FDA’s MedWatch Adverse Event Reporting Program - Opportunities to Collaborate -

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Office of Health and Constituent Affairs
Office of External Affairs
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Today’s Presentation

- About FDA Public Health Mission
- About the MedWatch Program
- Ways to Engage with FDA
- Challenges to Meaningful Engagement
FDA’s Public Health Mission

- Ensure the safety, effectiveness, and security of human and animal drugs, biological products and medical devices
- Ensure the safety of foods, cosmetics, and radiation-emitting products
- Regulate tobacco products
FDA Regulates $2.4 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 sunscreen
go grocery shopping
get a flu shot or a mammogram....

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

Approximately 20 cents on every dollar spent in the U.S.
FDA’s Oversight Responsibilities

→ 75% of U.S. food supply
→ 300,000 registered facilities, more than 80% of them abroad
→ Over 17,000 prescription drug products
→ Over 6,000 categories of medical devices

→ Over 320 FDA-licensed biologic products
→ Over 4,500 currently regulated tobacco products
What is MedWatch?

1. A way to send information you observe or experience from regulated medical products to FDA
2. A way to stay up-to-date on recently reported safety information from FDA

www.fda.gov/medwatch
Who Can Report to MedWatch?

Healthcare Professionals  Consumers and Patients

https://www.fda.gov/Safety/MedWatch/default.htm or https://go.usa.gov/xnuQy
Why Report to MedWatch?

“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
Why Report to MedWatch?

- Not all products have clinical data/trials before clearance to market
- Limitations of clinical trials to identify safety signals before marketing
- Number of patients tested may be too small to detect serious but rare problems
- Trials are brief
MedWatch: Safety Information

One person can make a difference
Safety Alerts will update you on new information about:

- Drugs and Therapeutic Biologics
- Medical devices
- Nutritional products
- Cosmetics
- Products with undeclared drugs
- Tobacco
MedWatch - What to Report

- Serious events such as:
  - death
  - life-threatening
  - permanently disabling
  - prolongs hospitalization
  - birth defect
  - Requires intervention to prevent permanent impairment or damage
- Medication errors
- Product quality problems
- Potential for error
- Non-serious events
Potential 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.

**WARNING:** Photographs depict IV tube erroneously connected to enteral feeding tube. DO NOT DO THIS!
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 - What Not to Report

- Tobacco Products
- Vaccines
- Investigational Drugs
- Dietary Supplements
- Veterinary Medicine
How to Report to MedWatch?

Clinician Form 3500

Consumer/Patient Form 3500B
How to Report to MedWatch?

Online Voluntary Report
MedWatch Form

- **Patient Identifier**
- **Event or Problem**
- **Reporter**
- **Product**
Quality is Key: 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?

YES

NO
Quality is Key: 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.
MedWatch Reporting - MANDATORY

MANDATORY Form 3500A
- User Facilities (medical devices)
- Manufacturers
  - Drugs
  - Biologics
  - Human Cell and Tissue Products
  - OTC Products
  - Medical Devices
Reporting Tutorial – MedWatchLearn

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

www.fda.gov/medwatchlearn
Reporting Tutorial - MedWatch Learn

MedWatchLearn teaches students, health professionals, and consumers how to complete the forms necessary to report a medical event or a side effect of a medical product. 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.”

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

Page Last Updated: 05/23/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
What happens to my report?

Did you see it??
MedWatch: Safety Information IN

**L-citrulline investigation 2014**

- Late January
  - Puzzling case at medical center
- February 7
  - Pharmacist submits report
  - Mother submits report
- February 7-13
  - FDA investigation
- February 14
  - Manufacturer recall
  - MedWatch Safety Alert communication

*FDA Healthcare Professionals in Action*
Safety Info Out
Safety Information

Possible FDA Actions

- Request Labeling Changes
- Enhance Education
- Send Safety Alert
- Request Removal from Market
- Pharmacovigilance More Studies or New Trials
- Request Change to Design, Packaging, Manufacturing
- Request Medication Guide
Lidocaine Viscous: Drug Safety Communication - Boxed Warning Required - Should Not Be Used to Treat Teething Pain

**ISSUE:** FDA notified health professionals, their provider organizations and caregivers for infants, that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain. FDA is requiring a Boxed Warning to be added to the prescribing information (label) to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death.

Topical pain relievers and medications that are rubbed on the gums are not necessary or even useful because they wash out of the baby's mouth when they are swallowed. Given too much viscous lidocaine is given to infants and young children or they accidently swallow it, it can result in seizures, severe brain injury, and problems with the heart. Cases of overdose due to withdrawal of accidental ingestion have resulted in infants and children being hospitalized or dying.

**BACKGROUND:** In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children 5 months to 3.5 years of age who were given oral viscous lidocaine 2 percent solution for the treatment of mouth pain, including teething and stomatitis, or who had accidental ingestions. See further details in the FDA Drug Safety Communication.

**RECOMMENDATION:** Health care professionals should not prescribe or recommend this product for teething pain. Parents and caregivers should follow the American Academy of Pediatrics’ recommendations for treating teething pain.

- Use a teething ring chilled in the refrigerator (not frozen).
- Gently rub or massage the child’s gums with your finger to relieve the symptoms.

FDA is also encouraging parents and caregivers not to use topical medications for teething pain that are available over the counter (OTC) because some of them can be harmful. FDA recommends following the American Academy of Pediatrics’ recommendations to help lessen teething pain.
Hydromorphone HCL Injection USP by Hospira: Recall - Potential For Empty Or Cracked Glass Vials

[Posted 03/05/2016]

AUDIENCE: Pharmacy, Risk Manager

ISSUE: Hospira is voluntarily recalling three lots of Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials lot numbers 7139DD (NDC 0409-2634-01), and 691859F and 700759F (NDC 0703-0110-01 – Teva lots) to the hospital/institution level. Hospira initiated this recall on February 07, 2016 due to the potential for empty or cracked at the bottom of the glass vial.

Cracked vials may compromise the sterility of the product. Use of or exposure to cracked units may be associated with adverse events such as sharps injury to healthcare professionals. Intravenous infusion of a non-sterile solution can lead to bloodstream infections, which may potentially lead to bacteremia or sepsis. These infections are of concern especially to immunocompromised patients.

BACKGROUND: Hydromorphone HCl is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. It is also indicated for use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials, is packaged in a carton of 10 x 1 mL Single-dose vials. The affected lots include the following NDC, lot numbers and expiry dates. Product was distributed nationwide to wholesalers/distributors/retailers/hospitals in the United States and Puerto Rico from October 2016 to July 2017.

RECOMMENDATION: Hospira, Inc. has notified wholesalers/distributors/retailers/hospitals by recall letter to arrange for return of any recalled product. Wholesalers/distributors/retailers/hospitals with an existing inventory of the lots subject to this recall should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall. If you have further questions, please contact Hospira, Inc. at 1-800-747-3831.

[Contact Information]

For more information, please visit the Medwatch website at MedWatch.gov or call 1-800-FDA-1088.
How Do I Stay Informed?

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

To subscribe, E-mail us at MedWatchSafetyAlerts@fda.hhs.gov

www.fda.gov/medwatch
Ways to Get Involved With FDA

SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

Search Regulations.gov

High doses of loperamide can cause serious cardiac events

DrugSafety

Search

Drugsafety.gov

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Professional Publications

Hospital Pharmacy
doi: 10.1310/hp5202-153

Summaries of Safety Labeling Changes Approved by the FDA: Boxed Warning Highlights October - December 2016
Brenda J. Rose, PharmD

Abstract
The FDA’s MedWatch program safety labeling changes for boxed warnings are compiled for biologic, biopharmaceutical, and therapeutic biologics where important changes have been made to the safety information. Drug Safety Labeling Changes (SLC) database was conducted on December 31, 2016 for the “10/1/2016-12/31/2016”, labeling section “Boxed Warning”. These and other label changes are available on the Drug Safety Labeling Changes (SLC) database, where data are available to the public in machine-readable and searchable formats. (Drug Safety Labeling Changes are available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugSafetyandavailability/ucm109672.htm)

Boxed warnings are ordinarily used to highlight either: adverse reactions so serious that there is a potential benefit from the drug that it is essential that it be considered in assessing the risks and benefits of using the drug; OR serious adverse reactions that can be prevented or reduced in frequency or severity by specific use of the drug; OR serious contraindications to use of the drug; OR serious data deficiencies which may lead to FDA’s conclusion that the drug can be safely used only if distribution or use is restricted.
FDA Case Studies

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.

Drugs, Devices, & Biologics: Health professionals encounter adverse events with medical products and learn about reporting to FDA MedWatch

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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. Still, he couldn’t help but wonder if his residency, workouts, and presentations on the latest advances in medicine and, most importantly, the resulting 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 braced himself when he saw the doctor’s name on the chart. It was a familiar one, but the patient’s face was new.

"Hello, Chris. How are you today?" Jim asked, shaking the young man’s hand. "I’m doing well, thanks for asking. I’m a first year resident and I’ve just finished my morning rounds."

"I’m glad to hear that," Jim replied. "What can I do for you?"

"I’m looking for some advice," Chris said. "I’ve been having some trouble with my ears."

"Let’s take a look," Jim said. "I’ll see what I can do.

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

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

LEARNING OBJECTIVES

- Identify how to receive information about the FDA.
- Cite the importance of reporting adverse events to the FDA.
- Explain how to report adverse events using the FDA MedWatch system.

SUGGESTED APPROACHES

1. Introduce the course material by having students review the case study.
2. After reviewing the case, discuss the importance of reporting adverse events.

LEARNING ACTIVITIES

- Review the case study.
- Discuss the importance of reporting adverse events.

STUDENT ACTIVITIES

- Students should complete the case study.

FDA Drug Information Curriculum Case Study: Instructor’s Guide

LEARNING OBJECTIVES

- Identify an online resource for FDA’s drug review process.
- Describe the importance of reporting adverse events.

SUGGESTED APPROACHES

1. Introduce the course material by having students review the case study.
2. After reviewing the case, discuss the importance of reporting adverse events.

LEARNING ACTIVITIES

- Review the case study.
- Discuss the importance of reporting adverse events.

STUDENT ACTIVITIES

- Students should complete the case study.

The following webstis are available:

1. Drugs@FDA
2. FDA Adverse Event Reporting
3. REMS@FDA
4. Drug Safety Program

Answer the following question before class:

1. What is the purpose of the case study?

Answer: The purpose of the case study is to increase awareness of the importance of reporting adverse events to the FDA.
Information for Health Professionals

- Healthcare Professional Network
- Bi-weekly Email Newsletter
- MedWatch
- Webinars and Education
- Disease Specific Email Updates
Information for Patients

- FDA Patient Network
- Bi-weekly Email Newsletter
- Website
- Webinars & In-person Meeting’s
- Disease Specific Email Updates
- Twitter
Updates for Health Professionals
from the FDA Office of Health and Constituency Services

February 21, 2018

ANNOUNCEMENTS

FDA issued a final rule titled “Human Subject Protection: Acceptance of Data from Clinical Investigational Devices.” The rule updates the FDA’s standards for accepting clinical data from medical device studies in the United States to support a device research or marketing application or submission, including 510(k), IDE, or premarket approval.

Statement on advancing the development of novel treatments for neurological conditions

New medical breakthroughs are altering how diseases are treated in ways that seem science fiction. Perhaps one of the most significant developments is the advent of new gene therapies, which identify the underlying genetic cause of a disease and seek to repair, replace, or mute faulty genes. These efforts are expanding our understanding of how genetic defects lead to disease and have the potential of curing severe or life-threatening conditions.

Statement on Administration’s request for new FDA funding to promote innovation and competition

New scientific opportunities, as well as advances in manufacturing and commerce, give the FDA new opportunities to make investments that will help the agency protect patients and promote public health. Leveraging these opportunities requires us to make investments in our own mission to protect and promote public health. 

Recall: Bella Diet Capsules by Bella All Natural – Presence of Sibutramine

This recall has been initiated due to presence of sibutramine in Bella Diet Capsules. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010 due to safety concerns. N-Desmethyl sibutramine is an active metabolite of sibutramine. It is possible that some patients may present significant health risks including heart attack, arrhythmia, and stroke.

Class I Recall: Cardiac Resynchronization Therapy with Defibrillation (CRT-Ds) and Implantable Cardioverter-Defibrillators (ICDs) by Medtronic

Manufacturing Error Preventing Electrical Shock Delivery Delay or inability to deliver shock may cause a patient’s heart whose heartbeat is too slow or irregular to receive the electrical shock that is needed to allow the patient to continue to live. In rare cases, the patient’s heart may stop. This type of defect is related to problems with a chip on the device that was manufactured by a single supplier.

Medical Product Safety

February 28, 2018

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FDA Patient Representative Program

- Began in 1990s
- Patients having an active role on FDA Advisory Committees and consultations with review divisions
- Patient voice represented in important discussions about regulatory decision-making
- Presence at the table
- 200 Patient Representatives, over 300 diseases/conditions
Submit Comments Through the Federal Register
Participate in an FDA Sponsored Public Meeting

In this section you will find a comprehensive list of all the meetings that the FDA is sponsoring, including meetings on a variety of topics. The meetings may include advisory committee meetings, public workshops, and public hearings. Most FDA meetings are open to the public and do not require prior registration. Other types of meetings listed may require prior registration or have specific requirements.

Advisory Committee Meeting: Risk Communication
Date: March 8, 2018, 8:00 am to 5:00 pm
Location: FDA White Oak Campus, Great Room, 10301 New Hampshire Avenue, Silver Spring, MD
Agenda: On March 8 and 9, 2018, the committee will discuss issues related to risk communication in the context of new drugs and biological products, including issues related to risk communication for products that require changes to labeling. The meeting will also include discussions on the impact of different risk communication strategies on public perception and behavior.

Advisory Committee Meeting: Risk Communication
Date: March 6, 2018, 9:00 am to 12:30 pm
Location: FDA White Oak Campus, Great Room, 10301 New Hampshire Avenue, Silver Spring, MD
Agenda: On March 6 and 7, 2018, the committee will discuss issues related to risk communication in the context of new drugs and biological products, including issues related to risk communication for products that require changes to labeling. The meeting will also include discussions on the impact of different risk communication strategies on public perception and behavior.

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Information for Health Professionals and Patients

Clinical Trials: What Patients Need to Know

Learn more about clinical trials and find a trial that might be right for you. Clinical trials are voluntary research studies conducted in people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other products, or new ways of using existing treatments. It is important to remember that the FDA does not conduct Clinical Trials.

Search for a Clinical Trial

Enter a word or phrase, such as the name of a medical condition or intervention. Example: Cancer AND Los Angeles or expanded access AND compassionate use

Search

Learn More About Clinical Trials

Clinical Research Versus Medical Treatment

Understand the differences between clinical research and medical treatment and what those differences mean for you. Find answers to your questions about clinical trials, such as why they are done, who should participate, and issues to consider before joining a trial.

What are the Different Types of Clinical Research?

Understand the different types of research and the role each plays in testing new treatments. For example, a single-center clinical trial conducted in the United States or an open-label trial conducted in Australia.

Informed Consent for Clinical Trials

Understand what informed consent is and the questions you need to know before signing informed consent.

Deciding on Clinical Trial Participation

It is important to test drugs and medical products in the people they are meant to help. Learn about FDA.gov and how FDA works to ensure that drugs are safe and effective for the people they are intended to treat.

What is Institutional Review Board?

Understand what Institutional Review Boards are, who is on them, and what they do.

On Spanish

Investigaciones Clínicas: ¿Qué Debe Saber un Paciente

Cómo encontrar una Investigación Clínica

Ingresar una palabra o frase, como el nombre de una condición médica o intervención. Ejemplo: Cáncer AND Los Ángeles o acceso ampliado AND compasión de uso

Buscar

Aprender más sobre Investigaciones Clínicas

Investigación Clínica vs Tratamiento Médico

Entender las diferencias entre la investigación clínica y el tratamiento médico y qué significan esas diferencias para usted. Encuentre respuestas a sus preguntas sobre las investigaciones clínicas, como por qué se realizan, a quiénes debería participar, y los problemas que podría realizar antes de unirse a una investigación.

¿Qué son los diferentes tipos de investigación clínica?

Entender los diferentes tipos de investigación y el papel que cada uno desempeña en el desarrollo de nuevos tratamientos. Por ejemplo, una investigación clínica de un solo centro realizada en los Estados Unidos o una investigación abierta realizada en Australia.

Consentimiento Informado para Investigaciones Clínicas

Entender qué es el consentimiento informado y las preguntas que necesita saber antes de firmar el consentimiento informado.

Decidir sobre la participación en una Investigación Clínica

Es importante probar medicamentos y productos médicos para las personas a las que están destinados para ayudar. Conozca sobre la FDA.gov y cómo la FDA trabaja para asegurar que los medicamentos sean seguros y efectivos para las personas a las que están destinados a tratar.

¿Qué es el Comité de Investigación Institucional?

Entender qué son los Comités de Investigación Institucionales, quiénes son, y qué hacen.
Information for Health Professionals and Patients

Learn About Expanded Access and Other Treatment Options

When a patient does not respond to current approved treatments or a severe or life-threatening condition exists, some patients may want to talk to their healthcare providers about trying an investigational drug. An investigational drug is one that is not approved for a particular use. Information about expanded access to investigational drugs is available on the FDA-approved drug label. This label usually includes a discussion of planned research use of an investigational drug as well as information about the drug that is used for a different purpose than what is based on the FDA-approved drug label (this is also called "over-labeling").

Understanding Unapproved Use of Approved Drugs "Off Label"

Has your healthcare provider ever talked to you about using an FDA-approved drug for a condition not approved by the FDA? This is called "off-label" use. It is important to know that because a drug can be approved by the FDA for a specific use or condition, it does not mean the drug has no side effects. However, the drug has been determined by the manufacturer to be safe and effective for its intended uses. "Safe and effective" does not mean that the drug has no side effects. Although it is not clear how the drug will work in your condition, it is important to talk with your healthcare provider about the benefits and risks of using this drug for your condition.

Understanding Investigational Drug Use

As your healthcare provider, we may discuss the use of investigational drugs in the treatment of your disease. Investigational drugs are drugs or biological products that are not yet approved by the FDA for use in the United States. The use of investigational drugs is regulated by the FDA.

Understanding Expansive Compassionate Use

Information about FDA's Compassionate Use Program (also called the Expanded Access Program) is available on the FDA-approved drug label. This program allows patients to receive investigational drugs in an emergency situation. Information about the drug and the patient's condition is provided to the FDA. The patient's healthcare provider can make decisions about the use of the drug in the patient's best interests.

Why might an approved drug be used for an unapproved use?

From the FDA perspective, once the FDA approves a drug, health care providers generally may prescribe the drug for any use they believe will benefit their patient. You may be asking yourself why your healthcare provider would want to prescribe an approved drug for an unapproved use? The answer is that there may be no other approved drug that is known to treat your condition or is not available. Another reason is the patient's disease or condition may respond to the drug in a way that has not been studied. In situations like these, you and your healthcare provider may agree to use the drug for an unapproved use to treat your disease or condition.
Watch Webinars Led by FDA Experts

Listen to Webinars and View Presentations Given by FDA Experts

Through our webinars and presentations, the Office of Health and Constituent Affairs brings information to you on many topics related to patient engagement, medical product (Drugs, Biologics, Devices) approval and medical product safety updates.

You can listen to past webinars or view recent presentations from FDA experts. It is as easy as downloading the presentations, watching the webinar, and reading the transcript.

If you would like to talk with the Office of Health and Constituent Affairs about ways your organization can engage with the FDA or if you have suggestions for future webinars, please email the Patient Network at patientwork@fda.hhs.gov

Webinar Library

2018 - 2014
2016 - 2014
2013 - 2012
2011 - 2010
2009 - 2008

2018
Sentinel Initiative and Sentinel Engagement Partners Workgroup
February 1, 2018
Presenter:
Learn How Medical Products are Developed and Approved
Disease Specific Email Updates

CardioBeat
from the FDA Office of Health and Constituent Affairs

Diabetes Monitor
from the FDA Office of Health and Constituent Affairs

Hepatitis Updates
from the FDA Office of Health and Constituent Affairs

HIV Email Updates
from the FDA Office of Health and Constituent Affairs
FDA Facebook and Twitter
Center for Drug Evaluation and Research

DRUG TRIALS SNAPSHOTs

Center for Tobacco Products

Public Health Education

Health Information
- Access the latest health information, including resources from our federal partners.
- Tips to Help Avoid Vape Battery Explosions
- Chemicals in Cigarettes: From Plant to Product to Pull
- Learn about tobacco-related health facts

Public Education Campaigns
We are investing in a number of public education campaigns, such as The Real Cost, Fresh Empire, and This Free Life to help educate the public—especially youth—about the dangers of regulated tobacco products. Related in science, these efforts are directly linked to our authority to regulate the marketing and sales of tobacco products.

Center for Devices and Radiological Health

Consumers (Medical Devices)

- Introduction
- What is a Medical Device?
- How are Devices Classified?
- How are Medical Devices Regulated in the United States?
- What is the Difference Between Cleared and Approved?
- How do I report a problem with a Medical Device?
- Contact CDRH

The Food and Drug Administration (FDA) assures that patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices. In addition, it provides consumers, patients, caregivers, and healthcare providers with understandable and accessible science-based information about the products it oversees.

In order to understand medical devices, it is important to understand what a medical device is and how the FDA classifies medical devices.

What is a Medical Device?
A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:
- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
Memoranda of Understanding

FDA Memoranda of Understanding

Overview

A memorandum of understanding (MOU) is a formal agreement between the Food and Drug Administration (FDA) and federal, state, or local government agencies, academic institutions, and other entities. The MOU establishes an understanding between the parties to a non-binding agreement. It is FDA's policy to enter into MOUs with entities whenever there is a need to confer levels of authority or responsibility or to clarify cooperative procedures. The spirit of the MOU is to improve consumer protection through effective use of collaborative resources and to eliminate duplication of effort.

FDA and Medscape

FDA Expert Commentary and Interview Series on Medscape

As part of the continuing collaboration between FDA and Medscape®, a series of interviews and commentaries are available to communicate important safety information to clinicians. Featuring FDA experts, these original commentaries cover 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.

Interviews

Postmarket Drug Safety: The View From the FDA

http://www.medscape.com/viewarticle/880216_1

Featuring Gerald Dai Pan, MD, MPH, Director, Office of Surveillance and Epidemiology, FDA Center for Drug Evaluation and Research, May 2017

Does Your Patient Need Both an Opioid and Benzodiazepine?


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

The Focus on Orphan Disease R&D at FDA


Featuring Dr. John Whyte, Director of Professional Affairs and Stakeholder Engagement, Office of Orphan Products Development, FDA Center for Drug Evaluation and Research, October 2016
Why is the Patient/Health Professional Voice Important?

- Provide insight on issues, problems, and/or questions that are important to patients and health professionals
- Both patients and health professionals have a vested interest in improving health
- Varied perspectives, both in terms of associated risk tolerance and perceived potential benefit
- The human element (judgment vs. empirical data)
What Value Might Be Added by Community Engagement?

- Faster recruitment and improved retention in trials
- Reducing the time for product development
- Cutting cost of drug development
- Help develop meaningful endpoints and measurements
- Medical products that better reflect outcome and quality of life measures most important to patients
Challenges to meaningful engagement

- **Understanding of trial design** (meaningful endpoints and data, measuring outcome, control arms)
- **Understanding the regulatory framework** standards, and requirements (level of evidence)
- **Legal and practical limitations** facing sponsors (promotion v. education and engagement)
- **Division** within patient communities and healthcare professional organizations
- **Different objectives** or agendas among organizations
- **Disagreement** on meaningful measurement
Testing Your Knowledge!
What is FDA’s Public Health Mission?

Ensure the ________, ____________, and _________of human and animal drugs, biological products and medical devices

a. Safety, effectiveness and security
b. Accuracy, effectiveness, and purity
c. Timelines, reliability and security
Who can report adverse events to the MedWatch Program?

a. Healthcare professionals
b. Patients
c. Consumers
d. Industry/Pharmaceutical Companies
e. All of the above
How can MedWatch reports result in improved product safety?

a. By updating the product label.
b. Requiring a medication guide.
c. Requesting a product to be removed from the market.
d. a and b
e. All of the above
How can you be involved in the FDA decision making process?

a. Attend an FDA Advisory Committee meeting.
b. Attend a protest at the FDA.
c. Participate in webinars and workshops hosted by FDA experts.
d. a and c
e. All of the above
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
Thank you

QUESTIONS

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