier

Event or Problem

Reporter

Product

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
 Tragic Unit: _____
 FDA Rec. Date: _____

A. PATIENT INFORMATION
 1. Patient Identifier: _____
 2. Age: _____
 3. Sex: Male Female
 4. Weight: _____
 5.a. Ethnicity (Check single best answer): _____
 5.b. Race (Check all that apply): _____

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 Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events)
 Disability or Permanent Damage Congenital Anomaly/Birth Defects
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)
 3. Date of Event (dd-mmm-yyyy): _____
 5. Describe Event, Problem or Product Use Error: _____
 6. Relevant Tests/Laboratory Data, Including Dates: _____
 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.): _____

C. PRODUCT AVAILABLE
 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 #: _____

E. 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: _____

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

G. REPORTER (See continuation/question 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 Distribution/Importer
 5. If you do NOT want your identity disclosed to the manufacturer, please mark this box:

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.

PLEASE TYPE OR USE BLACK INK

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.

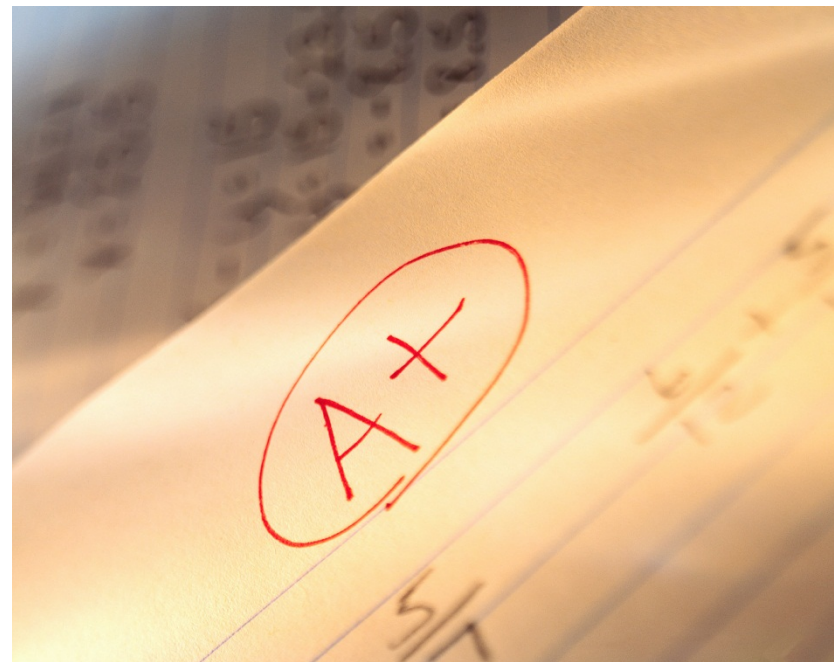
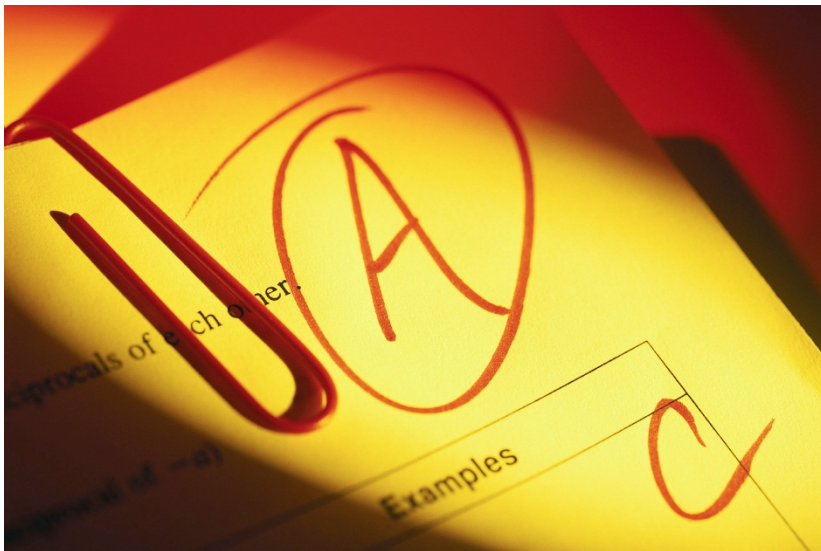
Question: Does Case #1 contain the four elements needed to file this report into the MedWatch database?

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

Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program

MedWatch The FDA Safety Information and Adverse Event Reporting Program

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- Consumer-Friendly Reporting Form 3500B (PDF - 1.2MB)

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

f SHARE t TWEET in LINKEDIN p PIN IT e EMAIL p PRINT

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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

[f 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 | العربية

English

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FDA

TWEETS 958 FOLLOWING 21 FOLLOWERS 34.3K LIKES 4 MOMENTS 0 [Edit profile](#)

US FDA MedWatch @FDAMedWatch
Clinically important safety information on human medical products from FDA.
Comments: MedWatchComments@fda.hhs.gov
Privacy: fda.gov/privacy
Silver Spring, MD
fda.gov/medwatch
Joined October 2010

Who to follow · Refresh · View all

- Million Hearts** @Millio...
Followed by FDA Minority H...
[Follow](#)
- NatHispCouncilAging** @N...
Followed by FDA Minority H...
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Find friends

Trends · Change

- #FreezerDig**
Win a year of never-frozen hamburgers. Freezerdig.com #Sweepstakes
Promoted by Wendy's
- Janet Reno**
Janet Reno, first female U.S. attorney general, has died

Tweets Tweets & replies Media

- US FDA MedWatch** @FDAMedWatch · Oct 28
HeartWare Ventricular Assist Device Pumps by HeartWare Inc: Class I Recall, Loose Connectors May Prevent Alarm
go.usa.gov/xkH2A
- US FDA MedWatch** @FDAMedWatch · Oct 26
TAH-t Companion 2 Driver System (C2) & Freedom Driver System by SynCardia Systems: Letter to Health Care Providers
go.usa.gov/xkAYZ
- US FDA MedWatch** @FDAMedWatch · Oct 25
Testosterone and Other Anabolic Androgenic Steroids (AAS): FDA Statement - Risks Associated w/ Abuse and Dependence
go.usa.gov/xkG4E
- US FDA MedWatch** @FDAMedWatch · Oct 25
HVAD Pumps by HeartWare Inc. : Class I Recall - Contamination Causing Electrical Issues
go.usa.gov/xkfGJ #FDA
- US FDA MedWatch** @FDAMedWatch · Oct 20
Willy Rusch Tracheostomy Tube Set by TeleFlex Medical: Class I Recall - Possible Disconnection During Patient Use
go.usa.gov/xkvzv
- US FDA MedWatch** @FDAMedWatch · Oct 20
Radiation Therapy Devices by Multidata Systems International: Discontinue Use, Concerns About Risks to Patients
go.usa.gov/xkvHC

FDA Case Studies

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' 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.

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

- Preparing Students:** Students are expected to read the case study prior to the training session.
- Engaging Students:** The training session should consist of a discussion of the case study and completion of a MedWatch form.
- 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:

- MedWatch Homepage
<http://www.fda.gov/Safety/MedWatch/default.htm>

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

Answer the following questions before class:

- 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.
- 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).

- Good case reports include the following elements:

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

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

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 walk, the steady and practiced steps of his chief resident, Dr. Andrea Nash, barel 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

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

- Preparing Students:** Students are expected to read the case study prior to the training session.
- Engaging Students:** The training session should consist of a discussion of the case study.
- 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:

- Drugs@FDA
<http://www.accessdata.fda.gov/scripts/cder/drugsatda/index.cfm>
- FDA Advisory Committee <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm>
- REMS@FDA
<http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>
- Drug Shortages Program <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/>

Answer the following questions before class:

- 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.

- 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

Reporting Tutorial – MedWatchLearn

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

The screenshot shows the FDA MedWatchLearn website. At the top, there is a dark blue header with the U.S. Department of Health & Human Services logo on the left, the FDA logo and text "U.S. Food and Drug Administration Protecting and Promoting Your Health" in the center, and the MedWatch logo on the right. Below the header, the "MEDWATCHLEARN" title is prominently displayed. The main content area includes a paragraph explaining that the site teaches students, health professionals, and consumers how to complete forms for reporting problems to the FDA. It mentions "FDA Form 3500" for health professionals and "FDA Form 3500B" for consumers. Below this text are two buttons: a blue button for "Students and Health Professionals (FDA Form 3500)" and a green button for "Consumers (FDA Form 3500B)". At the bottom of the page, there is a note about browser compatibility and a page update date of 05/29/2013.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

Food and Drug Administration
MEDWATCH

MEDWATCHLEARN

FDA **MedWatchLearn** teaches students, health professionals, and consumers how to complete the forms necessary to report problems to FDA. Here, you have the opportunity to practice filling out **FDA Form 3500** (for health professionals) or **FDA Form 3500B** (for consumers).

Learn more about MedWatch medical product safety or submit an actual report.

To start, select either "Students and Health Professionals" or "Consumers."

Students and Health Professionals
(FDA Form 3500)

Consumers
(FDA Form 3500B)

This site performs best with Internet Explorer 9 or higher, or recent versions of Firefox, Safari, and Chrome web browsers. If you experience problems viewing or printing pages, try updating your browser to the latest available version.

Page Last Updated: 05/29/2013
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
MedWatchLearn v1.0

Reporting Tutorial - MedWatch Learn

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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

MEDWATCHLEARN

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Students and Health Professionals
(FDA Form 3500)



Consumers
(FDA Form 3500B)

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MedWatchLearn v1.0

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

MEDWATCHLEARN
Students and Health Professionals

We provided case studies for the four categories of problems with medical products. You will have an opportunity to practice completing FDA Form 3500, our voluntary reporting form for health professionals, using these case studies. We encourage you to also become familiar with our form for consumers, FDA Form 3500B, and educate your patients on reporting adverse events.

These case studies are based on actual reports received by the FDA and selected for this portal because of the quality of the report. Personally identifiable information has been changed to maintain confidentiality. To begin, click on one of the case studies.

NOTE: This is a training site; therefore, reports you complete will not be saved and submitted to FDA. To submit an actual report, go to the MedWatch Online Voluntary Reporting page.

- Adverse Effects**
Any incident in which a medical product was suspected to have resulted in an undesirable experience for the patient.
 - Case Study 1 – Drug
 - Case Study 2 – Biologic Product
 - Case Study 3 – Medical Food
 - Case Study 4 – Dietary Supplement
- Product Use Error**
Any medication or medical product error regardless of patient involvement and outcome report circumstances that have the capacity to cause error, such as similar label appearance.
 - Case Study 1 – Human Factors
 - Case Study 2 – Medication Error
- Product Problem**
Any concerns about the quality, authenticity, performance, or safety of any medication or device.
 - Case Study 1 – Drug
 - Case Study 2 – Device
- Problem with Different Manufacturer of Same Medicine**
Any differences in therapeutic response after switching from one manufacturer to another.
 - Case Study 1 – Therapeutic Failure

Page Last Updated: 05/13/2013
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

FDA Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No Fear Act | Site Map | Transparency | Website Policies



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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