



FDA MedWatch and Patient Safety

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FDA MedWatch and Patient Safety

Some Context for this Presentation

- **Patient Safety** is on the agenda of many in recent years
 - Congress
 - Professional organizations
 - Academia [NEJM, JAMA]
- FDA is 'in the news' daily over its performance in post-marketing safety surveillance for drugs/devices
 - Vioxx [myocardial infarction]
 - Drug-eluting stents; ICD's [defibrillators]

FDA MedWatch and Patient Safety

Some Context for this Presentation

- **Patient safety** is important to all healthcare providers
 -even while keeping current on the safety of the drugs, devices and diagnostics is getting more difficult
- FDA often is the first to learn about new safety issues critical to patient safety and wants to share this safety information with clinicians and their patients at the point of care
- These unexpected safety issues are identified and evaluated by FDA only with help from point of care providers and patients
- Postmarket events of interest to FDA:
 - ❖ Adverse Events for drugs and devices
 - ❖ Product Quality Problems
 - ❖ Medication and device use errors
 - ❖ Therapeutic failures/inequivalence

FDA MedWatch and Patient Safety

How FDA Monitors the Safety of Drugs and Devices

- **Pre-Market Review and Approval**
 - FDA does not develop or routinely test products itself
 - FDA reviews the results of laboratory, animal, and human clinical testing done by companies
- **Post-Market Monitoring for Safety**
 - Careful review of adverse experiences with products once they are marketed is essential



Why Postmarketing Adverse Event Surveillance is Necessary?

- **Despite extensive evaluation of safety during drug development...**

there are significant limitations of phase 3 trials to identify safety signals before marketing

Limitations of phase 3 trials

The Five Too's

- **Too few - seldom more than 3000 pts**
- **Too simple –patients with complicated medical conditions excluded**
- **Too narrow – patients receiving concurrent meds are excluded**
- **Too median-aged –pediatric and elderly populations excluded**
- **Too brief – trials often no longer weeks to months; precluding identification of reactions due to long term use or latent effects**

Reporting In to MedWatch

What, when, how and why to report

- **What**
 - All clinical medical products
- **When**
 - If serious
- **How**
 - Online, or mail/fax/phone
- **Why**
 - Every report can make a difference



Reporting In to MedWatch

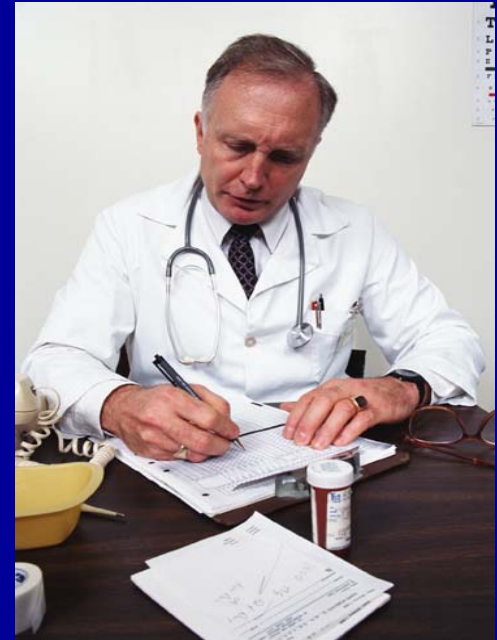
What products to report on

- **Drugs**
 - Prescription
 - Over the Counter
- **Medical Devices**
- **Biologics, except vaccines**
- **Special Nutritional Products**
 - Dietary supplements
 - Infant formulas
 - Medical foods
- **Cosmetics**

Reporting In to MedWatch

What To Report

- **Serious Adverse Events**
 - Drugs, biologics, devices, cosmetics and special nutritional products
- **Product Quality Problems**
 - Suspect counterfeit
 - Contamination, instability
 - Poor packaging, labeling
 - Defective components
 - Therapeutic failures
- **Medication and Device Use Errors**
- **Therapeutic Failures**



Reporting In to MedWatch

What is a serious adverse event

Any event that ...

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

Reporting to MedWatch

How to Report?

Phone (800-332-1088)
Fax
Mail

Online application for direct submission

www.fda.gov/medwatch/report.htm

Fillable pdf versions of voluntary form

offered for desktop use and submission by mail/fax

www.fda.gov/medwatch/getforms.htm

The screenshot displays the MedWatch Online Reporting Form 3500 in a Microsoft Internet Explorer browser window. The form is titled "U.S. Food and Drug Administration" and "Department of Health and Human Services". It includes sections for Patient Information, Adverse Event, Product Problem or Error, Suspect Product(s), Suspect Medical Device, Other (Concomitant) Medical Products, Reporter, and Product Availability. The form is divided into multiple pages, with the first page showing the top sections. A green arrow points from the "Event Date" field to the "Event Date" field in the "Event Abated After Use Stopped or Dose Reduced" section. Another green arrow points from the "Event Date" field to the "Event Date" field in the "Event Reappeared After Reintroduction" section.

Reporting In to MedWatch

How to report

Patient

Product

Description of Event
or Problem

Reporter

U.S. Department of Health and Human Services
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors
Page ____ of ____

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY
Titration sequence #

A. PATIENT INFORMATION
1. Patient Identifier
2. Age at Time of Event, or Date of Birth:
3. Sex: ☐ Female ☐ Male
Weight:
lb or
kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR
1. ☐ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine
2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - Initial or prolonged ☐ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy)
5. Describe Event, Problem or Product Use Error

C. PRODUCT AVAILABILITY
Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☐ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)
1. Name, Strength, Manufacturer (from product label)
#1
#2
2. Dose or Amount Frequency Route
#1
#2
3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1
#2
4. Diagnosis or Reason for Use (Indication)
#1
#2
5. Event Appeared After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply
7. Expiration Date
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#2
8. NDC # or Unique ID
#1
#2

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name
3. Manufacturer Name, City and State
4. Model # Lot # 5. Operator of Device
Catalog # Expiration Date (mm/dd/yyyy) ☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial # Other #
6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

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

G. REPORTER (your confidentiality will be protected)
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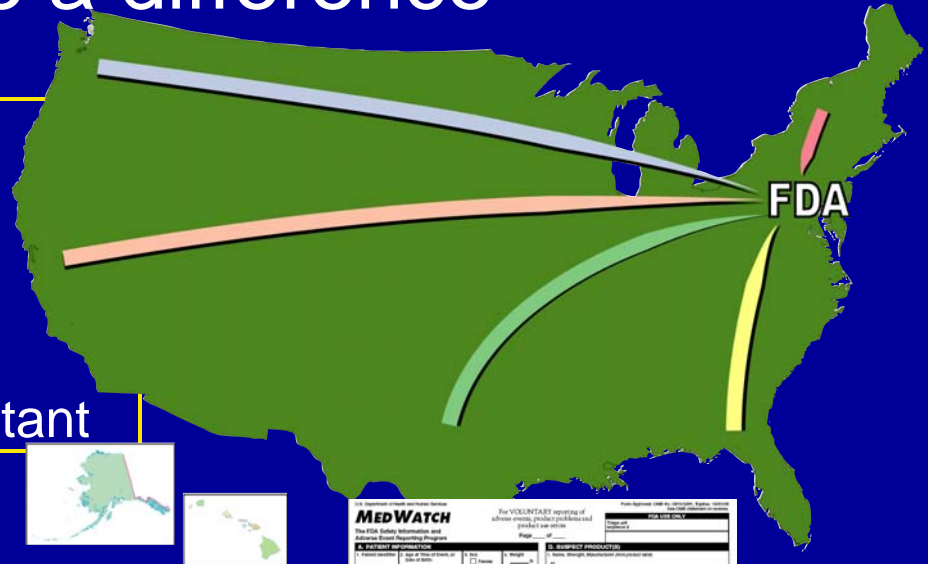
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Reporting In to MedWatch

Why Report?

Every report can make a difference

Walla Walla, WA – Oncologist
Sacramento, CA – Nurse
Houston, TX - Dentist
Tallahassee, FL – Pharmacist
Portland, ME – Physician Assistant



Even a few voluntary reports from individual reporters can become a '**signal**' and lead to a label change or other FDA action.

What Happens to Your Report

- When you report an ADE for a drug or biologic
- When you report a product quality problem for a drug or device
- When you report a medication or device use error



What Happens to Your Report

When you report a serious adverse event

- **Report captured in a database**
- **Database monitored by an FDA professional**
- **Review of a case series**
- **Consultation with medical review division and manufacturer**
- **Further epidemiological studies as needed**

What Happens to Your Report

When you provide information on a serious ADE

Labeling or Educational Options

- Boxed Warning
 - Drug-drug, drug-food interaction warnings
 - Monitoring recommendations
 - Dosage adjustments for sub-populations
- Contraindications, Warnings, Precautions or Adverse Reactions
- Medication Guide

What Happens to Your Report

When you report a serious ADE

- **Special programs - REMS**
 - Prescribing or dispensing limitations
 - Laboratory testing documentation
 - Registries
- **Product withdrawal**

What Happens to Your Report

When you report a product quality problem

- **For problems due to:**
 - Product design
 - Manufacturing quality or distribution/storage
 - Counterfeit product
- **FDA can:**
 - Work with manufacturer to issue a recall of product
 - Request a modification in product design
 - Request a modification in manufacturing process
 - Improve instructions or warnings for use

What Happens to Your Report

When you report a medication or device use error

- **Errors and ‘near misses’**
 - All reports are monitored and evaluated
- **For errors due to:**
 - Name confusion of drugs
 - Packaging or labeling of drugs
 - Device use
- **FDA can:**
 - Request name change or modification
 - Request packaging/labeling changes
 - Modify instructions for device use

Each Report Can Make a Difference



Every Report Can Make a Difference

Novantrone - mitoxantrone

- **Single voluntary MedWatch report received by FDA**
- **Safety Evaluator review of AERS database**
- **Further evaluation of ongoing data in phase 4 study**
- **Revision of boxed warning to include new monitoring recommendations**
- **DHCP letter and MedWatch alert issued**

Single voluntary MedWatch report received by FDA

- **Direct Report made 9/18/2004**
- **A 34 year-old woman with multiple sclerosis developed cardiogenic shock with an ejection fraction of 5% after being treated with mitoxantrone for 2 and ½ years. The patient needed a heart transplant.**

Safety Evaluator review of AERS database

- **There appear to be cases of mitoxantrone-induced cardiac toxicity at cumulative doses less than the current monitoring threshold of 100 mg/m²**

Further evaluation of ongoing data in phase 4 study

RENEW Interim Analysis

- **15 patients had a decline in LVEF to < 50%**
 - Cumulative doses 47.6 – 126 mg/m²
- **9 patients had LVEF measurements that decreased at least 10% but remained above 50% and mitoxantrone was discontinued**
 - Cumulative doses 55.3 – 105.3 mg/m²
- **These LVEF screenings were done at the discretion of the investigator**

Revision of boxed warning to include new monitoring recommendations

- **LVEF should be reevaluated by echocardiogram or MUGA prior to each dose administered to patients with MS.**
- **Baseline evaluation of LVEF by echocardiogram or MUGA should be performed.**
- **MS patients with a baseline LVEF < 50% should not be treated with Novantrone.**
- **Additional doses should not be administered to MS patients with a drop in LVEF to below 50% or a clinically significant reduction in LVEF.**

Novantrone mitoxantrone For injection concentrate

April 2005

Dear Healthcare Professional:

This letter is sent to you to supplement previously provided information concerning **the risks of cardiotoxicity associated with NOVANTRONE** (mitoxantrone for injection

concentrate) treatment for multiple sclerosis (MS) Reports received through postmarketing surveillance, have shown that diminished cardiac function may occur early on in the treatment with NOVANTRONE. cardiac monitoring of MS patients should be performed at baseline and prior to administration of every dose of NOVANTRONE.

NDA 19-297/S-028
Page 8

Novantrone
mitoxantrone
For injection concentrate

SERONO

April 2005

Dear Healthcare Professional:

This letter is sent to you to supplement previously provided information concerning the risks of cardiotoxicity associated with NOVANTRONE (mitoxantrone for injection concentrate) treatment for multiple sclerosis (MS) and also provides supplemental information regarding secondary acute myelogenous leukemia (AML) reported in MS patients treated with NOVANTRONE.

Reports received through post-marketing surveillance, have shown that diminished cardiac function may occur early on in the treatment with NOVANTRONE. Therefore, the Product Labeling for NOVANTRONE was updated in March 2005 to state that cardiac monitoring of MS patients should be performed at baseline and prior to administration of every dose of NOVANTRONE. Please refer to the Product Labeling (enclosed) for full prescribing information, including the specific sections on "Boxed Warnings," "Warnings," and "Dosage and Administration."

NOVANTRONE is indicated for reducing relapses in patients with secondary (chronic relapsing-remitting multiple sclerosis (i.e., abnormal between relapses). NOVANTRONE is not indicated for primary progressive multiple sclerosis.

Cardiotoxicity

How MedWatch Sends Safety Information To You

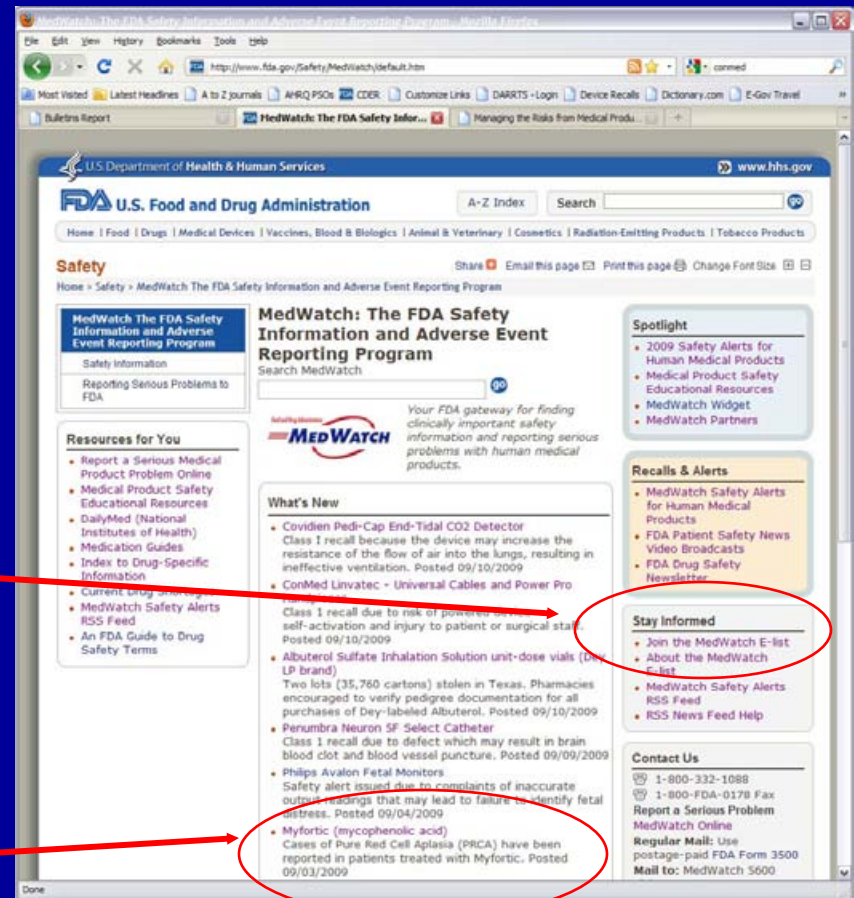


E-list notification and RSS feeds

**Listserve growth from
5K to 153,000 subscribers
since 2002**

***RSS feed –over 1 million pageviews
in December 2008***

E-list notification example:



“Novartis and FDA notified healthcare professionals that cases of Pure Red Cell Aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (MMF) in combination with other immunosuppressive agents. MMF is metabolized to mycophenolic acid (MPA), the active ingredient in Myfortic and the active form of the drug. The WARNINGS and ADVERSE REACTIONS sections of the Myfortic Prescribing Information have been revised

MedWatch website

Safety Alert example

Myfortic (mycophenolic acid) - Mozilla Firefox

File Edit View History Bookmarks Tools Help

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181505.htm

Most Visited Latest Headlines A to Z Journals AHRQ PSOs FDA CDER Customize Links DARRTS - Login Device Recalls Dictionary.com E-G

Bulletins Report Myfortic (mycophenolic acid) Managing the Risks from Medical Products

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

A-Z Index Search

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

Safety Share Email this page Print this page Change Font

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

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Safety Alerts for Human Medical Products

- 2009 Safety Alerts for Human Medical Products
- 2008 Safety Alerts for Human Medical Products
- 2007 Safety Alerts for Human Medical Products
- 2006 Safety Alerts for Human Medical Products
- 2005 Safety Alerts for Human Medical Products
- 2004 Safety Alerts for Human Medical Products
- 2003 Safety Alerts for Human Medical Products

Myfortic (mycophenolic acid)

Audience: Renal, cardiac, and hepatic transplantation healthcare professionals

[Posted 09/03/2009] Novartis and FDA notified healthcare professionals that cases of Pure Red Cell Aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (CellCept) in combination with other immunosuppressive agents. MMF is metabolized to mycophenolic acid (MPA), the active ingredient in Myfortic and the active form of the drug. The WARNINGS/ADVERSE REACTIONS sections of the Myfortic Prescribing Information have been revised to reflect this new safety information.

PRCA is a type of anemia in which there is a selective reduction of red blood cell precursors on bone marrow examination. Patients with PRCA may present with fatigue, lethargy, and/or abnormal paleness of the skin (pallor). In some cases, PRCA was found to be reversible with dose reduction or cessation of MMF therapy. In transplant patients, however, reduced immunosuppression may place the graft at risk.

[09/03/2009 - Dear Healthcare Professional Letter - Novartis]
[07/10/2009 - Prescribing Information and Medication Guide - Novartis]
Related MedWatch Alert:
[08/14/2009 - CellCept (mycophenolate mofetil)]

Philips Avalon Fetal Monitors: Safety alert due to complaints of inaccurate output readings that may lead to failure to identify fetal distress

From: FDA MedWatch
To: Watterberg, J
Cc:
Subject: Philips Avalon Fetal Monitors: Safety alert due to complaints of inaccurate output readings that may lead to failure to identify fetal distress

Sent: Fri 9/4/2009 10:38 PM

MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Philips Avalon Fetal Monitors

Audience: Obstetric healthcare professionals, hospital risk managers

FDA issued a Dear Healthcare Provider Letter to notify healthcare professionals and facilities of a number of complaints of inaccurate readings when using the Philips Avalon Fetal Monitors, Models FM20, FM30, FM40, and FM50 with the ultrasound transducer. In September 4, 2009, Philips issued an Important Device Safety Alert. Inaccurate output readings, if not properly addressed, may lead to unnecessary interventions, failure to identify the need for interventions, and failure to identify fetal distress. The complaints most commonly occur during the second stage of labor. Recognizing these conditions and appropriately is important to avoiding serious adverse health consequences.

This alert describes the most common complaints reported, steps for the user to minimize the risk, and urges the user to review the Instructions for Use for Philips Avalon Fetal Monitors.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online, by phone [1-800-332-1088], or by returning the postage-paid FDA Form 3500 by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Read the complete MedWatch 2009 Safety summary including a link to the FDA Dear Provider letter and the Philips Healthcare alert, at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181505.htm>

You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at www.fda.gov/medwatch/report.htm

Update your subscriptions, modify your e-mail address, or stop subscriptions at any time on your [Subscriber Preferences Page](#). You will need to use your e-mail address to log in. If you have questions or problems with the subscription service, please contact support@fda.gov

This service is provided to you at no charge by U.S. Food & Drug Administration (FDA).

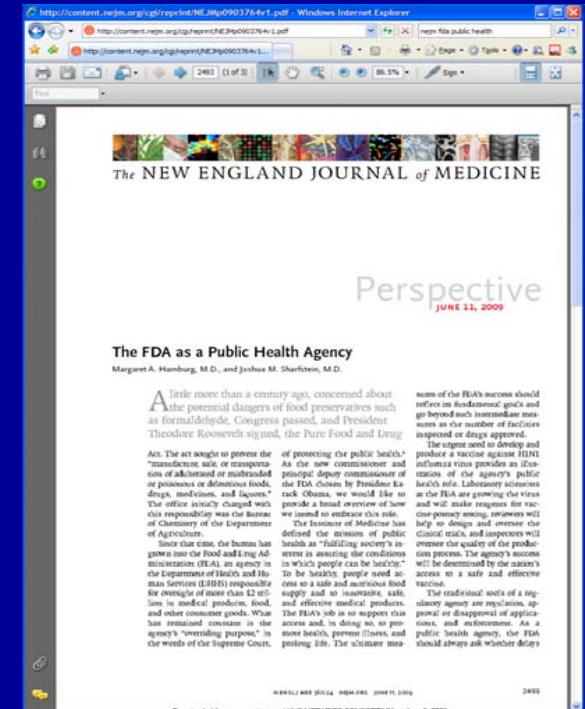
FDA
Delivery, Inc. sending on behalf of U.S. Food & Drug Administration (FDA) - 8600 Fishers Lane - Rockville MD 20857 - 800-438-1420

Drug Safety - FDA's Risk Management focus

Opportunities for improved risk communication

“Beyond the Label” strategies

- Request that sponsor send DHCP letter
- Announce the information to the press
- Post the information on the FDA website
- Notify targeted organizations and enlist their help in disseminating information to members
- Send a notification by email/text message to individual or RSS feed to work setting
- Incorporate notification into workflow at point at which provider is considering the product



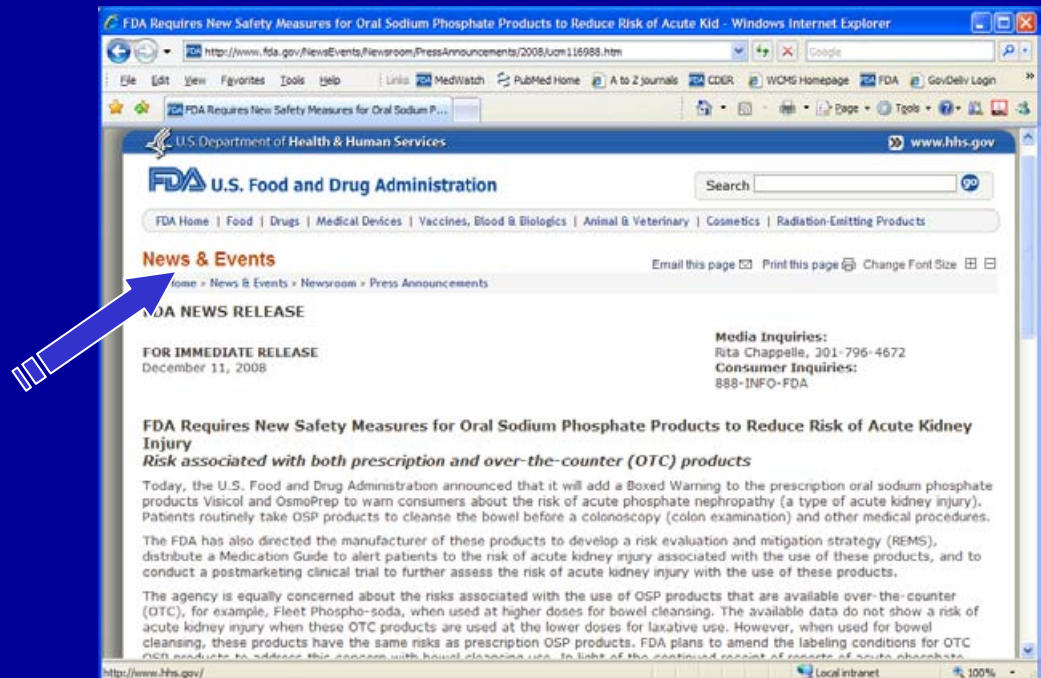
Transparency and
public health role

Reaching Point-of-Care Providers With Timely and Actionable Safety Information

The Oral Sodium Phosphate example

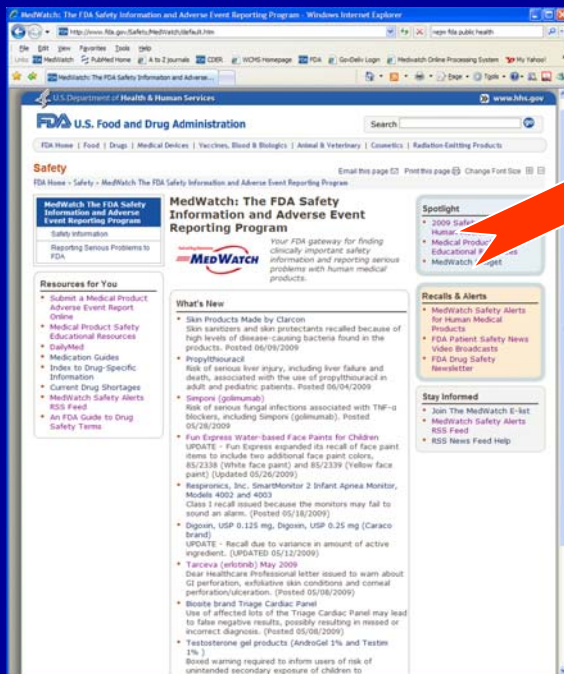
- ✓ Announce the information to the press

“As a result of new safety information received, FDA is requiring the manufacturer of Visicol and OsmoPrep, the two OSPs available by prescription only, to add a Boxed Warning to the labeling for these products. FDA is also requiring that the manufacturer develop and implement a risk evaluation.....”

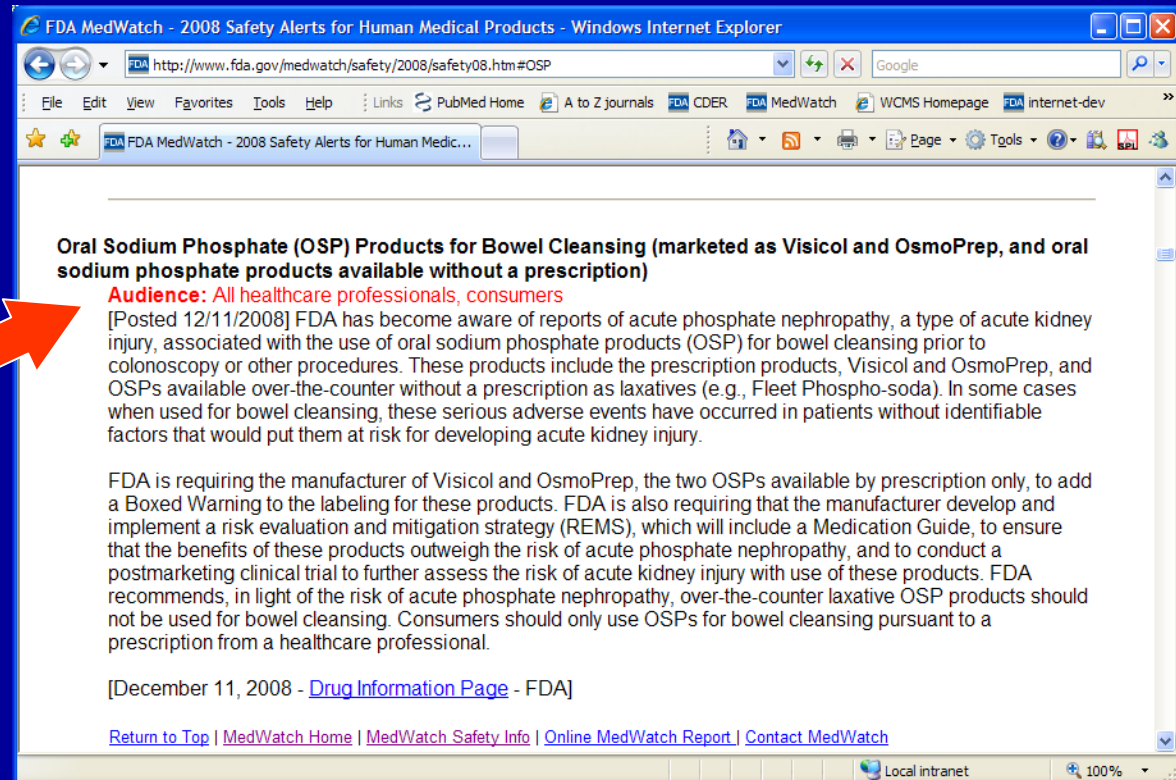


FDA MedWatch

Post the information on the FDA MedWatch website



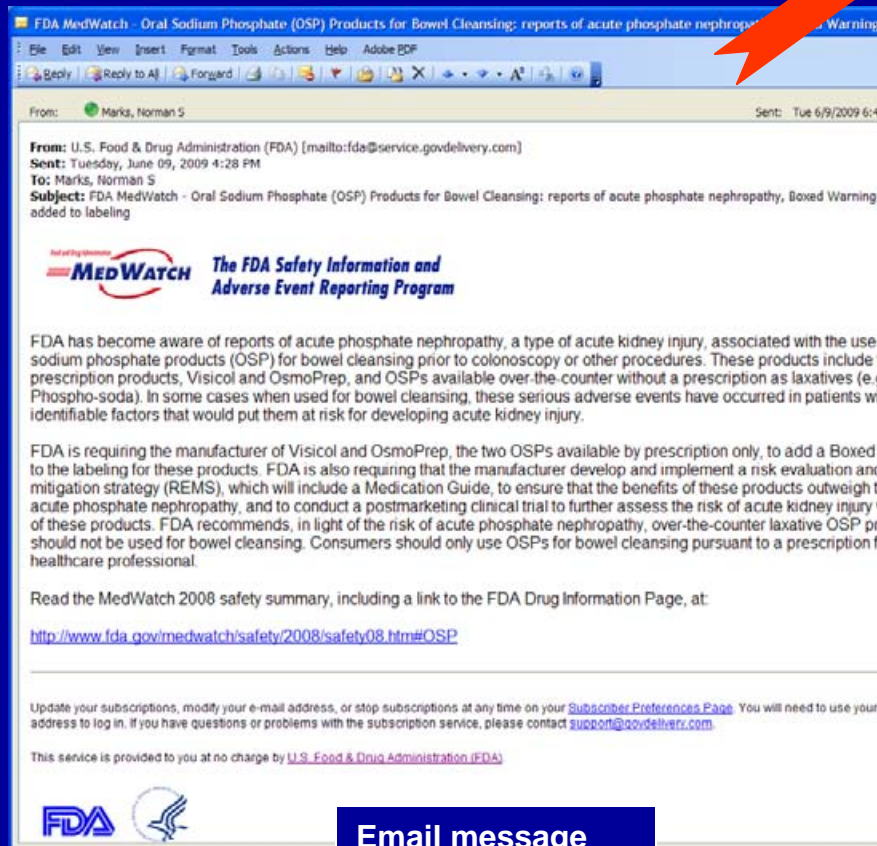
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Safety Alert item

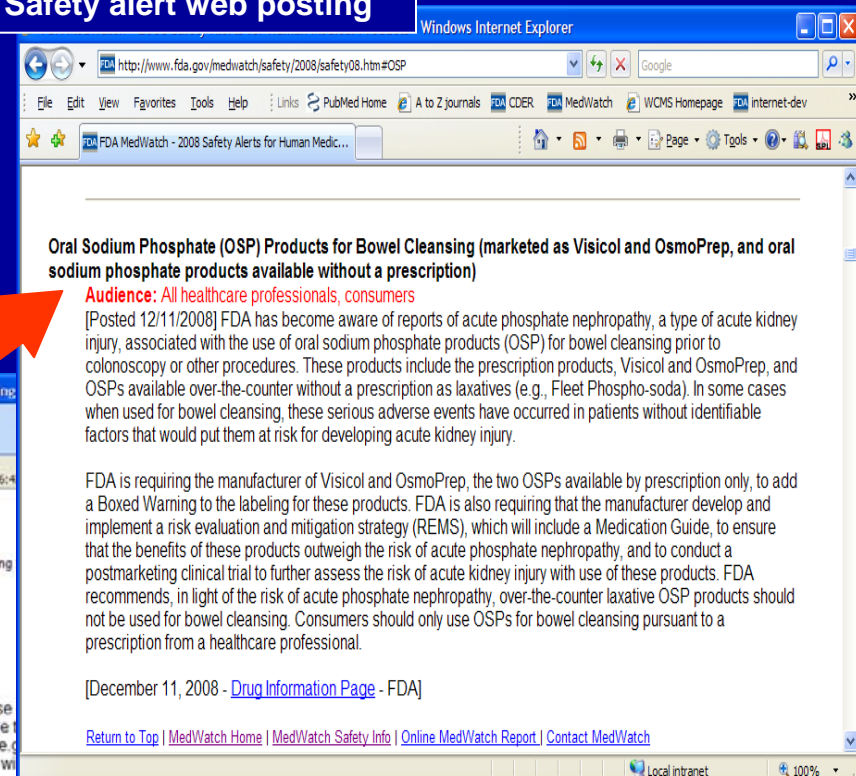
FDA MedWatch

Send notification by email/text message to individual or work setting



Email message

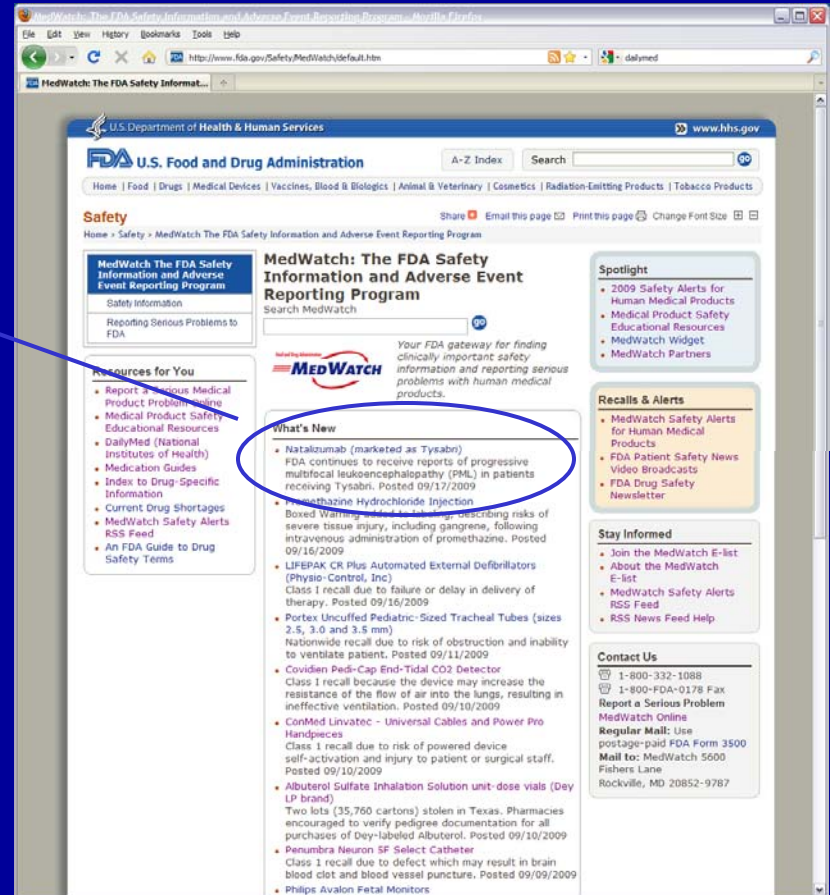
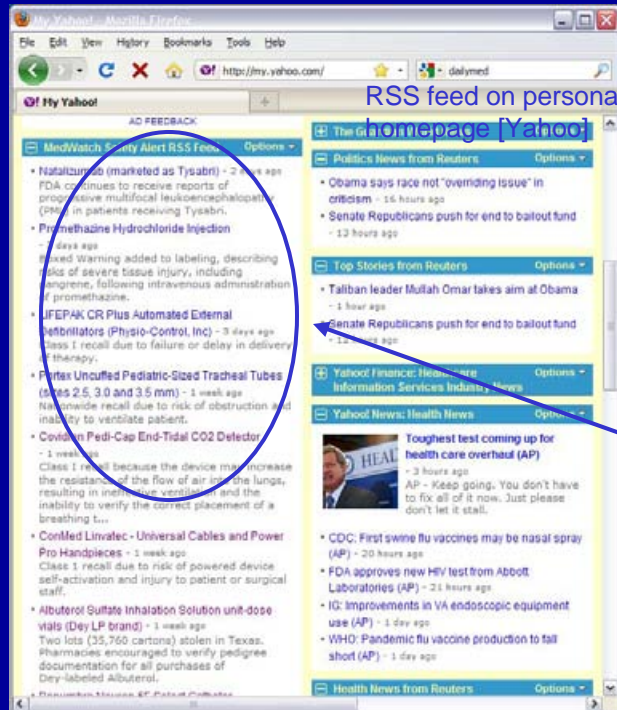
Safety alert web posting



Listserve Notification
GovDelivery distribution
now reaches over 153,000
individuals

FDA MedWatch

Send notification by RSS feed to internet/intranet browsers



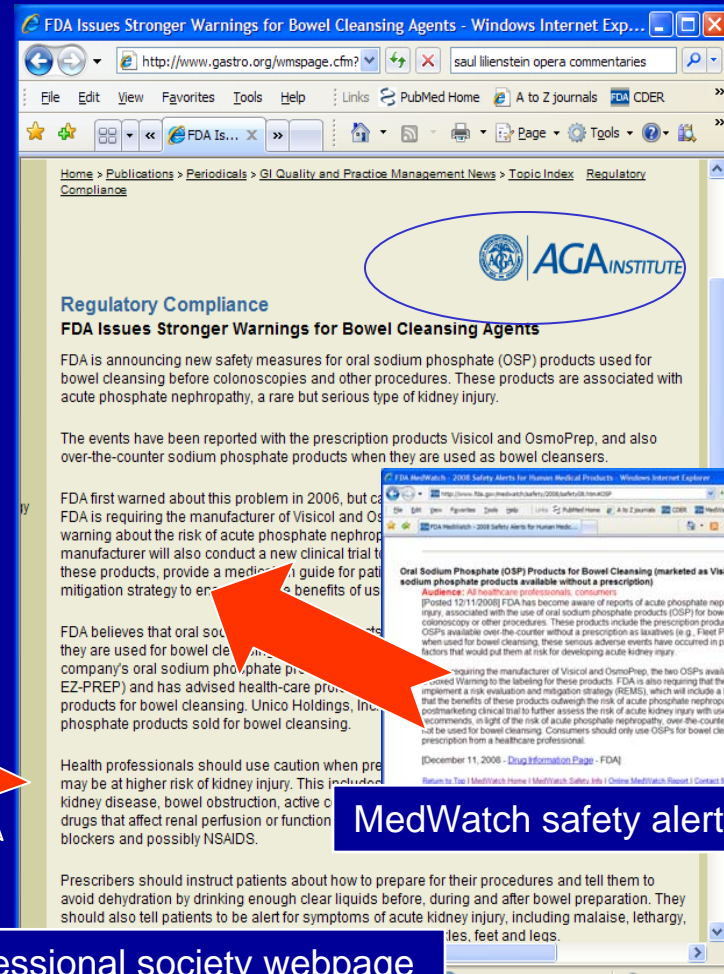
1. Alternative channel to individuals who want to avoid another email message
2. Automatic populating of intranet information for medical centers, hospital systems

FDA MedWatch

Notify targeted organizations and enlist their help in disseminating information to their members



Information for HCPs [FDA]



MedWatch safety alert posting

Professional society webpage

MedWatch Partners program
Am Gastroenterological Association

FDA MedWatch

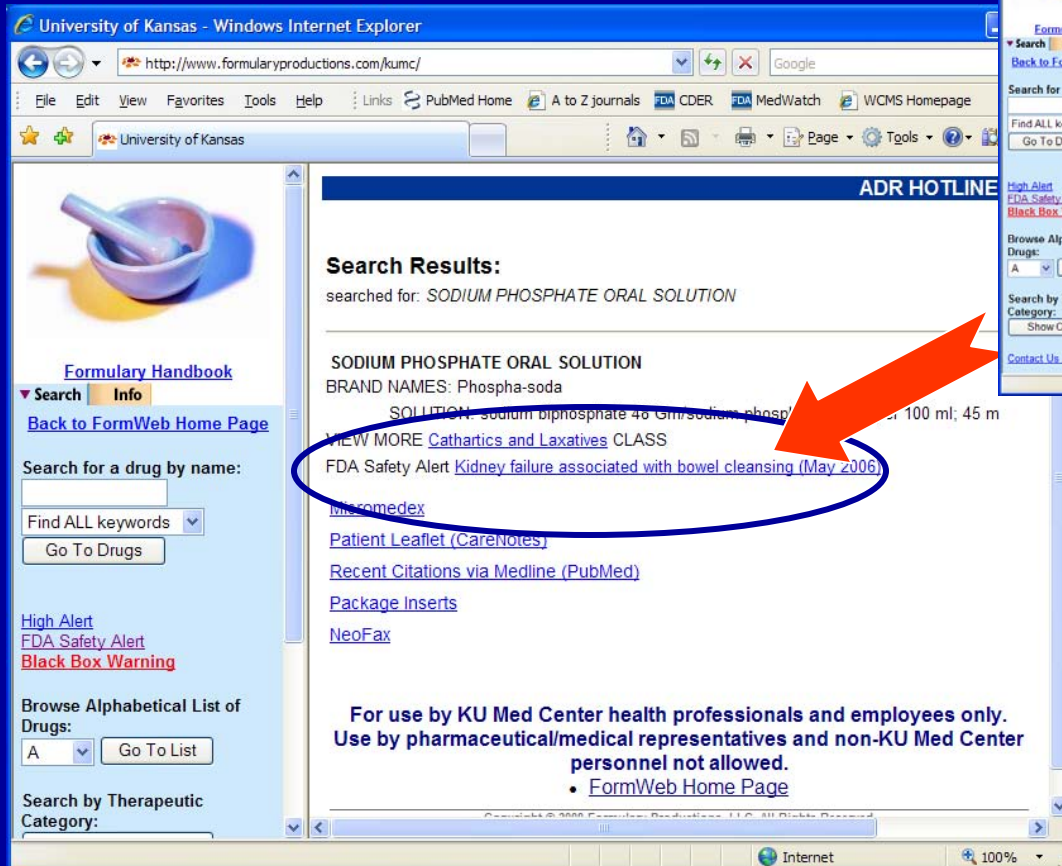
Incorporate new safety information into workflow at point when provider is considering the product

- **Mobile drug references**
 - 650,000 registered users
 - 250,000 confirmed M.D.'s
 - 40,000 medical students
- **Regular updates of references weekly/monthly**
- **DocAlerts** notify physicians when updates are made, such as new drug approvals, additional indications, recalls
 - received by 5607 GI docs
 - received by over 131,000 primary care docs



FDA MedWatch

Incorporate new safety information into workflow at point when provider is considering the product



Kansas University
Medical Center

FDA MedWatch and Patient Safety



Visit us online at
www.fda.gov/medwatch



Safety Information Resources for HCPs

FDA MedWatch and Patient Safety

MedWatch: Safety Information and Adverse Event Reporting

Safety Share Print this page Change Font Size

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

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Reporting Serious Problems to FDA

Medical Product Safety Educational Resources

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

Safety Information Resources for Health Professionals

Learn about medical product safety information available from FDA.

Video, approximately 11 minutes

Windows: **300k** | **150k**
Real: **300k** | **150k**

Choose 150k bit rate videos for slower internet connections.



"Busy healthcare professionals need the best safety information at the right time to help manage their patients' care."

Dr. Janet Woodcock, FDA

FDA MedWatch and Patient Safety

A **self-learning tutorial** covering the MedWatch program goals of broadcasting safety information and encouraging adverse event reporting.

- Video, approximately 24 minutes.
- Powerpoint presentation [25 slides]
- Transcript
- Self-administered quiz with answers



"... Even a few voluntary reports ... can become the signal that leads to a label change or other FDA actions to improve the safe use of a medical product."

Dr. Norman Marks, FDA

MedWatch: Safety Information and Adverse Event Reporting

In this **expert column**, Norman Marks, MD, Director of the FDA's MedWatch program, discusses the role of MedWatch in adverse event reporting and in disseminating timely and targeted safety information.

From Medscape Pharmacists-Expert Column, March 11, 2009

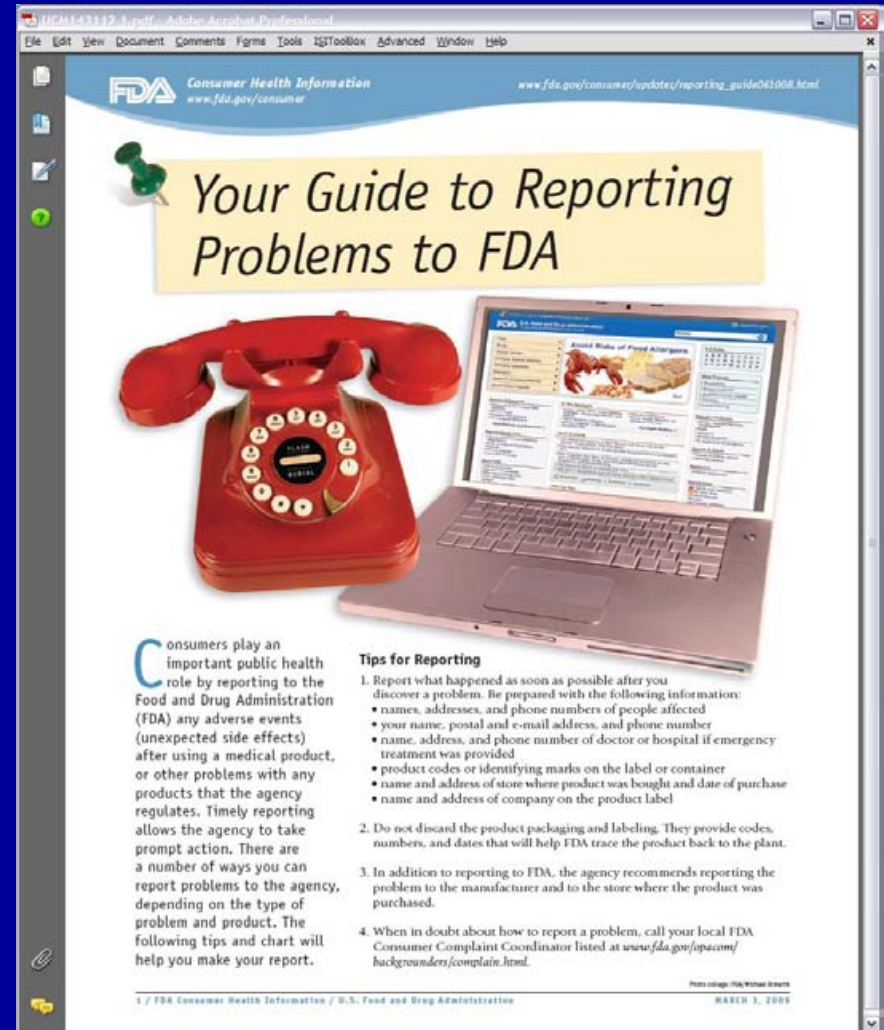


"[MedWatch is] a trusted source of safety information as you provide the best care for your patients."

Dr. Norman Marks, FDA

<http://www.fda.gov/Safety/MedWatch/ucm133050.htm>

Your Guide to Reporting Problems to the FDA



<http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143112.pdf>