FDA's Bad Ad Program

Empowering HCPs to Recognize and Report False or Misleading Drug Promotion

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

March 24, 2016

Objectives

- Understand FDA's role in regulating prescription drug promotion and advertising
- Understand 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
- Understand how HCPs can effectively report misleading prescription drug promotion to the FDA through the Bad Ad Program

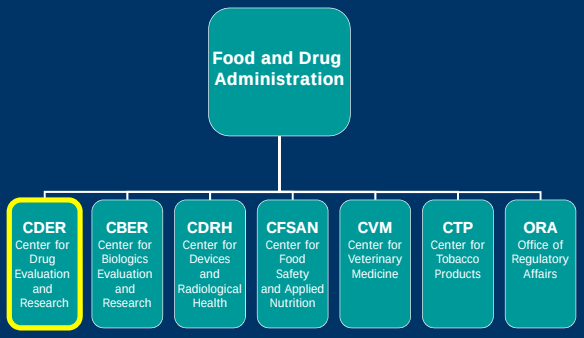
FDA's Mission – part 1

- 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



CDER Review (Approving) Divisions

Office of New Drugs

- Division of Cardiovascular and Renal Products
- Division of Neurology Products
- Division of Psychiatry Products
- Division of Botanical Drug Products
- Division of Anesthesia, Analgesia, and Addiction Products
- Division of Metabolism and Endocrinology Products
- Division of Anti-Infective Products
- Division of Antiviral Products
- Division of Hematology Products
- Division of Pulmonary, Allergy, and Rheumatology Products
- Division of Dermatology and Dental Products
- Division of Gastroenterology Products
- Division of Reproductive and Urologic Products
- Division of Medical Imaging Products
- Division of Nonprescription Drug Products
- Division of Oncology Products
- Division of Transplant and Ophthalmology Products

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.

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

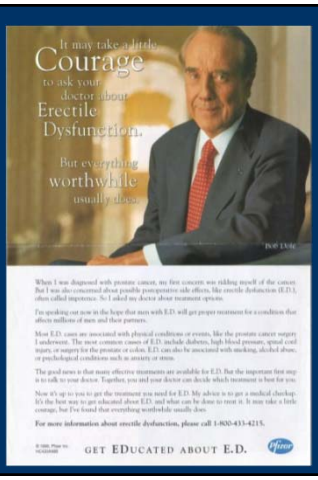
⇦ **Cannot make any representations about a specific product**

Full Product

Help Seeking

- May discuss a medical condition or disease state
- May include a company name
- May <u>NOT</u> include drug names

Help-Seeking Ad



Institutional

- Company name
- Area of research
- May NOT mention drug names

Institutional Ad

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

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

Product Claim DTC Ad Brief Summary

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

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Adequate Provision

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

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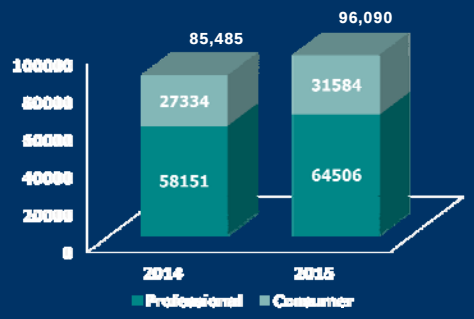
Total # of promotional pieces



What does OPDP do?

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

False or Misleading Promotion

- Generally makes a drug appear better or safer than clinical testing has actually demonstrated
- Is against the law
- 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

BadAd@fda.gov
BadAd
FOOD AND DRUG ADMINISTRATION FDA

- 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

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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 **877-RX-BADAD** (877-792-2323)
  - 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.

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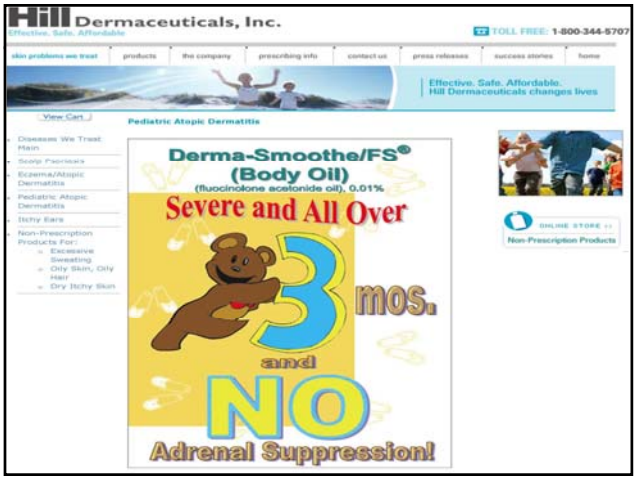
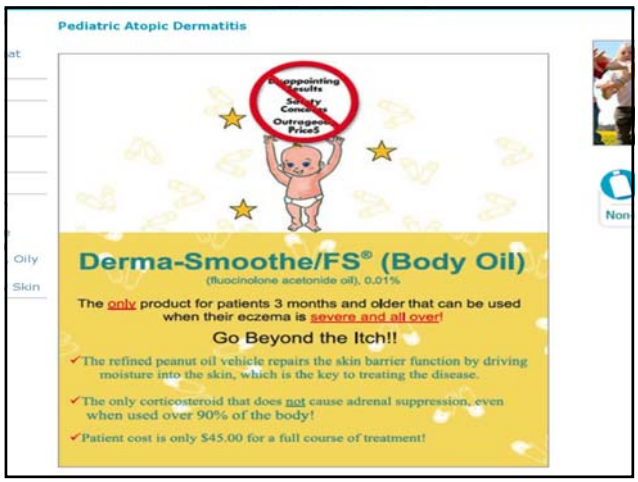
Enforcement Action Example:

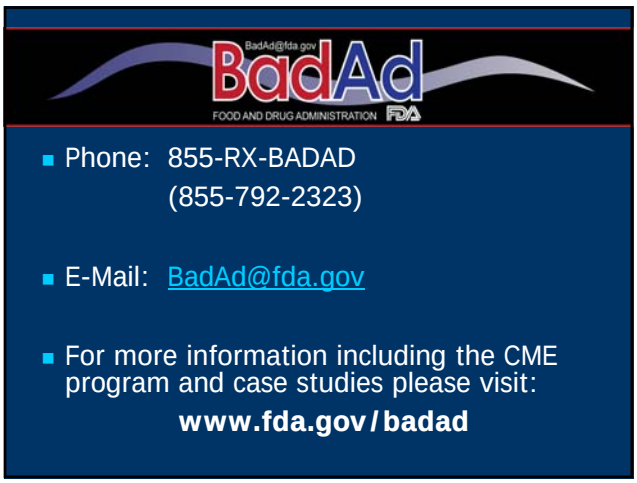
DermaSmoothe
(fluocinolone acetonide)

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.




Pediatric Atopic Dermatitis
Derma-Smoothe/FS® (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!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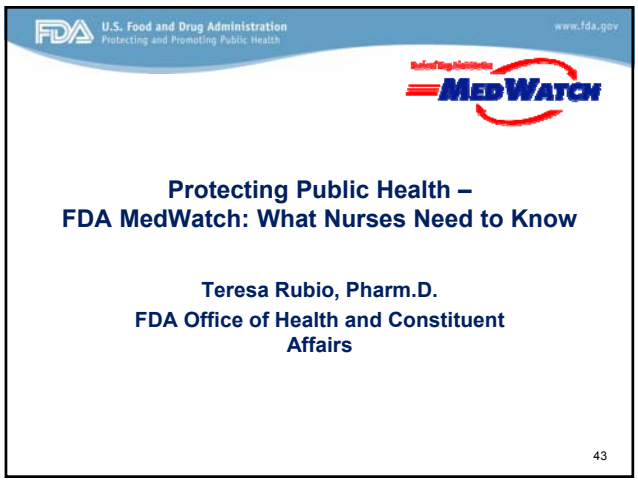
BadAd
FOOD AND DRUG ADMINISTRATION
FDA
Phone: 855-RX-BADAD
(855-792-2323)
E-Mail: BadAd@fda.gov
For more information including the CME program and case studies please visit:
www.fda.gov/badad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Protecting Public Health –
FDA MedWatch: What Nurses Need to Know
Teresa Rubio, Pharm.D.
FDA Office of Health and Constituent Affairs
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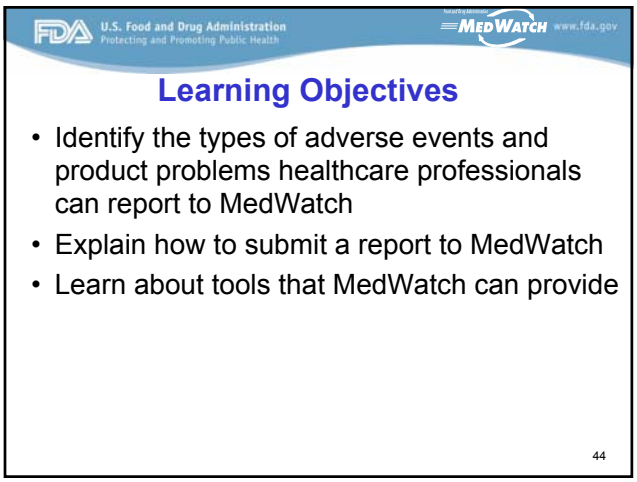
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Learning Objectives
Identify the types of adverse events and product problems healthcare professionals can report to MedWatch
Explain how to submit a report to MedWatch
Learn about tools that MedWatch can provide
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FDA 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.

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What is MedWatch?

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

Food and Drug Administration
MEDWATCH

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

www.fda.gov/medwatch

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Who should report?

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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: Safety Information *IN*

- One person can make a difference

What should I report?

Any event that:

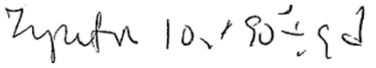
- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires/prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage

Potential Harm

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

Potential Errors

- Prescribing
  - handwriting, abbreviations



- Label/Packaging
  - placement of information, expression of strength/dose, readability of label, lack of appropriate labeling during repackaging
- Miscommunication of Orders/Nomenclature
  - sound alike, look alike

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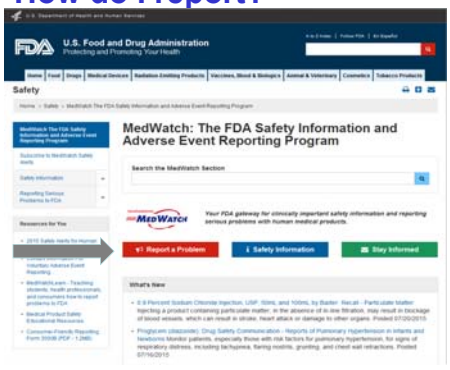
How do I report?

- Online
- Mail/Fax
- By Phone

1-800-332-1088



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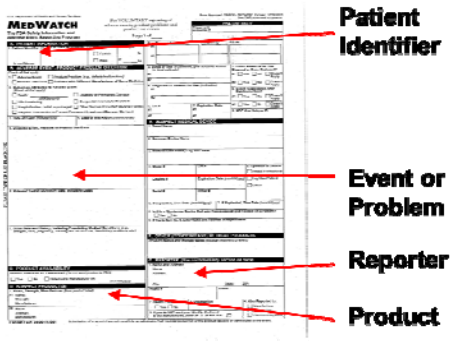
MedWatch Form



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Quality is Key: Case #1

- Health care worker ST reported male patient A3 started Drug X at 5 mg daily for type 2 diabetes on February 11, 2015.
- The patient developed liver failure.

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Question: Does Case #1 contain the four elements?

☑ Yes

☒ No

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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

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MedWatch Learn: Teaching Tool

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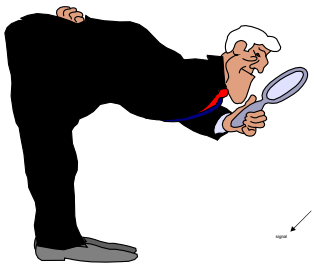
What happens to my report?



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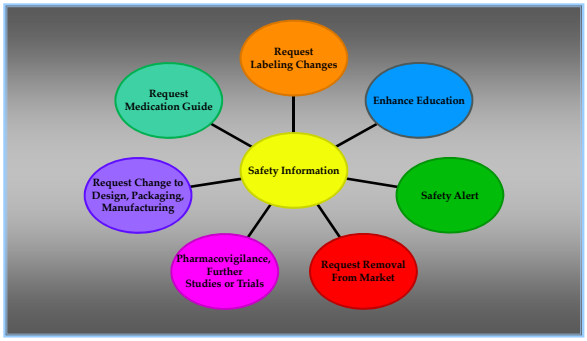
Safety Info *Out*



Lidocaine Viscous: Drug Safety Communication - Boxed Warning Required - Should Not Be Used to Treat Teething Pain

MedWatch Safety Alert Example

ISSUE: FDA notified health professionals, their provider organizations and caregivers for infants, that [illegible] 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 [illegible] rubbed on the gums are not necessary or even useful because they wash out of the baby's mouth [illegible] when too much viscous lidocaine is given to infants and young children or they accidentally swallow [illegible] result in seizures, severe brain injury, and problems with the heart. Cases of overdose due to [illegible] dental ingestion have resulted in infants and children being hospitalized or dying.

22 case reports

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: [illegible] health care professionals should not prescribe or recommend this product for teething pain. Patients 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.

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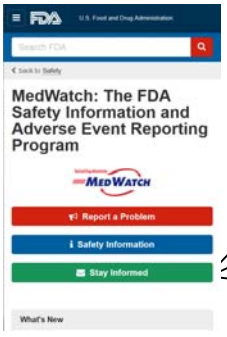
How do I sign up?



E-mail

RSS Feed

Twitter
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MedWatch: Safety Information *OUT*

- Drug Safety Labeling Changes


June 2015

Drug Safety Labeling Changes

The summary view includes drug products with safety labeling changes to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE sections. The "quick view" table below provides the drug name and sections modified. Click on the drug name to go to the detailed view. The detailed view includes sections and subsections modified, a description of new or modified safety information in the BOXED WARNING, CONTRAINDICATIONS, or WARNINGS sections, and a link to the revised prescribing information.

Key to Label Section Acronyms:

BW=BOXED WARNING, C=CONTRAINDICATIONS, W=WARNINGS, P=PRECAUTIONS
AR=ADVERSE REACTIONS, PPI/MG=PATIENT PACKAGE INSERT/MEDICATION GUIDE

DRUG NAME	SECTIONS MODIFIED					
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Enjuvia (synthetic conjugated estrogens, B) Tablets	X	X	X	X	X	
Hycamtin (Topotecan) Injection	X					
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Capoten (captopril) Tablets			X	X		
Jevtana (cabazitaxel) Injection			X	X	X	
Rolvedon (eltrombopag olamine) for Injection			X	X		X
(Click on drug name to go to detailed view)	BW	C	W	P	AR	PPI/MG
Angeliq (drospirenone and estradiol) Tablets				X	X	

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MedWatch: Safety Information *OUT*

❖AJHP Quarterly Boxed Warning Highlights

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

Ref: Am J Health-Syst Pharm—Vol 72, 2015

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Key MedWatch Takeaways

❖Key MedWatch Takeaway #1: Send information to FDA
- Nurses should report problems
- Quality reports are key
- MedWatch Learn tool to practice reporting

❖Key MedWatch Takeaway #2: Get safety information from FDA
- Sign Up to receive alerts
- Use the MedWatch website for safety info