



Best Practices in Stakeholder Involvement

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PATHS Annual Meeting

September 2008

Challenges – Drug Products

- 10,000+ products marketed in US
 - Branded
 - Generic
 - Over-the-counter
- For wide variety of uses and conditions
 - Life saving
 - Preventative
 - Symptomatic
- Over 900 safety-related label changes/year
 - Warnings, precautions, adverse events

Challenges – Drug Products

- Everyone uses drugs
 - Language
 - Health literacy
- Information everywhere
 - Professional label
 - Consumer Medication Information
 - Patient Package Inserts
 - Medication Guides
 - FDA Alerts

Reaching the Audience

The Role of Partners

- MedWatch
- Patient Safety News
- Meeting the needs of 'busy' healthcare professionals and their patients
- Providing easy and quick access to timely and actionable information

FDA PATIENT SAFETY NEWS

<http://www.fda.gov/psn>



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FDA Patient Safety News

FDA Patient Safety News is a televised series for health care personnel, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. It features information on new drugs, biologics and medical devices, on FDA safety notifications and product recalls, and on ways to protect patients when using medical products.



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Windows Media



Real Media

Food and Drug Administration



MED WATCH

- 105,000+ listserv subscribers
- 160 healthcare professional and consumer groups who participate in partner program



MedWatch

Safety Information OUT

Broadcasting safety information by:

- *MedWatch website*
- *MedWatch e-list & RSS feed*
- *MedWatch Partners program*



U.S. Food and Drug Administration
Protecting and Promoting Public Health

MedWatch

home page

www.fda.gov/medwatch

Stay Informed

Subscribe to the E-list [105,000+ recipients]

RSS feed

What's New

Safety Information

Medical Product Reporting

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FDA MedWatch FDA 2006 Internet-Dev FDA FDA CDER

U.S. Food and Drug Administration

Department of Health and Human Services

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Welcome to MedWatch, your Internet gateway for timely safety information on drugs and other medical products regulated by the U.S. Food and Drug Administration.

What's New

[NeutraGard 0.05% and NeutraGard Plus 0.2% Neutral Sodium Fluoride Anticavity Treatment Rinse](#) - Recall of all lots and flavors due to possible contamination with Burkholderia cepacia and Pseudomonas aeruginosa bacteria. (Posted 04/28/2006)

[Baxter Healthcare Corporation COLLEAGUE Volumetric Infusion Pumps](#) - FDA issues important safety recommendations when using Baxter's Colleague Infusion Pumps. (Posted 04/28/2006)

[Promethazine HCl \(marketed as Phenergan and generic products\)](#) - Medications containing promethazine hydrochloride should not be used for children less than two years old because of possible breathing problems. This includes promethazine HCl in any form: syrup, suppositories, tablets, or injectables. (Posted 4/25/2006)

[Oxygen Regulator Fires Resulting from Incorrect Use of CGA 870 Seals](#) - Regulators used with oxygen cylinders have burned or exploded, in some cases injuring personnel. (Posted 04/25/2006)

[Ortho-Clinical Diagnostics VITROS Immunodiagnostic Products Signal Reagent](#) - Class 1 recall due to inaccurate results affecting the outcome of diagnostic tests for cardiac disease, hepatitis (A, B, or C), thyroid disorders, HIV, and pregnancy. (Posted 4/18/2006)

[Boca Medical Ultillet Insulin Syringe 30g 1/2cc](#) - Recall of insulin syringes because of possible bacterial contamination with Bacillus cereus and Staphylococcus intermedius. (Posted 4/17/2006)

[Blackstone Medical ICON Modular Fixation System](#) - Recall of spinal segment stabilization system due to component failure after implantation. (Posted 4/17/2006)

[January 2006 Monthly Safety Labeling](#) - Summary posted with revisions noted to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections.

Safety Information

Medical Product Reporting

MedWatch now features an RSS feed. XML Find out more about RSS. (Posted 04/25/2006)

Forms FDA 3000 (voluntary reporting) and FDA 3500A (mandatory reporting) have been revised and re-authorized through an expiration date of 10/31/2008. Mandatory reporters may continue to use the [previous version](#) of Form FDA 3500A until 11/01/2006. (Posted 11/01/2005)

gov

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MedWatch Partners

- Infectious Disease Society of America
- American Society of Health-System Pharmacists
- Texas Medical Society
- Medscape
- ePocrates



MedWatch

Power of Leveraging by Partners

Bextra withdrawal and MedWatch alert

Apr. 2005

Special Alert - Another COX-2 Inhibitor Withdrawn; FDA Asks for Revised Labeling on All...

From: Medscape Drug & Device Digest [Medscape_Drug_Device_Digest@mp.medscape.com] Sent: Thu 4/7/2005 5:03 PM
To: marksn@cdcr.fda.gov
Subject: Special Alert - Another COX-2 Inhibitor Withdrawn; FDA Asks for Revised Labeling on All NSAIDs

Ensure delivery - add Medscape_Drug_Device_Digest@mp.medscape.com to your address book.

Medscape
from WebMD

DRUG & DEVICE DIGEST
Medscape's monthly Drug & Device Digest brings you the latest in alerts and approvals.

A MEDSCAPE DRUG AND DEVICE DIGEST SPECIAL ALERT

MEDSCAPE ALERT
From the FDA
Apr 7, 2005 [Bextra Withdrawn From Market](#)
In addition, the FDA is requiring that all NSAID product labels include stronger warnings on cardiovascular and gastrointestinal adverse events.

FDA MedWatch - Pfizer asked to voluntarily remove Bextra (valdeco xib) from the market & all manufactur...

From: CDER MEDWATCH LISTSERV [MEDWATCHLIST@CDER.FDA.GOV] Sent: Thu 4/7/2005 10:09 AM

MedWatch - The FDA Safety Information and Adverse Event Reporting Program

After concluding that the overall risk versus benefit profile is unfavorable, FDA has requested Pfizer, Inc. to voluntarily withdraw Bextra (valdecoxib) from the market. This request is based on:

- * The lack of adequate data on the cardiovascular safety of long-term use of Bextra, along with the increased risk of adverse cardiovascular (CV) events in short-term coronary artery bypass surgery (CABG) trials that FDA believes may be relevant to chronic use.
- * Reports of serious and potentially life-threatening skin reactions, including deaths, in patients using Bextra. The risk of these reactions in individual patients is unpredictable, occurring in patients with and without a prior history of sulfa allergy, and after both short- and long-term use.

1. MedWatch e-mail alert to Medscape



Bextra Withdrawn From Market - Mozilla Firefox

http://www.medscape.com/view...

Medscape
from WebMD

The difference between SUI and UUI
How do you differentiate SUI and UUI in y...

Medicine Specialist | Medscape Today | MedNet | eSource | Newsletters | ACP Medicine

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Printable Version

Medscape Alert
Bextra Withdrawn From Market

April 7, 2005 — At the request of the U.S. Food and Drug Administration (FDA), Pfizer, Inc. has agreed to suspend sales and marketing of valdecoxib (Bextra) pending further discussions with the agency. The FDA claims that the drug's overall risks outweigh the potential benefits, according to an alert sent today from MedWatch, the FDA's safety information and adverse event reporting program.

The decision follows a joint public meeting of the FDA's Arthritis Drugs/Drug Safety and Risk Management Advisory committees, held in February to review safety data compiled from clinical trials and postmarketing reports.

According to the FDA, the request was based on a lack of adequate data regarding the cardiovascular (CV) safety of long-term valdecoxib use and the increased risk of adverse CV events observed in trials of valdecoxib in coronary artery bypass postsurgical patients that may be relevant to chronic use.

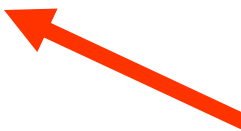
In addition, the FDA has received reports of serious and potentially life-threatening skin reactions causing some fatalities in patients receiving valdecoxib therapy. The risk of these reactions is considered unpredictable, the reactions have occurred with both short- and long-term use and in patients with and without a history of sulfa allergy.

Patients receiving valdecoxib therapy are advised to contact their healthcare providers to arrange for alternative therapy. The FDA notes that valdecoxib has not been associated with any advantages compared with other nonsteroidal anti-inflammatory drugs (NSAIDs).

As a result of the meeting, the FDA has also asked manufacturers to revise the labeling for all prescription NSAIDs, including celecoxib (Celebrex, made by Pfizer, Inc.), to include stronger warnings on the increased risk of CV events and potentially life-threatening gastrointestinal (GI) bleeding.

2. WebMD Medscape web posting

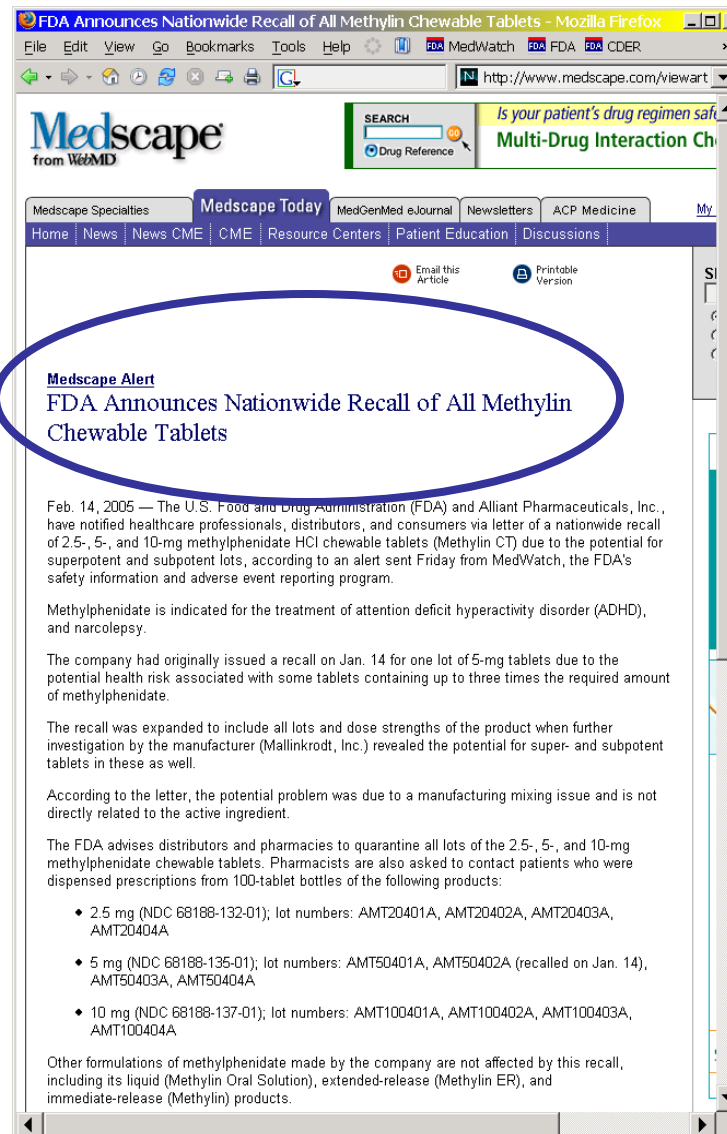
3. Medscape listserv notice sent to over 220,000 individuals



MedWatch

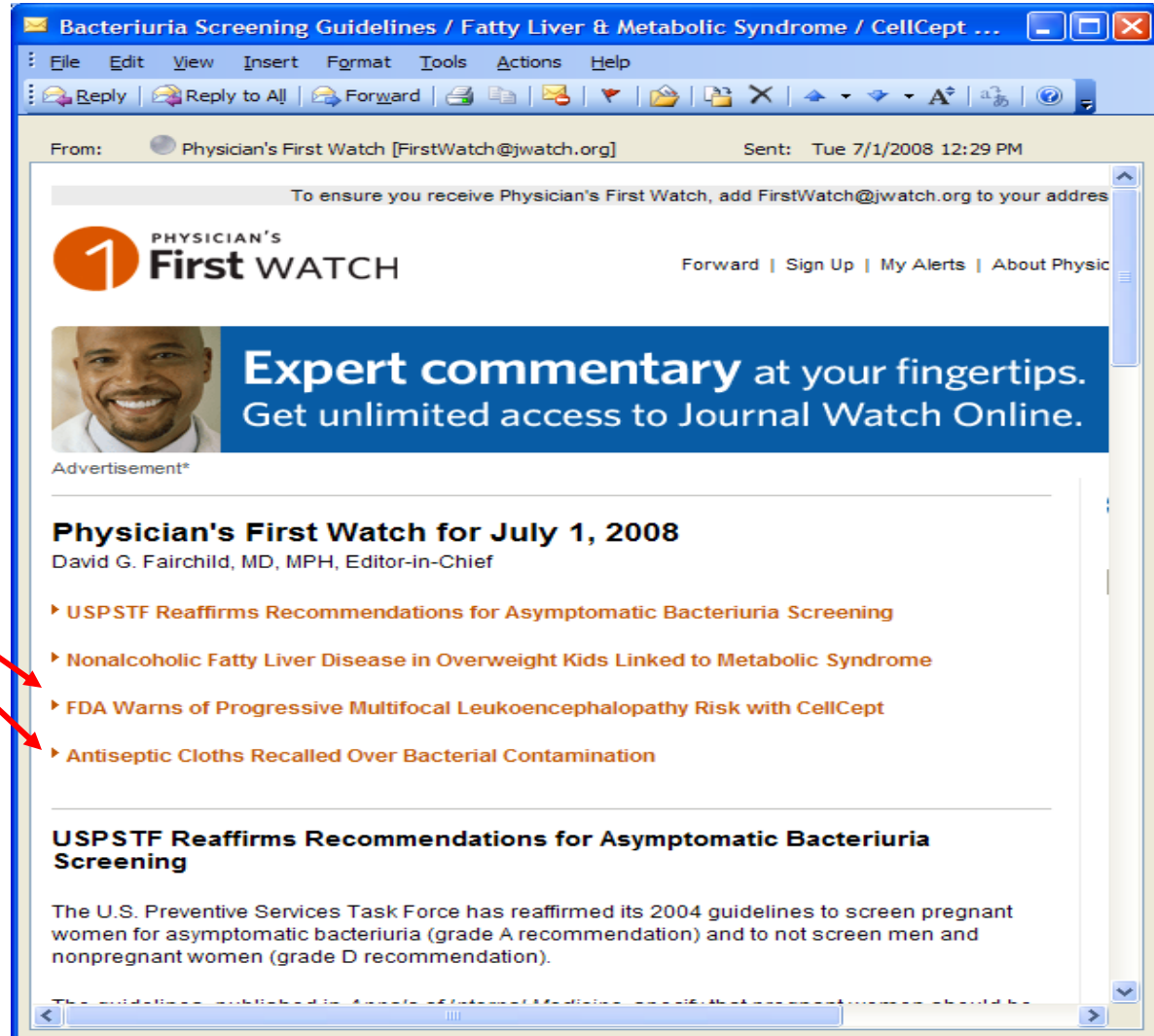
*Partners program
Medscape*

MedWatch safety alert for recall of drug product is broadcast to clinicians on Medscape websites and by email to Medscape listserves

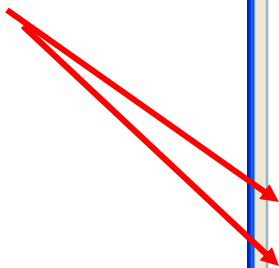


NEJM/Physician's FirstWatch

Email drug/device safety alerts each morning



Links to
MedWatch
alerts





American Society of Anesthesiologists MedWatch safety alert

FDA MedWatch: Zyvox (linezolid) - Mozilla Firefox

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http://www.asahq.org/news/alert031907.htm

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ASA AMERICAN SOCIETY OF ANESTHESIOLOGISTS

December 18, 2007

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ALERT

MedWatch - 2007 Safety Information Alerts - Mozilla Firefox

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Zyvox (linezolid)

Audience: Infectious disease specialists, other healthcare professionals
[Posted 03/16/2007] FDA notified healthcare professionals of new emerging safety concerns about Zyvox (linezolid) from a recent clinical study. This open-label, randomized trial compared linezolid to vancomycin, oxacillin, or dicloxacillin in the treatment of seriously ill patients with intravascular catheter-related bloodstream infections including those with catheter-site infection. Patients treated with linezolid had a higher chance of death than any comparator antibiotic, and the chance of death from the organism causing the infection. Patients with Gram negative organisms had a higher mortality according to their antibiotic treatment. Mortality was higher in patients treated with linezolid than in patients treated with any comparator antibiotic, with both Gram positive organisms, or who had no infection when they entered the study.

Information Page - FDA

MedWatch Safety Info | Online MedWatch Report | Contact MedWatch

Related Organizations News Archives Links of Interest Done

linezolidHCP.pdf (application/pdf object) - Mozilla Firefox

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49%

FDA
Information for Healthcare Professionals

Linezolid
(marketed as Zyvox)

In patients with only Gram positive infections, however, no difference in mortality was seen between the linezolid and comparator arms.

Physicians and other healthcare professionals are reminded that:

- Linezolid is not approved for the treatment of catheter-related bloodstream infections or catheter-site infections.
- Linezolid is not indicated for the treatment of Gram negative infections. Infections with Gram negative bacteria is known or suspected, appropriate therapy should be started immediately.

Information for the Patient

Physicians and other healthcare professionals should discuss with patients for whom linezolid might be prescribed that use of this medication increases the risk of death for the treatment of catheter-related bloodstream infections including those with catheter-site infections, and for those who have, or may get, infections with type of bacteria other than linezolid's particular target.

Data Summary

Linezolid was studied in an open-label, randomized, clinical trial in patients with intravascular catheter-related bloodstream infections including those with catheter-site infections due to Gram positive bacteria. Patients in the study were randomly assigned to receive either 600 mg linezolid given intravenously or orally every 12 hours, or to one gram vancomycin given intravenously every 12 hours for 14-28 days. Patients in the vancomycin arm could have their therapy switched to oxacillin or dicloxacillin if the organism was methicillin-susceptible. Patients could also receive combination therapy for Gram negative infections. Patients with intravascular catheters were enrolled in the study if they had signs/symptoms of a catheter site infection or fever by definition with other signs of infection such as hypotension, tachycardia, tachypnea, leukocytosis/leukopenia or elevated bands.

The study included 726 patients 13 years of age or older with catheter-related bloodstream infections including those with catheter-site infections. In the linezolid arm, 171 of the 360 (47%) patients had bloodstream infections; in the comparator arm, 216 of the 360 (57%) patients had bloodstream infections. About 48% of patients were being treated in an intensive care unit and 26% were intubated.

This study showed an increased number of deaths up to 84 days after the first dose of study drug in patients treated with linezolid (78 of 360 (21.7%)) compared to those treated with comparator (58 of 360 (16.1%)). At baseline 24 patients in the linezolid arm and 32 patients in the comparator arm had Gram-negative bloodstream infections; an additional 29 patients in the linezolid arm had Gram-negative bloodstream infections.

Report adverse adverse events to FDA's MedWatch reporting system by completing Form on web at <http://www.fda.gov/medwatch> or by mail using the postage-paid address from provided online (FDA, CDER, HFD-2005-0022).

2 of 3

March 19, 2007

FDA ALERT

FDA MedWatch: Zyvox (linezolid) - Clinical trial showed higher chance of death in the treatment of seriously ill patients with intravascular catheter-related bloodstream infections

MedWatch - The FDA Safety Information and Adverse Event Reporting Program

FDA notified healthcare professionals of new emerging safety concerns about Zyvox (linezolid) from a recent clinical study. This open-label, randomized trial compared linezolid to vancomycin, oxacillin, or dicloxacillin in the treatment of seriously ill patients with intravascular catheter-related bloodstream infections including those with catheter-site infections. Patients treated with linezolid had a higher chance of death than did patients treated with any comparator antibiotic, and the chance of death was related to the type of organism causing the infection. Patients with Gram positive infections had no difference in mortality according to their antibiotic treatment. In contrast, mortality was higher in patients treated with linezolid who were infected with Gram negative organisms alone, with both Gram positive and Gram negative organisms, or who had no infection when they entered the study.

Linezolid is not approved for the treatment of catheter-related bloodstream infections, catheter-site infections, or for the treatment of infections caused by Gram negative bacteria. If infection with Gram negative bacteria is known or suspected, appropriate therapy should be started immediately.

Read the complete MedWatch 2007 Safety summary, including a link to the Drug Information Page, at:

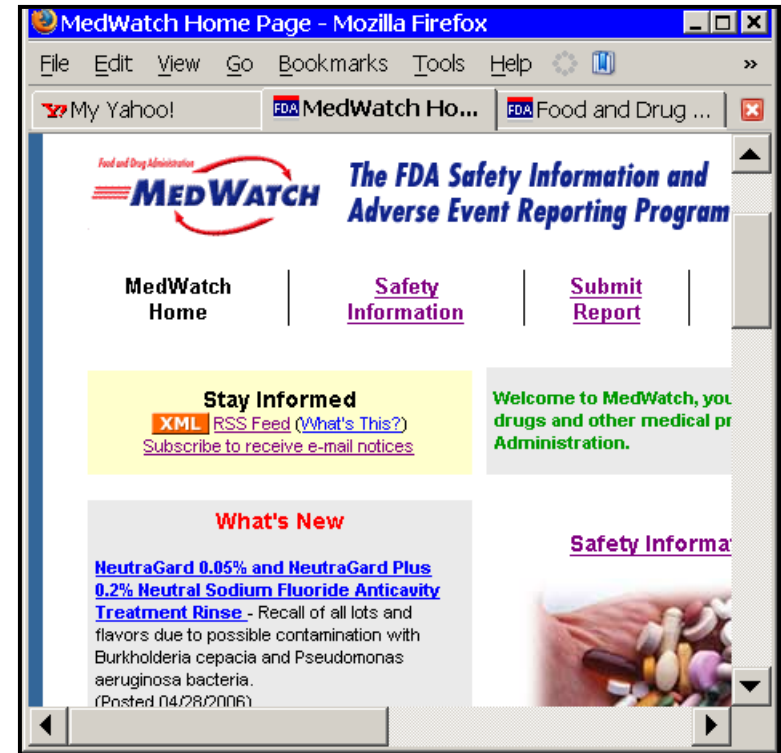
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Zyvox>

Data Summary

Risk Communication

Use of electronic tools for dissemination

- E-mail notification;
RSS feeds
- PDAs, MP3 and other portable devices
 - Drug reference databases
 - Other clinical resources
- Integration in Electronic Medical Records



Risk Communication

Use of electronic tools for dissemination

- Hand-Held PDAs
 - Portable drug reference information
 - e-Pocrates
 - >300,000 active MD subscribers
 - >300,000 ‘other’ subscribers
 - RN – 60K; NP – 29K
 - Instant updates of database and ‘DocAlerts’ at time of synchronization
 - Wireless ‘push’ of safety info to handheld

My Epocrates

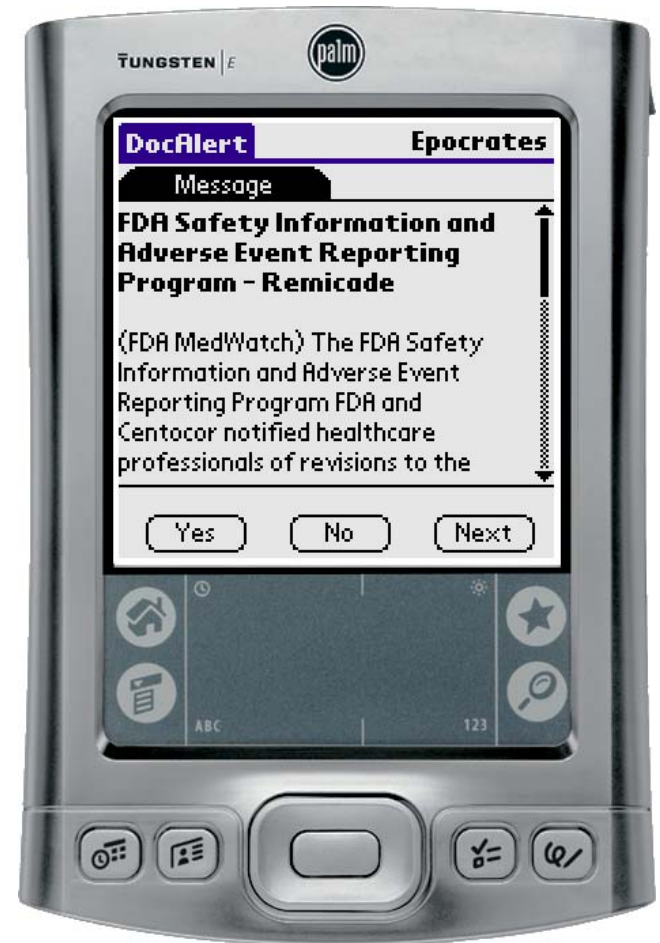


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 - Search history
 - Request specialized content (v2)
- **Better highlight content/features**
 - Drug warnings, safety alerts
 - MedTools, mCME, DocAlerts, Formulary
 - New monographs

DocAlert[®] message content

- Epocrates clinical includes:
 - Gov't (MedWatch, CDC, HHS, CMS)
 - Content providers – Reuters, InfoPOEMs, Primary Psychiatry and other trusted sources
 - National specialty and state medical associations

- DocAlert content includes
 - Safety alerts/product recalls
 - New journal articles
 - Clinical trial information





Making the FDA Website More Accessible



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Consumer Health Information

Consumer Updates

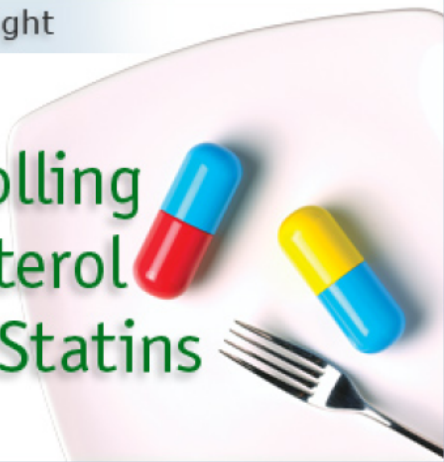
All Consumer Updates »

SEARCH Consumer Updates by title, topic, or date.



In the Spotlight

Controlling Cholesterol with Statins



Several medicines are effective at lowering blood cholesterol levels—a key factor in good heart health. Chief among them are the statins ... FULL STORY »

• [Your Guide to Reporting Problems to FDA](#)

• [Pregnant Women to Benefit from Better](#)

Top Consumer Updates as of June 17, 2008

- [Beware of Online Cancer Fraud](#)
- [Warning for Regranex—Cream for Leg and Foot Ulcers](#)
- [Your Guide to Reporting Problems to FDA](#)
- [Using the Consumer Complaint System and MedWatch](#)
- [Red Tomato Warning Expanded Nationwide](#)
- [Warning on Certain Types of Raw Red Tomatoes](#)
- [Albuterol Inhalers: Time to Transition](#)
- [Contaminated Nipple Cream](#)
- [Pregnant Women to Benefit from Better Information](#)
- [Enforcement Actions for Food Safety Violations](#)
- [FDA Takes Action Against Scientific Laboratories Inc.](#)
- [Sentinel System to Monitor Medical Product Safety](#)
- [Controlling Cholesterol with Statins](#)
- [Bayer Removes Remaining Trasylol Stock](#)

[All Consumer Updates »](#)

Key FDA Initiatives

- [FDA's Food Protection Plan](#)
- [Generic Initiative for Value and Efficiency \(GIVE\)](#)
- [All Key Initiatives](#)

Subscribe to Consumer Updates

- [Receive via e-mail](#)
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Content Collaboration

Integrate Consumer Updates into your program, publication, or Web site. Ask how ... consumerinfo@fda.hhs.gov

Contact FDA

- [Send Consumer Update questions or story ideas](#)
- [Find your local FDA office](#)



FDA's Risk Communication Products/Outlets

Risk Communication Outlets

- For Healthcare Professionals
 - Drug Safety Newsletter
 - www.fda.gov/cder.dsn/default.htm
 - MedWatch Listserv
 - www.fda.gov/medwatch/index.html
 - Healthcare Professional Information Sheets
 - Patient Safety News
 - www.accessdata.fda.gov/scripts/cdrh.cfdocs/psn/index.cfm



DRUG SAFETY NEWSLETTER

VOLUME 1 | ISSUE 1 | FALL 2007

IN THIS ISSUE

- 2 WELCOME**
An introduction to the inaugural issue of the Drug Safety Newsletter from the Commissioner, Dr. Andrew C. von Eschenbach.
- 2 EDITOR'S NOTE**
Overview of the content of this issue of the Drug Safety Newsletter.
- POSTMARKETING REVIEWS**
- 3 Rituximab**
Reports of progressive multifocal leukoencephalopathy associated with use of rituximab (marketed as Rituxan).
- 5 Modafinil**
Reports of serious skin reactions associated with use of modafinil (marketed as Provigil).
- 7 Temozolomide**
Reports of aplastic anemia associated with use of temozolomide (marketed as Temodar).
- NEW MOLECULAR ENTITY (NME) – EARLY SAFETY FINDINGS**
- 8 Deferasirox**
Overview of reported adverse events of interest associated with the use of deferasirox, an oral chelating agent, in early postmarketing experience (marketed as Exjade).
- 9 DRUG SAFETY COMMUNICATIONS**
List of advisories on drug safety posted on FDA's Web site from January 1, 2007, through June 1, 2007, with related links.

THE NEWSLETTER'S MISSION

This publication provides postmarketing information to healthcare professionals to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event reporting. For more information, visit the FDA Drug Safety Newsletter Fact Sheet at www.fda.gov/cder/dsn/factsheet.htm

REPORTING ADVERSE EVENTS

FDA encourages the reporting of all suspected adverse reactions to all drugs, all suspected drug interactions, and all suspected reactions resulting in death, life-threatening outcomes, hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, or congenital anomaly/birth defects.

Report serious adverse events to FDA's MedWatch reporting system by completing a form online at www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178), by mail using the postage-paid address form provided online (5600 Fishers Lane, Rockville, MD 20852-9787), or by telephone (1-800-FDA-1088).

<http://www.fda.gov/cder/dsn/default.htm>

FDA Healthcare Professional Sheet

Information for Healthcare Professionals Fentanyl Transdermal System (marketed as Duragesic and generics)

FDA ALERT 7/15/2005; Update 12/21/2007: This update highlights important information on appropriate prescribing, dose selection, and the safe use of the fentanyl transdermal system.

In July 2005, FDA issued a *Public Health Advisory and Information for Healthcare Professionals* that emphasized the appropriate and safe use of the fentanyl transdermal system (fentanyl patch), marketed as Duragesic and generics). Despite these efforts FDA has continued to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naïve patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source.

Risk Communication Outlets

- *For Patients and the General Public*
 - Public Health Advisory
 - Early Communication of an Ongoing Safety Review
 - **NEW** Consumer Information Website
www.fda.gov/consumer/default.htm
 - Podcasts

Drug Safety Communications have been used to...

- Inform about an emerging drug safety concern
- Respond to a Citizen's Petition request
- Summarize a new Risk Management Program
- Describe a risk (and actions to take) when we request new safety labeling
- Share FDA's perspective on an issue raised by another drug regulatory agency
- Other situations yet to be defined!

Drug Safety Public Health Advisories & Health Care Professional Information Sheets

- 85 drugs with safety postings in calendar 2007
 - 10 Public Health Advisories
 - 21 Healthcare Provider Information Sheets
 - 4 Early Communications

Risk Communication Challenges

- Striking the right balance
- Communicating complex information simply
- Deciding when to inform when data is early & evolving
- Anticipating & managing unintended consequences
- Balancing communication of emerging risk with known benefit

What we do know...

- Healthcare professional and public feedback is very positive
- Cited in news, newsletter and scientific journals
- Redistributed by
 - medical information vendors
 - healthcare institutions
 - medical and consumer organizations

What we don't yet know...

- What is the best way to communicate to our target audiences?
 - Language and reading levels
 - Venues beyond the written word—videos, podcasts, tool kits
- What is our reach and how do we broaden it?
- How do we measure effectiveness?