

# FDA Office of Health and Constituent Affairs- Collaborating with FDA



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

FDA Office of Health and Constituent Affairs

October 6, 2016



# Presentation Overview

- Introduce the FDA Office of Health and Constituent Affairs (OHCA)
- Share examples of collaborations to advance FDA messages
- How you can engage with FDA

# FDA Regulates Over \$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.





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Tobacco  
Products**



**Office of  
Regulatory  
Affairs**



# Office of Health and Constituent Affairs



OHCA works to help patients, patient advocates, and their healthcare professionals connect with FDA science and policy staff.

# Collaboration and Engagement Examples

- Webinars
- Publishing
- Memorandum of Understanding
- MedWatch





# Advance our Reach *through* Webinars

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Webinar Series

Collaborating With the FDA to Manage Drug Shortages

**AACN Critical Care Webinar Series**

**Presented by: Capt. Joughayna 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 Joughayna 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.

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A Joint Commission/FDA Webinar on Reprocessing of Scopes

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NAHN National Association of Hispanic Nurses® is a non-profit professional association committed to the promotion of the professionalism and dedication of Hispanic nurses by providing equal access to educational, professional, and economic opportunities for Hispanic nurses.

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

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2016 NAHN Annual Conference  
July 12-15, 2016  
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**NAHN News**

CONTACT: Celia Besore, MBA, CAE, Executive Director/CEO  
National Association of Hispanic Nurses, (501) 367-8616  
[director@thehispanicnurses.org](mailto:director@thehispanicnurses.org)  
[www.nahnnet.org](http://www.nahnnet.org)

For immediate release:

**FDA MedWatch Adverse Event Reporting Program and Introduction to Post-marketing Drug Safety Surveillance**

Washington, DC (January 15, 2015) — Please join us on Tuesday, February 10, 2015 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 and analyzed by FDA/CDER/DPV.

Presenters: Teresa Rubio, 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/6222891606279511234>  
Webinar ID: 126-378-211.

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!

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For more information regarding contact hours, please call  
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RENEW YOUR MEMBERSHIP  
APhA CORPORATE SUPPORTERS

**Wholesale drug distribution: Pharmacists should know their source of drugs**

November 01, 2014  
*FDA offers tips, reminders for frontline pharmacists*

Wholesale drug distributors are a link between manufacturers and pharmacists. Their role is to ensure prescription medications are delivered safely and efficiently every day to thousands of health care practitioners and pharmacies nationwide.

While the U.S. health care supply chain is one of the most secure and sophisticated in the world, the network of rogue wholesale drug distributors is selling potentially unsafe drugs in the U.S. market.

Counterfeit, adulterated, and unapproved medicines are sold or rogued wholesale drug distributors and are of major concern. FDA pharmacists who purchase prescription drug products to know their source of drugs.

**Buyer beware**  
FDA offers these tips and reminders for pharmacists:

**75 OFF**  
Beware of Offers Too Good to be True

Manufacturer → Drug Distributor → Pharmacy → Patient



**News**

## Summaries of Safety Labeling Changes Approved By FDA—Boxed Warnings Highlights April–June 2015

As part of FDA's MedWatch program, important changes to the safety labeling of drugs and therapeutic biologics, including boxed warnings, are posted on the agency's website. 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.<sup>1</sup> The following revisions to seven boxed warnings were implemented in the three months ending June 2015.

**Pomalyst (pomalidomide) Capsules**  
*Edited Boxed Warning (truncated to show changes)*

Pomalyst Boxed Warning updated as of April 2015 (truncated)	Pomalyst Previous Boxed Warning (truncated)
<b>Venous and Arterial Thromboembolism</b> ... Thromboprophylaxis is recommended and the choice of regimen should be based on assessment of the patient's underlying risk factors.	<b>Venous Thromboembolism</b> ... Consider prophylactic measures after assessing an individual patient's underlying risk factors.

**Sporanox (itraconazole) Oral Solution and Capsules**  
*Edited Boxed Warning as of April 2015*  
The following drugs were added as drug interactions: ticagrelor, fesoteridine, telithromycin, and solifenacin.

**Erivedge (vismodegib) Capsules**  
*Edited Boxed Warning (truncated to show changes)*



# Advance our Reach *through* Memorandum of Understanding (MOU)

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**MEDWATCH LEARN**

**FDA**

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.

**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 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.



**FDA RESOURCES**

FDA on Medscape > [FDA Expert Commentary](#)  
**What To Do About Misleading Drug Ads**  
 Michael A. Sauers  
 Disclosures | December 16, 2011

**Michael A. Sauers**  
 US Food and Drug Administration

00:08 / 05:33

# AOA and Entertainment Industries Council (EIC) Co-Sponsorship Agreement



# Engaging with FDA: MedWatch

1. A way to send information *IN* to FDA



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

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

# MedWatch- What should I report?

Any event that:

- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires/prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage
- Potentially cause harm or near miss



Drugs



Medical Devices



Biologics



Cosmetics



Combination Products



Special Nutritional Products



MedWatch-  
How do I  
report?

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

The screenshot shows the FDA MedWatch website interface. At the top, it features the U.S. Department of Health and Human Services logo and the FDA logo with the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A search bar is located in the top right corner. Below the header is a navigation menu with categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products.

The main content area is titled "Safety" and includes 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 header "MedWatch The FDA Safety Information and Adverse Event Reporting Program". Below this header are links for "Subscribe to MedWatch Safety Alerts", "Safety Information", and "Reporting Serious Problems to FDA". A "Resources for You" section lists various documents and guides, including "2015 Safety Alerts for Human Medical Products" and "Consumer-Friendly Reporting Form 3500B (PDF - 1.2MB)".

The main content area features a large heading "MedWatch: The FDA Safety Information and Adverse Event Reporting Program" and a search box labeled "Search the MedWatch Section". Below this is the MedWatch logo and the tagline "Your FDA gateway for clinically important safety information and reporting serious problems with human medical products." Three prominent buttons are displayed: a red "Report a Problem" button, a blue "Safety Information" button, and a green "Stay Informed" button. A blue arrow points from the "Report a Problem" button to the "Resources for You" sidebar. At the bottom, a "What's New" section lists recent safety alerts, such as "0.9 Percent Sodium Chloride Injection, USP, 50mL and 100mL by Baxter: Recall - Particulate Matter" and "Proglycem (diazoxide): Drug Safety Communication - Reports of Pulmonary Hypertension in Infants and Newborns".

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

# MedWatch - Safety Info OUT

Staying Informed:  
Information Delivered  
to You

Subscribe to  
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RSS feeds



The screenshot shows the FDA MedWatch website. At the top is the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". There is a search bar and navigation tabs for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main heading is "Safety" with a breadcrumb trail: Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program. A sidebar on the left contains a blue box for "MedWatch The FDA Safety Information and Adverse Event Reporting Program" with a link to "Subscribe to MedWatch Safety Alerts", and a "Resources for You" section with links to 2014 Safety Alerts, contact information, MedWatchLearn, educational resources, and a reporting form. The main content area has a search bar, the MedWatch logo, and the tagline "Your FDA gateway for clinically important safety information and reporting serious problems with human medical products." Below this are three buttons: "Report a Problem", "Safety Information", and "Stay Informed". A "What's New" section lists recent recalls, including GemStar Power Supply, V26 Slimming Coffee, and 10 Percent Neutral Buffered Formalin.

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

# Challenge Question 1

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





# Engaging with FDA- FDA Advisory Committees

- 50 committees and panels to obtain independent expert advice
- Membership types
  - Academician/Practitioner
  - Consumer Representative
  - Industry Representative
  - Patient Representative
- Open Public Hearing
- <http://www.fda.gov/AdvisoryCommittees/default.htm>

# Challenge Question 2

- Which of the following are ways to collaborate and engage with the FDA?
  - A. Report a product problem to MedWatch
  - B. Participation in Advisory Committee Meetings
  - C. FDA Bad Ad Program
  - D. All of the above





# FDA's Bad Ad Program

*Empowering HCPs to Recognize  
and Report False or Misleading  
Drug Promotion*



Office of Prescription Drug Promotion (OPDP)  
United States Food & Drug Administration

# Objectives

- Discuss FDA's role in regulating prescription drug promotion and advertising
- Recognize the role that healthcare professionals (HCPs) can play in protecting the public health by ensuring that prescription drug promotion and advertising is truthful and not misleading
- Describe how HCPs can effectively report misleading prescription drug promotion to the FDA through the Bad Ad Program

# FDA's Mission – part 1

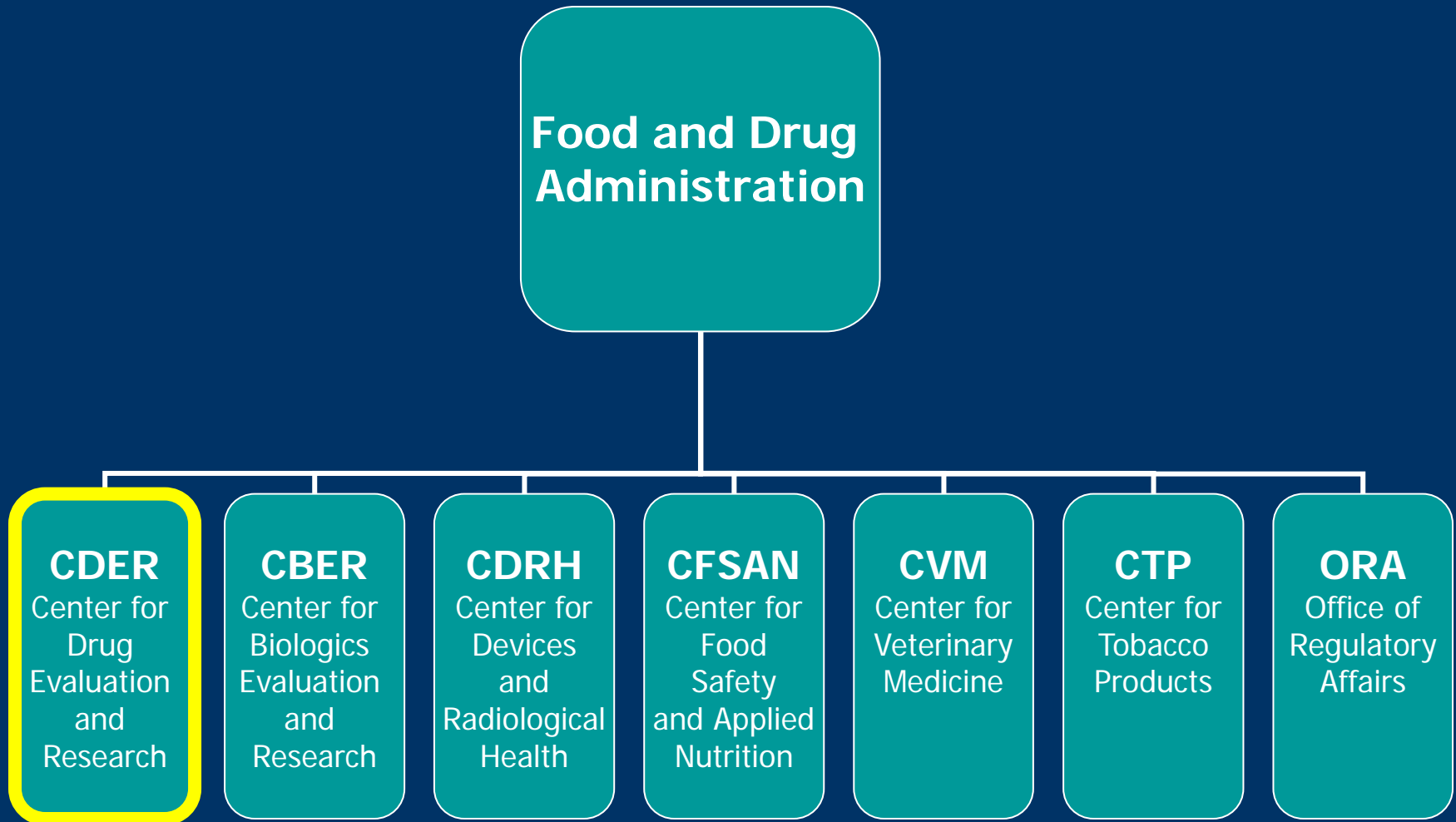
- The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution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



# FDA's Mission – part 2

- The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health.

# FDA Structure



# Office of Prescription Drug Promotion (OPDP)

- To protect the public health by ensuring prescription drug information is truthful, balanced, and accurately communicated.
- This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers.

## Challenge Question #3

- Which of the following statements is true?
  - A. FDA approves promotional materials
  - B. The pharma industry spends the majority of its advertising budget on direct-to-consumer (DTC) advertising
  - C. FDA can ban DTC advertising
  - D. None of the above

# Advertising Myths and Misconceptions

- FDA "legalized" DTC advertising in the late 1990's
- Industry spends most of its advertising budget on DTC advertising
- FDA has the authority to ban DTC advertising
- FDA can restrict DTC advertising to certain types of products
- FDA approves ads
- FDA regulates "good taste"

# What does OPDP regulate?

- Written and broadcast prescription drug promotional materials made by the company which include:
  - TV and radio commercials
  - Sales aids, journal ads, and patient brochures
  - Drug websites, e-details, webinars, Epocrates, and email alerts

# Regulatory Authority: FD&C Act

- Prescription drug promotion **must...**
  - Not be false or misleading
  - Have balance between efficacy and risk information
  - Reveal facts material with respect to consequences that may result from the use of the drug as recommended or suggested

# Regulatory Authority

- Code of Federal Regulations (CFR)
  - 202.1 - Prescription Drug Advertising
  - 312.7 - Preapproval Promotion
  - 314.550 - Subpart H, Accelerated Approval for Drugs
  - 601.40 - Subpart E, Accelerated Approval for Biologics



# Regulatory Authority

- Post-Approval Regulations located in 21 CFR 314.81(b)(3):
  - Require the submission of all promotional materials at the time of initial dissemination or publication
  - Must include Form FDA-2253 and current PI

\*OPDP generally does NOT "pre-clear" promotional materials

# Categories of Promotional Materials

## ■ Labeling

- Audio, video, or printed matter (e.g., brochures, booklets, mailing pieces, exhibits, slides)
- Supplied or disseminated by the manufacturer, distributor, packer, or any party acting on behalf of the sponsor
- Accompanied by the approved product labeling

## ■ Advertising

- Advertisements in published journals, magazines, newspapers, and other periodicals
- Broadcast (e.g., TV, radio, telephone communication systems)
- Accompanied by a "Brief Summary" of the approved product label

# Categories of Promotional Materials

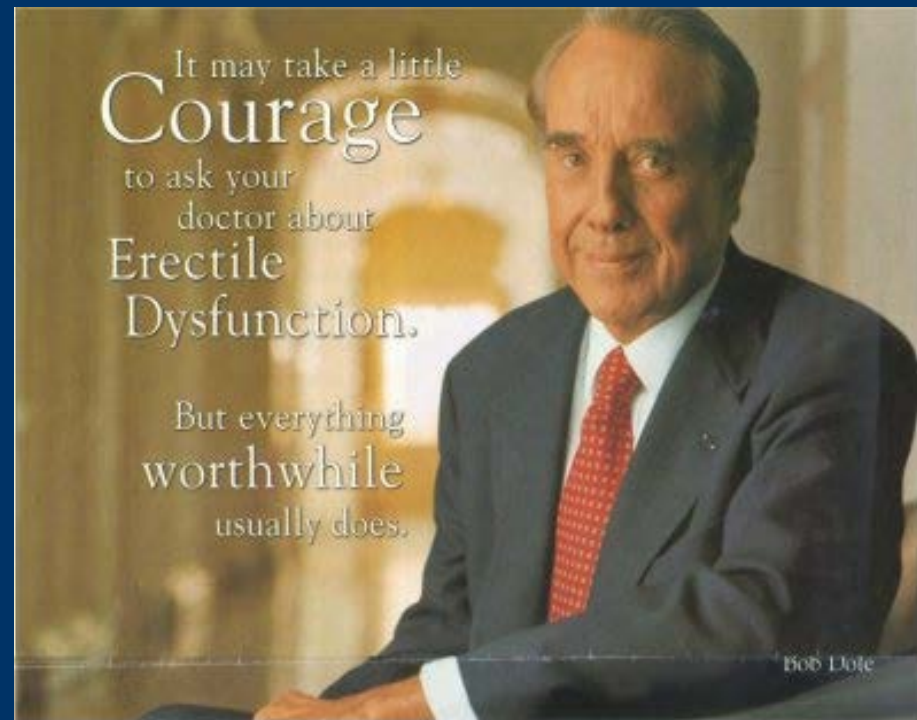
Help-Seeking  
Institutional  
Reminder

Full Product

Cannot make any  
representations  
about a specific  
product



# Help-Seeking Ad



It may take a little  
**Courage**  
to ask your  
doctor about  
**Erectile  
Dysfunction.**

But everything  
worthwhile  
usually does.

Bob Lute

When I was diagnosed with prostate cancer, my first concern was ridding myself of the cancer. But I was also concerned about possible postoperative side effects, like erectile dysfunction (E.D.), often called impotence. So I asked my doctor about treatment options.

I'm speaking out now in the hope that men with E.D. will get proper treatment for a condition that affects millions of men and their partners.

Most E.D. cases are associated with physical conditions or events, like the prostate cancer surgery I underwent. The most common causes of E.D. include diabetes, high blood pressure, spinal cord injury, or surgery for the prostate or colon. E.D. can also be associated with smoking, alcohol abuse, or psychological conditions such as anxiety or stress.

The good news is that many effective treatments are available for E.D. But the important first step is to talk to your doctor. Together, you and your doctor can decide which treatment is best for you.

Now it's up to you to get the treatment you need for E.D. My advice is to get a medical checkup. It's the best way to get educated about E.D. and what can be done to treat it. It may take a little courage, but I've found that everything worthwhile usually does.

For more information about erectile dysfunction, please call 1-800-433-4215.

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HC133A99B

**GET EDUCATED ABOUT E.D.**



# Institutional Ad

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DERMATOLOGY  
IMMUNOLOGY  
INFECTIOUS DISEASE  
UROLOGY



Changing tomorrow



## Inspired by the vision of a healthier world

We are Astellas, established in 2005 with the merger of two leading Japanese pharmaceutical companies—Yamanouchi and Fujisawa. And already ranked 2 in Japan and among the top 20 worldwide, with locations in over 30 countries, including the US.

At Astellas Pharma US, Inc., our commitment is to develop innovative, relevant products that people truly need. Our mission is to change tomorrow by bringing about a healthier world today.

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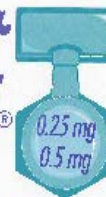


# Reminder

- Must include proprietary and established name
- May call attention to drug name but may NOT contain any representation or suggestion relating to the advertised drug product
- May include dosage form, package contents, price, name of manufacturer, packer, distributor.
- Not permitted for drug with a Boxed Warning

# Reminder Ad

**Pulmicort**  
**RESPULES**<sup>®</sup>  
*(budesonide inhalation suspension)*



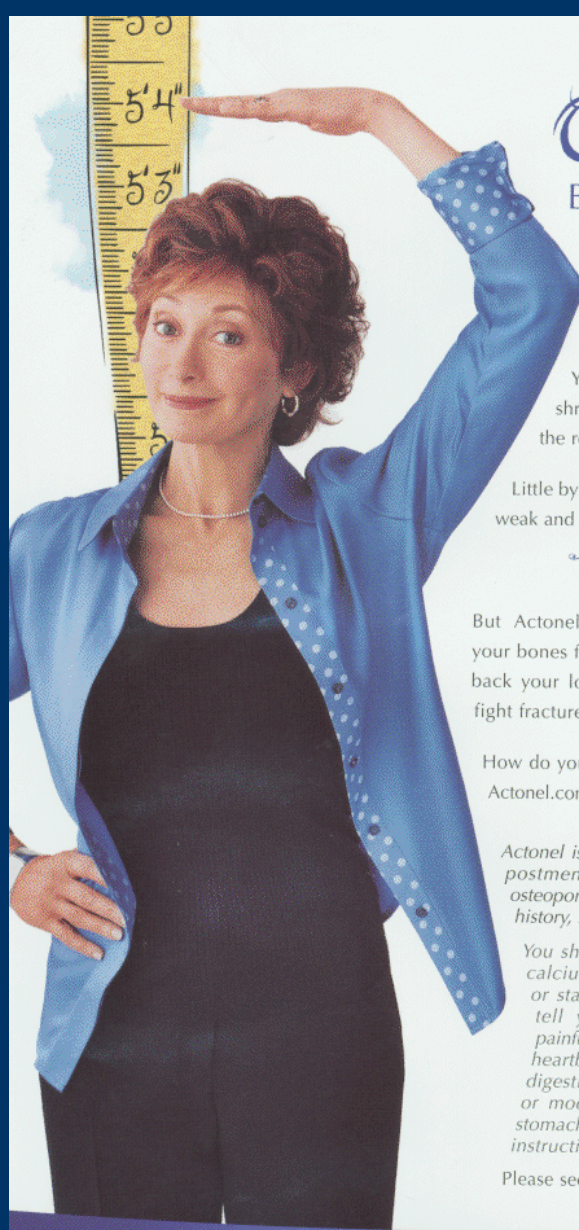
*Learn more at [PulmicortRespules.com](http://PulmicortRespules.com)*

# Full Product Claim Ads

- Include representation or suggestion relating to the advertised drug product
- Must include a balanced risk presentation ("fair balance")
- Must include the Brief Summary or PI



# Full Product Claim DTC Ad



Oh no! I've lost an inch.  
But I've found a way to fight  
osteoporosis with Actonel.

Wait a minute. Did you lose something?  
Like maybe an inch or so of height?  
You're not the only one. After menopause,  
shrinking can be a sign of osteoporosis,  
the result of tiny fractures over time.



Little by little, osteoporosis can make your bones  
weak and brittle, even if you take calcium every day.

That's how fractures can happen!

But Actonel once-a-week helps protect  
your bones from osteoporosis. It won't get  
back your lost inch. But it will help you  
fight fracture.



How do your bones measure up? Get more information at  
[Actonel.com](http://Actonel.com) and ask your doctor if Actonel is right for you.

*Actonel is a prescription medication to treat and prevent  
postmenopausal osteoporosis. Some risk factors for  
osteoporosis include Caucasian or Asian race, family  
history, small frame or smoking.*

*You should not take Actonel if you have low blood  
calcium, have severe kidney disease, or cannot sit  
or stand for 30 minutes. Stop taking Actonel and  
tell your doctor if you experience difficult or  
painful swallowing, chest pain, or severe or continuing  
heartburn, as these may be signs of serious upper  
digestive problems. Side effects are generally mild  
or moderate and may include back or joint pain,  
stomach pain or upset, or constipation. Follow dosing  
instructions carefully.*

Please see important information on the following page.

Actonel.com  
1-877-Actonel

Help fight fracture. **Actonel**  
(risedronate sodium tablets)



# Product Claim DTC Ad Brief Summary

## ACTONEL® (AK-toh-nel) Tablets Patient Information

### ACTONEL (risedronate sodium tablets) 5 mg and ACTONEL (risedronate sodium tablets) 35 mg for Osteoporosis

Read this information carefully before you start to use your medicine. Read the information you get every time you get more medicine. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions or are not sure about something, ask your healthcare provider or pharmacist.

#### What is the most important information I should know about ACTONEL?

ACTONEL may cause problems in your stomach and esophagus (the tube that connects the mouth and the stomach), such as trouble swallowing (dysphagia), heartburn (esophagitis), and ulcers (see "What are the possible side effects of ACTONEL?").

You must follow the instructions exactly for ACTONEL to work and to lower the chance of serious side effects (see "How should I take ACTONEL?").

#### What is ACTONEL?

ACTONEL is a prescription medicine used:

- to prevent and treat osteoporosis in postmenopausal women (see "What is osteoporosis?").
- to prevent and treat osteoporosis in men and women that is caused by treatment with steroid medicines such as prednisone.
- to treat Paget's disease of bone (ostitis deformans). The treatment for Paget's disease is very different than for osteoporosis and uses a different type of ACTONEL. This leaflet does not cover using ACTONEL for Paget's disease. If you have Paget's disease, ask your healthcare provider how to use ACTONEL.

ACTONEL may reverse bone loss by stopping more loss of bone and increasing bone mass in most people who take it, even though they won't be able to see or feel a difference. ACTONEL helps lower the risk of breaking bones (fractures). Your healthcare provider may measure the thickness (density) of your bones or do other tests to check your progress.

See the end of this leaflet for information about osteoporosis.

#### Who should not take ACTONEL?

- Do not take ACTONEL if you:
- have low blood calcium (hypocalcemia).
  - cannot sit or stand up for 30 minutes.
  - have kidneys that work poorly.
  - have an allergy to ACTONEL. The active ingredient in ACTONEL is risedronate sodium (see the end of this leaflet for a list of all the ingredients in ACTONEL).

#### Tell your doctor before using ACTONEL if:

- you are pregnant. We do not know if ACTONEL can harm your unborn child.
- you are breast-feeding. We do not know if ACTONEL can pass through your milk and if it can harm your baby. You will need to decide whether to stop breast-feeding or not take ACTONEL.
- you have kidney problems. ACTONEL may not be right for you.

#### How should I take ACTONEL?

The following instructions are for both ACTONEL 5 mg (daily) and ACTONEL 35 mg (Once-a-Week):

- Take ACTONEL first thing in the morning before you eat or drink anything except plain water.
- Take ACTONEL while you are sitting or standing up.
- Take ACTONEL with 6 to 8 ounces (about 1 cup) of plain water. Do not take it with any other drink besides plain water. Do not take it with coffee, tea, juice, or milk or other dairy drinks.

- Swallow ACTONEL whole. Do not chew the tablet or keep it in your mouth to melt or dissolve.
- After taking ACTONEL you must wait at least 30 minutes BEFORE:

- lying down. You may sit, stand, or do normal activities like read the newspaper or take a walk,
- eating or drinking anything except plain water.
- you take vitamins, calcium, or antacids. Take vitamins, calcium, and antacids at a different time of the day from when you take ACTONEL.

- Keep taking ACTONEL for as long as your healthcare provider tells you.
- For ACTONEL to treat your osteoporosis or keep you from getting osteoporosis, you have to take it as often and in the way it is prescribed.
- Your healthcare provider may tell you to take calcium and vitamin D supplements and to exercise.

#### What is my ACTONEL schedule?

If your doctor has prescribed ACTONEL 5 mg (daily)

- (a yellow tablet):
- Take 1 ACTONEL 5-mg tablet every day in the morning.
  - If you forget to take your ACTONEL 5 mg in the morning, do not take it later in the day. Take only 1 ACTONEL 5-mg tablet the next morning and continue your usual schedule of 1 tablet a day. Do not take 2 tablets on the same day.

If your doctor has prescribed ACTONEL 35 mg Once-a-Week (an orange tablet):

- Choose 1 day of the week that you will remember and that best fits your schedule to take your ACTONEL 35 mg. Every week, take 1 ACTONEL 35-mg tablet in the morning on your chosen day.
- If you forget to take your ACTONEL 35 mg in the morning, do not take it later in the day. Take only 1 ACTONEL 35-mg tablet the next morning and continue your usual schedule of 1 tablet on your chosen day of the week. Do not take 2 tablets on the same day.

#### What should I avoid while taking ACTONEL?

- Do not eat or drink anything except water before you take ACTONEL and for at least 30 minutes after you take it.
- Do not lie down for at least 30 minutes after you take ACTONEL.
- Foods and some vitamin supplements and medicines can stop your body from absorbing (using) ACTONEL. Therefore, do not take the following products at or near the time you take ACTONEL: food, milk, calcium supplements, or calcium-, aluminum-, or magnesium-containing medicines, such as antacids (see "How should I take ACTONEL?").

#### What are the possible side effects of ACTONEL?

Stop taking ACTONEL and tell your healthcare provider right away if:

- swallowing is difficult or painful.
- you have chest pain.
- you have very bad heartburn and it doesn't get better.

ACTONEL may cause:

- pain or trouble swallowing (dysphagia).
- heartburn (esophagitis).
- ulcers in your stomach and esophagus (the tube that connects the mouth and the stomach).

For patients with osteoporosis, the overall occurrence of side effects with ACTONEL was similar to placebo (sugar pill) and most were either mild or moderate. The most common side effects with ACTONEL include back pain, joint pain, upset stomach, abdominal (stomach area) pain, constipation, diarrhea, gas, and headache. Tell your healthcare provider if you have pain or discomfort in your stomach or esophagus.

These are not all the possible side effects of ACTONEL. You can ask your healthcare provider or pharmacist about other side effects.

#### What is osteoporosis?

Osteoporosis is a disease that causes bones to become thinner. Thin bones can break easily. Most people think of their bones as being solid like a rock. Actually, bone is living tissue, just

like other parts of the body—your heart, brain, or skin, for example. Bone just happens to be a harder type of tissue. Bone is always changing. Your body keeps your bones strong and healthy by replacing old bone with new bone.

Osteoporosis causes the body to remove more bone than it replaces. This means that bones get weaker. Weak bones are more likely to break. Osteoporosis is a bone disease that is quite common, especially in older women. However, young people and men can develop osteoporosis, too. Osteoporosis can be prevented, and with proper therapy, it can be treated.

#### How can osteoporosis affect me?

- You may not have any pain or other symptoms when osteoporosis begins.
- You are more likely to break (fracture) a bone especially if you fall because osteoporosis makes your bones weaker. You are most likely to break a bone in your back (spine), wrist, or hip.
- You may "shrink" (get shorter).
- You may get a "hump" (curve) in your back.
- You may have had back pain that makes you stop some activities.

#### Who is at risk for osteoporosis?

Many things put people at risk for osteoporosis. The following people have a higher chance of getting osteoporosis:

Women who:

- are going through or who are past menopause ("the change").
- are white (Caucasian) or Asian.

People who:

- are thin.
- have family members with osteoporosis.
- do not get enough calcium or vitamin D.
- do not exercise.
- smoke.
- drink alcohol often.
- take bone-thinning medicines (like prednisone or other corticosteroids) for a long time.

#### General information about ACTONEL

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use ACTONEL for a condition for which it was not prescribed. Do not give ACTONEL to other people, even if they have the same symptoms you have. It may harm them.

#### What if I have other questions about ACTONEL?

This leaflet summarizes the most important information about ACTONEL for osteoporosis. If you have more questions about ACTONEL, ask your healthcare provider or pharmacist. They can give you information written for healthcare professionals. For more information, call 1-877-ACTONEL (toll-free) or visit our Web site at [www.actonel.com](http://www.actonel.com).

#### What are the ingredients of ACTONEL?

ACTONEL (active ingredient): risedronate sodium.

ACTONEL (inactive ingredients): croscopolidone, ferric oxide red (35-mg tablets only), ferric oxide yellow, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, and titanium dioxide.

ACTONEL® is marketed by:

Procter & Gamble Pharmaceuticals  
Cincinnati, OH 45202  
and  
Aventis Pharmaceuticals Inc.  
Kansas City, MO 64137  
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MAY 2002

**Actonel**  
(risedronate sodium tablets)

# Broadcast Advertising

- "Major Statement"
  - Information relating to the major side effects and contraindications

- "Adequate Provision"

- Provides for dissemination of the PI

Recognizes the inability of broadcast advertisements of reasonable length to present and communicate this information effectively

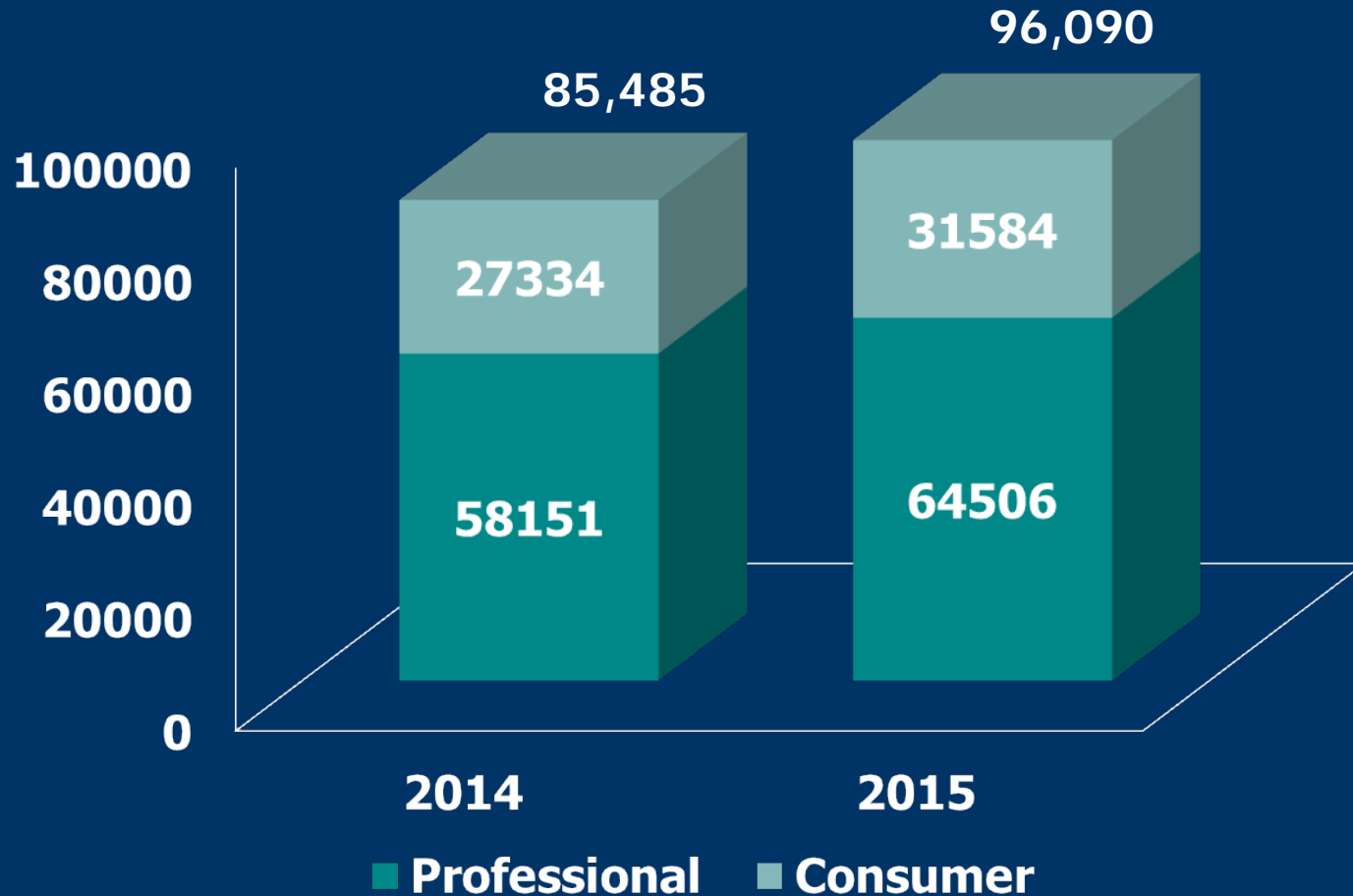
# Adequate Provision

- Currently acceptable adequate provision:
  - Toll-free number
  - Simultaneously running magazine ad
  - Reference to a healthcare provider
  - Website

## Challenge Question #4

- How many promotional pieces did OPDP receive in 2015?
  - A. 5,000
  - B. 15,000
  - C. 55,000
  - D. 95,000

# Total # of promotional pieces



# What does OPDP do?

- Advice to industry
- Advice within FDA
- Guidance and policy development
- Research
- **Surveillance and enforcement**



# False or Misleading Promotion

- May have public health consequences, e.g.
  - Providers writing inappropriate prescriptions
  - Patients using medication incorrectly or for the wrong purpose
  - Medicare fraud
  - Adverse events



# Common Violations

- Omitting risk information
- Downplaying drug risks
- Distorting scientific research
- Overstating the efficacy of a drug
- Using suggestive language or imagery that gives a false overall impression

# Surveillance and enforcement

- OPDP's normal surveillance activities include:
  - Monitoring drug promotional materials sent to us by industry
  - Monitoring medical convention exhibit halls
  - Reviewing complaints submitted by industry competitors

# Limitations to surveillance

- However, these surveillance activities do not allow us to monitor certain types of drug promotion, such as what occurs in places such as physician offices and industry-sponsored dinner and lunch programs.

That's one of the reasons why we developed the **Bad Ad Program**



- An FDA-sponsored outreach program designed to educate HCPs about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading
  
- Bad Ad's dual mission:
  1. Education and outreach
  2. Hotline (email and telephone) for HCPs to report potential violations

- Bad Ad Education and Outreach
  - Pharmaceutical companies spend billions of dollars each year to promote drugs, yet many HCPs are not trained to identify false or misleading promotion
  - Main educational outreach includes:
    - 1-credit CME course
    - Case studies for educational settings
    - Media campaigns and conference outreach

# Bad Ad CME Program

- 1-hour, self-paced training for 1.00 ANCC contact hours for nurses and nurse practitioners
- Training modules include:
  - Video presentations by OPDP reviewers
  - Video presentation on "the psychology of influence" by an expert psychologist consultant
  - Simulated interactive scenarios to test knowledge including a pharmacy scenario
- Over 1,000 course completions to date and excellent overall feedback

# Bad Ad Case Studies

- Three case studies based on real OPDP enforcement actions that originated via Bad Ad
- Designed to be used as part of an educational curriculum or training
- Includes the violative promotional material, the resulting enforcement letter, the FDA-approved PI, and a facilitator guide



# What should you do if you see misleading drug promotion?

## ■ Bad Ad Hotline

- Any HCP can report potentially misleading promotion to OPDP by:
  - sending an e-mail to **BadAd@fda.gov** or
  - calling **855-RX-BADAD** (855-792-2323)
- Can be submitted anonymously. However, FDA encourages you to include contact information in case follow-up is necessary for more information.

# What will OPDP do with your complaint?

- Once a Bad Ad complaint is received, OPDP will evaluate it to determine if it meets the criteria needed to take an enforcement action.
- If OPDP finds the promotion to be false or misleading, we will move forward with a risk-based enforcement strategy to put a stop to the promotion ourselves, or refer it for further criminal investigation.
- If the report does not meet the required criteria at the time, it will serve as valuable information in focusing our ongoing surveillance activities.



# Enforcement Action Example:

DermaSmoothie  
(fluocinolone acetonide)

# Enforcement Example: Derma-Smoothe (fluocinolone acetonide)

- Indication: Topical treatment of moderate to severe atopic dermatitis in pediatric patients, 3 months and older for up to 3 weeks
  - Also states to apply the least amount of Derma-Smoothe to cover the affected areas, and not to apply to the diaper area, face, axillae, or groin unless directed
- Warning: The systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency...Children may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

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### Pediatric Atopic Dermatitis

- Diseases We Treat
- Main
- Scalp Psoriasis
- Eczema/Atopic Dermatitis
- Pediatric Atopic Dermatitis
- Itchy Ears
- Non-Prescription Products For:
  - Excessive Sweating
  - Oily Skin, Oily Hair
  - Dry Itchy Skin

**Derma-Smoothe/FS<sup>®</sup>**  
**(Body Oil)**  
(fluocinolone acetonide oil), 0.01%

**Severe and All Over**

**3 mos.**

and

**NO**

**Adrenal Suppression!**



[ONLINE STORE >>](#)

[Non-Prescription Products](#)





## Derma-Smoothe/FS<sup>®</sup> (Body Oil)

(fluocinolone acetonide oil), 0.01%

The **only** product for patients 3 months and older that can be used when their eczema is **severe and all over!**

**Go Beyond the Itch!!**

- ✓ The refined peanut oil vehicle repairs the skin barrier function by driving moisture into the skin, which is the key to treating the disease.
- ✓ The only corticosteroid that does **not** cause adrenal suppression, even when used over 90% of the body!
- ✓ Patient cost is only \$45.00 for a full course of treatment!



- Phone: 855-RX-BADAD  
(855-792-2323)
- E-Mail: [BadAd@fda.gov](mailto:BadAd@fda.gov)
- For more information including the CME program and case studies please visit:  
**[www.fda.gov/badad](http://www.fda.gov/badad)**