FDA & Related Web Sites

www.fda.gov

Marc A. Marti-Renom, Ph.D.

Lecture goals

The lecture pretends that...

- you know how-to navigate the FDA web site
- you get an idea on what it is useful for
- you get minimally bored ;-)

The lecture **does not** pretend to...

- be exhaustive
- be general

Next 2 hours...

1h. FDA web site walkthrough

- About
- Information
- What is there?

2h. FDA web site used

- Question ...
- Problem ...
- Analysis ...
- Conclusions ...

www.fda.gov

FDA U.S. Food and Drug Administration — Department of Health and Human Services

Search

GO

Powered by Google

A-Z Index
Site Map

Products FDA Regulates

Food
Foodborne Illness, Nutrition, Dietary Supplements...
Drugs
Prescription, Over-the-Counter, Generic...
Medical Devices
Pacemakers, Contact Lenses, Hearing Aids...
Biologics
Vaccines, Blood Products...
Animal Feed and Drugs
Livestock, Pets...
Cosmetics
Safety, Labeling...
Radiation-Emitting Products
Cell Phones, Lasers, Microwaves...
Combination Products

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Sign up for any of more than 20 lists.

FDA NEWS

FDA Warns Public About Counterfeit Lipitor, Viagra, Evista for Sale in Mexico
First DNA Test for Cystic Fibrosis Approved
FDA Approves Requip for Restless Legs Syndrome
FDA Proposes Safety Labeling in Carton Lid of Eggs
Anesthesiology and Respiratory Therapy Devices Panel Meets May 13

Recalls, Product Safety
Product Approvals
More FDA News - Press Releases, Meetings, Congressional Testimony, Speeches, More

Let Us Hear From You

Report a Problem with a Product
Comment on Proposed Regulations
Petition FDA
Job Opportunities
Contact FDA

Reference Room

Laws FDA Enforces
Code of Federal Regulations
Federal Register
Guidance Documents
Forms
Dockets
Warning Letters
Manuals and Publications

www.healthfinder.gov FIRSTGOV.gov

U. S. Food and Drug Administration
5600 Fishers Lane, Rockville MD 20857-0001
1-888-INFO-FDA (1-888-463-6332)

Food Industry

- Register a Facility
- Prior Notice of Imports

Hot Topics

- Food Pyramid
- Seasonal Allergies
- Losing Weight
- Cell Phones
- Imported Drugs
- Counterterrorism
- Bioterrorism Act
- Buying Medicines Online
- Counterfeit Drugs
- **More Hot Topics...**

FDA Activities

- About FDA
- Advisory Committees
- Clinical Trials
  - Consumers
  - Professionals
- Commissioner's Page
- Field Operations
- Freedom of Information
- Imports
- International
- Major Initiatives
- MedWatch
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Information For

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KIDS

Summary

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Enforcement Activities
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- Clinical Trials--Guidance for Researchers
- Enforcement Activities Home Page
- Enforcement Report
- Field Operations
- Import Program
- Laws Enforced by FDA
- Product Recalls, Alerts, and Warnings
- Warning Letters

Hot Topics
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Major Initiatives/Activities
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- FDA Modernization Act
  - Communicating with Stakeholders
  - Implementation Chart
- FDA Strategic Plan Initiatives:
  - Efficient Risk Management
  - Better Informed Consumers
  - Patient and Consumer Safety
  - Counterterrorism
  - A Strong FDA
- Food Security--Combating Terrorist Threat
- Government Performance & Results Act
- International
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- Medical Device User Fees
- Pediatrics
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  - PDUFA II 5-Year Plan
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News
- Congressional Testimony
- Meetings
- New Reports and Publications
- Press Releases & Talk Papers
- Product Approvals
- Product Recalls, Alerts and Warnings
- Public Calendar
- Public Speeches by FDA Officials
- Warning Letters

Products Regulated by FDA
- Allergy Therapies
- Animal Drugs and Food
- Aquaculture
- Bioengineered Food
- Biologics
- Blood
- Breast Implants
- Cell Phones
- Cosmetics
- Dietary Supplements
- Drugs
- Food
- Gene Therapy
- Infant Formula
- LASIK
- Mammography Facilities
- Medical Devices
- Mobile Phones
- Nanotechnology Products
- Orphan Products (drugs and devices)
- Radiation-Emitting Electronic Products
- Tattoos
- Tissue for Transplantation
- Vaccines
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- Xenotransplantation

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Publications
- Backgrounders
- "Bad Bug Book" (on food pathogens)
- Blue Book (no longer published)
- Consumer Publications Catalog
- Easy-to-Read Publications
- Enforcement Report
- FDA Consumer magazine
- Federal Register Documents
- Foreign Language Documents
- General Publications Catalog
- Green Book (approved animal drugs)
- Industry Guidance Documents
- Investigations Operations Manual
- Just the Facts series
- Medical Bulletin (no longer published)
- National Drug Code Directory
- Orange Book (approved drug products)
- Press Releases
- Public Speeches by FDA Officials
- Regulatory Research Perspectives
- Talk Papers
- Yellow Book (List of U.S. Industries)

About This Website
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Specialized Site Maps
- Biologics Evaluation & Research
- Drug Evaluation & Research
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- Toxicological Research
- Regulatory Affairs

Search FDA's Online Databases

Information for Specific Audiences
- AIDS Patients
- Cancer Patients
- Cancer Liaison Program
- Clinical Trials -- Consumers
- Clinical Trials -- Professionals
- Consumers
- Español
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FDA's Mission Statement

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. 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 to improve their health.

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Laws Enforced by the FDA and Related Statutes

Federal Food, Drug, and Cosmetic Act

Additional Laws:

1997 Modernization Act (PDF 398 KB)

Administrative Procedures Act

Animal Drug User Fee Act of 2003

Best Pharmaceuticals for Children Act (PDF 76.1 KB)

Bioterrorism Act of 2002 (PDF 297 KB)

Congressional Reports Elimination Act of 1982

Controlled Substances Act

Controlled Substances Import and Export Act

Delegations of Authority to the Commissioner of Food and Drugs

Department of Education Organization Act

Dietary Supplement Health and Education Act of 1994

Egg Products Inspection Act

Fair Packaging and Labeling Act

Federal Advisory Committee Act

Federal Advisory Committee Amendments

Federal Anti-Tampering Act

Federal Food and Drugs Act of 1906

Federal Fines and Sentencing Laws

Federal Import Milk Act

Federal Meat Inspections Act

Federal Trade Commission Act

Filled Milk Act

Food Quality Protection Act of 1996

Foods and Drugs

GATT Uruguay Round Patent Provisions

Related Information

Code of Federal Regulations

Federal Register

Dockets

FDA Manuals and Publications

http://www.access.gpo.gov/

United States Code

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U.S. Food and Drug Administration — Department of Health and Human Services

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Frequently Asked Questions (FAQs)

The Frequently Asked Questions (FAQs) below, as well as others reached through the links on the left, cover basic and timely information and guidance for those interested in the many products FDA regulates and other agency responsibilities. Answers usually include further links to in-depth information included throughout FDA's Website, as well as on the sites of other government agencies.

If you can't find the answer to a question here, try one of the following options:

- Search the FDA Website.
- Check out the FDA Website index.
- Refer to the site map.
- Go to Information for Consumers for more consumer-oriented materials or to learn how to contact the agency directly.

Other FAQs

- Animal Drugs
- Biologics
- Cosmetics
- Food
- Human Drugs

What does FDA do?
How big is FDA?
What FDA do with defective drugs?
How to contact FDA? ...

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U.S. Food and Drug Administration — Department of Health and Human Services

Contact FDA

Contact Us On-Line

Your comments, thoughts, and feedback are important to us, and they can help FDA serve you better. We'd like to know what you think about the job we're doing. Every message will be read by the person responsible for that subject area, and we'll follow up in whatever manner is appropriate. But please understand that we cannot respond directly to every comment.

If you want to communicate your comments, questions or suggestions to FDA through the Internet, please start by selecting your area of concern:

Drugs Go

Need Information About the Registration of Food Facilities:
Submit questions to the Help Desk.
Phone: 1-800-216-7331

Have a comment/question about the Website? We'd like to hear it. Please let us know if you need assistance with a broken link, a page loading incorrectly, or other technical problems. Please provide the URL (address) of the troublesome page. You can report these problems or let us know what you think about our Website by using our Website Feedback form.

Contact Us by Mail or Telephone

If you have comments or questions you can also contact us by mail:

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

or by telephone:

- 1-888-INFO-FDA (1-888-463-6332) -- main FDA Phone Number (for general inquiries)
- Electronic Employee Directory
- FDA Public Affairs Specialists

Freedom of Information: FDA cannot accept on-line Freedom of Information Act requests (because such requests must be signed in writing); however, information about filing such requests is available in FDA's Electronic FOI Reading Room.

Where to Look for Answers

- Website Index
- Search FDA Website
- Site Map
- How to Report Problems with FDA-regulated Products
- Frequently Asked Questions
- Getting Information from FDA
- FDA Field Offices
- FDA Job Information
- About FDA

Information For:

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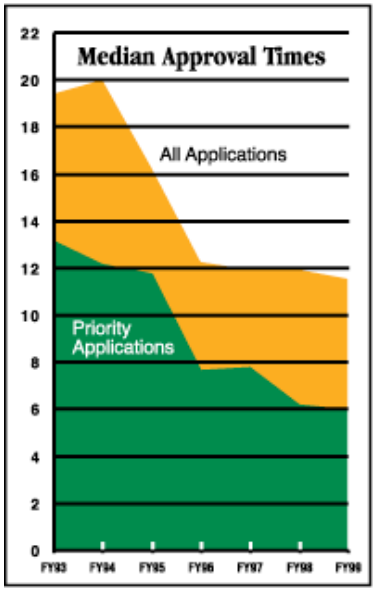
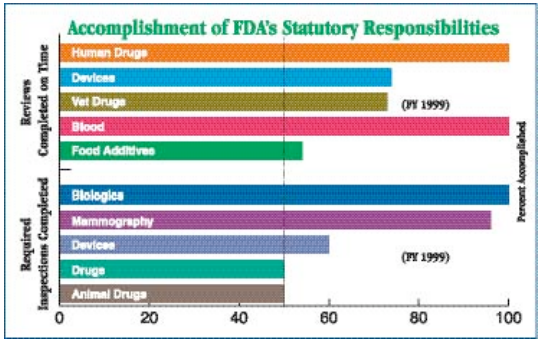
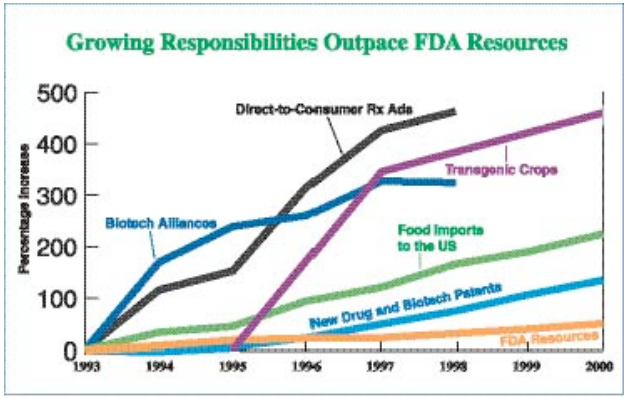
The Nation's Foremost Consumer Protection Agency

FDA's Growing Responsibilities for the Year 2001 and Beyond







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Just the Facts
A series of FDA information sheets

Drugs Foods Medical Devices/Radiological Health
Biologics Veterinary Products Miscellaneous

Drugs

Confronting Cancer: FDA's Long Fight Against America's Bane HTML PDF
en Español: HTML PDF

FDA and the Drug Development Process: How the Agency Ensures that Drugs are Safe and Effective HTML PDF
en Español: HTML PDF

FDA-Approved Bargain Drugs: Generic Products Must Meet High Standards HTML PDF
en Español: HTML PDF

FDA Fights Rare Diseases: New Help for Patients Without Treatments HTML PDF
en Español: HTML PDF

Improving Public Health: Promoting Safe and Effective Drug Use HTML PDF
en Español: HTML PDF

English Publications

Publicaciones en Español

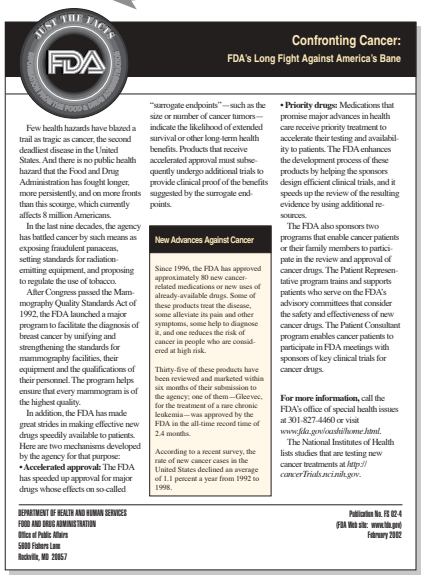
Easy-to-Read Publications

Backgrounders

FDA Consumer
The official magazine of the U.S. Food and Drug Administration

How to Order

Have Questions?
E-mail us at wmail@oc.fda.gov



JUST THE FACTS

Confronting Cancer:
FDA's Long Fight Against America's Bane

Few health hazards have blazed a trail as tragic as cancer, the second deadliest disease in the United States. And there is no public health hazard that the Food and Drug Administration has fought longer, more persistently, and on more fronts than this scourge, which currently affects 8 million Americans.

In the last nine decades, the agency has battled cancer by such means as exposing fraudulent panaceas, setting standards for radiation-emitting equipment, and proposing to regulate the use of tobacco.

After Congress passed the Mammography Quality Standards Act of 1992, the FDA launched a major program to facilitate the diagnosis of breast cancer by unifying and strengthening the standards for mammography facilities, their equipment and the qualifications of their personnel. The program helps ensure that every mammogram is of the highest quality.

In addition, the FDA has made great strides in making effective new drugs speedily available to patients. Here are two mechanisms developed by the agency for that purpose:

• **Accelerated approval:** The FDA has speeded up approval for major drugs whose effects on so-called "surrogate endpoints"—such as the size or number of cancer tumors—indicate the likelihood of extended survival or other long-term health benefits. Products that receive accelerated approval must subsequently undergo additional trials to provide clinical proof of the benefits suggested by the surrogate endpoints.

New Advances Against Cancer

Since 1996, the FDA has approved approximately 80 new cancer-related medications or new uses of already-available drugs. Some of these products treat the disease, some alleviate its pain and other symptoms, some help to diagnose it, and one reduces the risk of cancer in people who are considered at high risk.

Thirty-five of these products have been reviewed and marketed within six months of their submission to the agency; one of them—Gleevec, for the treatment of a rare chronic leukemia—was approved by the FDA in the all-time record time of 2.4 months.

According to a recent survey, the rate of new cancer cases in the United States declined an average of 1.1 percent a year from 1992 to 1998.

• **Priority drugs:** Medications that promise major advances in health care receive priority treatment to accelerate their testing and availability to patients. The FDA enhances the development process of these products by helping the sponsors design efficient clinical trials, and it speeds up the review of the resulting evidence by using additional resources.

The FDA also sponsors two programs that enable cancer patients or their family members to participate in the review and approval of cancer drugs. The Patient Representative program trains and supports patients who serve on the FDA's advisory committees that consider the safety and effectiveness of new cancer drugs. The Patient Consultant program enables cancer patients to participate in FDA meetings with sponsors of key clinical trials for cancer drugs.

For more information, call the FDA's office of special health issues at 301-827-4460 or visit *www.fda.gov/oashi/home.html.* The National Institutes of Health lists studies that are testing new cancer treatments at *http://cancerTrials.nci.nih.gov.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Office of Public Affairs
5600 Fishers Lane
Rockville, MD 20857

Publication No. FS 02-4
(FDA Web site: www.fda.gov)
February 2002

Interacting with FDA

Anything to say?

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MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Search MedWatch

Go

MedWatch Home | Safety Information | Submit Report | How To Report | Download Forms | Join the E-list

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

Join the E-list
Get safety alerts by e-mail

What's New

MRL Inc. AED20 Automatic External Defibrillators - Class I recall due to a problem which may prevent the defibrillator from resuscitating a patient. (Posted 05/12/2005)

LifeScan, Inc. Blood Glucose Meters - Worldwide notification to all users of OneTouch Ultra, InDuo and OneTouch FastTake glucose meters. It is possible, in the course of setting the meter's date and time, to accidentally change the unit of measure and thereby misinterpret blood glucose results. (Posted 05/11/2005)

Counterfeit Drugs Purchased in Mexico - Public warned about the sale of counterfeit Lipitor, Viagra, and an unapproved product promoted as "generic Evista" at pharmacies in Mexican border towns. The counterfeit products were found to contain no active ingredients. (Posted 05/11/2005)

MRI-Caused Injuries in Patients with Implanted Neurological Stimulators - Healthcare professionals notified that

Safety Information

Medical Product Reporting

NEW **The expiration date for FDA forms 3500 and 3500A has been extended by OMB through 6/30/2005.**

NEW **Adverse Event Reporting System (AERS) quarterly data files (January 2004 - present) are available for downloading**

Anything to say?

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MedWatch E-list

MedWatch safety alerts delivered to you

- Clinically important medical product safety alerts, delivered via e-mail
- Concise, timely information about the drugs and devices you use, prescribe, or dispense every day, directly from the U.S. Food and Drug Administration
- Each e-mail contains a summary of the safety alert. When you need to know more, a hyperlink in the e-mail directs you to more detailed information
- The MedWatch E-list (Listserv) is an automated message delivery system -- it does not allow users to post messages or to reply to messages. If you have questions about reporting or comments regarding the MedWatch web site, please contact us through our comments & feedback web page, http://www.fda.gov/MedWatch/feedback.htm

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MedWatch Online Voluntary Reporting Form (3500)

A Message About HIPAA Compliance for Reporters to FDA MedWatch NEW

Our MedWatch Online form is available to you for the voluntary reporting of serious adverse events, potential and actual medical product errors, and product quality problems associated with the use of FDA-regulated drugs, biologics, devices, and dietary supplements.

With the click of a button, you can complete, print, and submit the voluntary MedWatch Form (3500) online through the World Wide Web.

The MedWatch Online application uses Secure Socket Layers (SSL) and Pretty Good Protection (PGP) to encrypt and ensure the security and confidentiality of your MedWatch submission across the Internet.

We want to make it easy for you to submit your information successfully. Before beginning the submission process, please take a few minutes to review the information below.

Anything to say?

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Food and Drug Administration MEDWATCH

A

MedWatch Online Voluntary Submission Form 3500

A. PATIENT INFORMATION

Clear Section [HELP]

1. **Patient Identifier** (In confidence)
2. **Age at Time of Event:** or **Date of Birth**: (MM/DD/YYYY)
3. **Sex** Female Male
4. **Weight** lbs. or kgs.

Clear Section [HELP]

Anything to say?

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B

MedWatch Online Voluntary Submission Form 3500

B. ADVERSE EVENT OR PRODUCT PROBLEM

Clear Section [HELP]

1. ☐ **Adverse Event** and/or ☐ **Product Problem** (e.g., defects/malfunctions)

2. **Outcomes Attributed to Adverse Event** (Check all that apply)

- ☐ Death
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability
- ☐ Congenital Anomaly
- ☐ Required Intervention to Prevent Permanent Impairment/damage
- ☐ Other

3. **Date of Event**
If necessary, use Section B5 to explain or clarify dates.
(MM/DD/YYYY)

4. **Date of This Report**
05/13/2005 (MM/DD/YYYY)

5. **Describe Event or Problem** *up to a total of 6400 characters allowed*

6. **Relevant Tests/Laboratory Data,** Including Dates
up to a total of 1000 characters allowed

7. **Other Relevant History, Including Preexisting Medical Conditions** (e.g. allergies, race,pregnancy, smoking and alcohol use,hepatic/renal dysfunction,etc.)
up to a total of 500 characters allowed

Clear Section [HELP]

Previous Section | View/Print Submission as a PDF | Next Section

Anything to say?

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C

MedWatch Online Voluntary Submission Form 3500

C. SUSPECT MEDICATION(S) Clear Section [HELP]

1. **Name (Give labeled strength & mfr/labeler, if known)**

	(Product Name)	(Label Strength)	(Mfr/Labeler)
#1			
#2			

2. **Dose/Frequency/Route Used**

#1 / /

#2 / /

3. **Therapy Dates** (If unknown, give duration) from/to (or best estimate) *If necessary, use Section B5 to explain or clarify dates.*

	From	To
#1		-
#2		-

4. **Diagnosis for Use** (separate indications with commas)

#1

#2

5. **Event Abated After Use Stopped or Dose Reduced**

#1 Yes No Doesn't Apply

#2 Yes No Doesn't Apply

6. **Lot #** (if known)

#1

#2

7. **Exp. Date** (if known)If necessary, use *Section B5 to explain or clarify dates.*

#1

#2

8. **Event Reappeared After Reintroduction**

#1 Yes No Doesn't Apply

#2 Yes No Doesn't Apply

9. **NDC #**(For product problems only)

10. **Concomitant Medical Products and Therapy Dates** (Exclude treatment of event)

Anything to say?

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Food and Drug Administration
MEDWATCH

D

MedWatch Online Voluntary Submission Form 3500

D. SUSPECT MEDICAL DEVICES

Clear Section [HELP]

1. **Brand Name**
2. **Type of Device**
3. **Manufacturer Name, City & State**
   Please use no more than 3 lines.
4.
   - **Model #**
   - **Catalog #**
   - **Serial #**
   - **Lot #**
   - **Expiration Date** (MM/DD/YYYY)
     If necessary, use Section B5 to explain or clarify dates.
   - **Other #**
5. **Operator of Device** ☐ Health Professional ☐ Lay User/Patient ☐ Other
6. **If Implanted, Give Date** (MM/DD/YYYY)
   If necessary, use Section B5 to explain or clarify dates
7. **If Explanted, Give Date** (MM/DD/YYYY)
   If necessary, use Section B5 to explain or clarify dates
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**
   Please use no more than 4 lines.
10. **Device Available for Evaluation?** (Do not send to FDA)
    ☐ Yes ☐ No ☐ Returned to Manufacturer on
11. **Concomitant Medical Products** and Therapy Dates (Exclude treatment of event)
    up to a total of 1000 characters allowed

Anything to say?

Interacting with FDA

- Advisory Committees
- Contact FDA
- Dockets
  - View Pending Regulations
  - Comment on Proposed Dockets
- Electronic Regulatory Submissions
- FDA-Private Sector Partnerships
- Field Offices
- Freedom of Information
- Grants
- Leveraging
- Ombudsman
- MedWatch
- Online Forms
- Petition FDA
- Product Code Builder
- Register for FDA Meetings
- Reporting Problems with FDA Products
- Technology Transfer

E

MedWatch Online Voluntary Submission Form 3500

E. REPORTER (See Confidentiality Section) Clear Section [HELP]

1. Name & Address

Name * (required)

Street Address * (required)

Include facility/department/mailcode as appropriate.

City * (required)

State/Territory

Postal/Zip Code * (required)

Country United States

Phone

E-mail

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also reported to** ☐ Manufacturer ☐ User Facility ☐ Distributor

5. **If you do NOT want your identity disclosed to the manufacturer, check here.** ☐

Clear Section [HELP]

Information for specific audiences

Specialized information

Information for Specific Audiences

- AIDS Patients
- Cancer Patients
- Cancer Liaison Program
- Clinical Trials -- Consumers
- Clinical Trials -- Professionals
- Consumers
- Español
- Health Professionals
- Industry
- International
- Kids
- Seniors
- Small Business
- State and Local Officials
- Press
- Women

Good Clinical Practice in FDA-Regulated Clinical Trials

Report to FDA:

- **Complaints relating to clinical trials**
- IRB termination of studies

Good Clinical Practice (GCP) is a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.

What We Do

Related Websites

Freedom of Information

Dockets Management

FDA Site Map

Regulations

- Good Clinical Practice/Clinical Trials Regulations
- Preambles to GCP Regulations
- Laws Enforced by FDA

Guidances and Information Sheets
Current guidance on good clinical practice and the conduct of clinical trials.

Proposed Regulations and Draft Guidances
Details about these proposals and instructions for submitting comments.

Enforcement Information
Warning letters, disqualification proceedings, restricted list, adequate assurances list ...

Approved Products
Approvals of drugs, medical devices, biologicals, animal drugs, food additives.

Bioresearch Monitoring Program
Links to relevant Compliance Program Guidance Manuals.

Educational Materials
Useful literature references and training information about good clinical practices.

In the News

- Draft Guidance: centralizing the IRB review process
- FDA pilots electronic dataset submissions using SDTM
  Print version (PDF)
- Computerized Systems Used in Clinical Trials
- Use of clinical holds following investigator misconduct
- FDA announces standard format for clinical trial data
- *Other News*

New Guidances

- Pharmacogenomic Data Submissions
- Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
- Premarketing Risk Assessment
- Risk Minimization Action Plans

Workshops & Meetings

- 12/7-8: Conference on FDA's clinical trial requirements
- *Additional Information*

Contact GCP Staff

Contacts for Related Program Areas

Join the FDAGCPP list
Get up-to-date information on FDA's activities concerning good clinical practice and human subject protection

Specialized information

Information for Specific Audiences

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- Women

What We Do

The Good Clinical Practice Program is the focal point within FDA for Good Clinical Practice issues arising in human research trials regulated by FDA. In relation to Good Clinical Practice, the Good Clinical Practice Program:

- Coordinates FDA policies
- Provides leadership and direction through the administration of FDA's Human Subject Protection/Good Clinical Practice Steering Committee
- Coordinates FDA's Bioresearch Monitoring program with respect to clinical trials, working together with FDA's Office of Regulatory Affairs (ORA)
- Contributes to international Good Clinical Practice harmonization activities
- Plans and conducts training and outreach programs
- Serves as a liaison with the HHS Office of Human Research Protection (OHRP) and other federal agencies and external stakeholders committed to the protection of human research participants.

Specialized information

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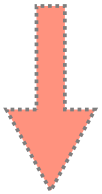
- New and Generic Drug Approvals
  - Actonel (risedronate sodium) Tablets, Procter & Gamble Pharma, Labeling Revision
  - Cefazolin for Injection USP and Dextrose Injection, B. Braun Medical, Labeling Revision
  - Cefazolin for Injection USP and Dextrose Injection, B. Braun Medical, Labeling Revision
  - Ceftriaxone Injection, Sandoz, Approval
  - Doryx (doxycycline hyclate) Delayed-Release Tablets, F. H. Faulding and Co., Approval
  - Doryx (doxycycline hyclate) Delayed-Release Capsules, F. H. Faulding and Co., Labeling Revision
  - Ipratropium Bromide Inhalation Solution, Breath Ltd., Approval
  - ORTHO EVRA (norelgestromin/ethinyl estradiol) transdermal system, Johnson & Johnson Pharma, Labeling Revision
  - Triglide (fenofibrate) Tablets, Skye Pharma, Approval



Drugs@FDA

Specialized information

Information for Specific Audiences

- AIDS Patients
- Cancer Patients
- Cancer Liaison Program
- Clinical Trials -- Consumers
- Clinical Trials -- Professionals
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- Español
- Health Professionals
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- Small Business
- State and Local Officials
- Press
- Women

Information for Health Professionals

Clinical Trials

FDA Information

- Good Clinical Practice
- Guidance--Financial Disclosure by Clinical Investigators

Other Information

- AIDS
- ClinicalTrials.gov
- Human Research Protections
- Human Subjects Research

Institutional Review Boards (IRBs)

- FDA Letter on Human Cloning
- Guidance for IRBs and Clinical Investigators--1998 Update (includes important FDA contacts, the Belmont Report, informed consent regulations, IRB regulations, and links to related Websites)
- Questions: **Phone: 301-594-0020** Fax: 301-594-1204

Clinical Investigators, Administration Hearings

- Disqualified/Restricted/Assurances List for Clinical Investigators
- Debarment List

Pharmacists

- Pharmacy Compounding
- Pharmacy Students

Biologics

- Contact: 301-827-2000

Dietary Supplements

- Warnings and Safety Information
- Office of Dietary Supplements
- International Bibliographic Information on Dietary Supplements database
- Dietary Supplement Health and Education Act of 1994

Drugs

- Contact: 301-827-4570
- New Drug Approval
- Approved Drug Products
- PostMarketing Commitments Database
- Oncology
- FDA's Proposed Revisions to Prescription Drug Labeling
- Guidance documents
- Patent Term Restoration Program
- Report fraudulent or misleading advertising of FDA-regulated products: 301-827-2828

Food Safety

- "Bad Bug Book"

Medical Devices

- Contact: 301-827-3990
- Mammography Matters newsletter
- Medical Device User Facility Reporting Bulletin
- Clinical Laboratory Improvement Amendments (CLIA)

Products for Rare Diseases

- Contact: 301-827-3666

Adverse Reactions and Patient Safety

- Recalls and Safety Alerts
- MedWatch: 1-800-FDA-1088 (1-800-332-1088)
- FDA Patient Safety News
- Reporting Problems with FDA-Regulated Products
- Biologics Errors and Accidents Reports
- Vaccine Adverse Event Reporting System: 1-800-822-7967
- Journal Publication

Information for Patients

Advisory Committees

- Contact: 1-800-741-8138

Contact FDA

- Submit Electronic Records
- Submit Comments About Proposed Regulations
- Request Information and Records
- Employee Directory

JAMA Articles--Archived articles by FDA Commissioners originally printed in the *Journal of the American Medical Association*

MEDLINEplus--**Health information from the National Library of Medicine**

Positions Available at FDA

FDA Publications

Science at FDA

CDER

Goals and Objectives

The FDA Pharmacy Student Experiential Program provides an opportunity to learn about the FDA's multidisciplinary processes for addressing public health issues involving drugs, biologics, and medical devices. Pharmacy students who participate in the FDA Pharmacy Student Experiential Program acquire knowledge, skills, and abilities beneficial to their professional career.

Products regulated by FDA

FDA regulation

Products Regulated by FDA

- Allergy Therapies
- Animal Drugs and Food
- Aquaculture
- Bioengineered Food
- Biologics
- Blood
- Breast Implants
- Cell Phones
- Cosmetics
- Dietary Supplements
- Drugs
- Food
- Gene Therapy
- Infant Formula
- LASIK
- Mammography Facilities
- Medical Devices
- Mobile Phones
- Nanotechnology Products
- Orphan Products (drugs and devices)
- Radiation-Emitting Electronic Products
- Tattoos
- Tissue for Transplantation
- Vaccines
- Whole-Body CT Scans
- Xenotransplantation

Office of Nutritional Products, Labeling, and Dietary Supplements

The Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) is responsible for developing policy and regulations for dietary supplements, nutrition labeling and food standards, infant formula and medical foods as well as for scientific evaluation to support such regulations and related policy development. ONPLDS staff also support compliance/enforcement actions and is responsible for the clinical review, data summaries, and, as appropriate, follow-up and research related to adverse events associated with dietary supplements and infant formula.

Dietary Supplements

Search | Q & A | Help | Select a Topic – Supplements | Go

Contents

- Overview
- Warnings and Safety Information
- Adverse Event Reporting
- Announcements & Meetings
- Consumer Education & General Information
- Industry Information
  - Labeling Regs
- Label Claims
- Questions & Answers
- Other Sources of Information

Overview

Overview
About the Office of Nutritional Products, Labeling, and Dietary Supplements
FDA-DSFL Electronic Newsletter | Recent Announcements | Frequently Requested Information

FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements.* Manufacturers must make sure that product label information is truthful and not misleading.

FDA's post-marketing responsibilities include monitoring safety, e.g. voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

*Domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are required to register their facility with the FDA. For more information, see Registration of Food Facilities.

FDA regulation

Products Regulated by FDA

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Cellular & Gene Therapy

The Center for Biologics Evaluation and Research (CBER) regulates human gene therapy products - products that introduce genetic material into the body to replace faulty or missing genetic material, thus treating or curing a disease or abnormal medical condition. CBER uses both the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight.

FDA has not yet approved any human gene therapy product for sale. However, the amount of gene-related research and development occurring in the United States continues to grow at a fast rate and FDA is actively involved in overseeing this activity. FDA has received many requests from medical researchers and manufacturers to study gene therapy and to develop gene therapy products. Such research could lead to gene-based treatments for cancer, cystic fibrosis, heart disease, hemophilia, wounds, infectious diseases such as AIDS, and graft-versus-host disease.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Cellular & Gene Therapy

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Features

Cellular Therapy: Potential Treatment for Heart Disease

New Human Gene Transfer Research Data System

Type I Diabetes / Pancreatic Islet Transplantation

Use of Cloning Technology to Clone a Human Being

Topics

Cellular, Tissue & Gene Therapies Adv Comm

Publications

Warning Letters

Xenotransplantation Action Plan

GT Patient Tracking System

Human Gene Therapy & Role of FDA

Recomb DNA & Gene Transfer, NIH

FDA regulation

Products Regulated by FDA

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MedWatch

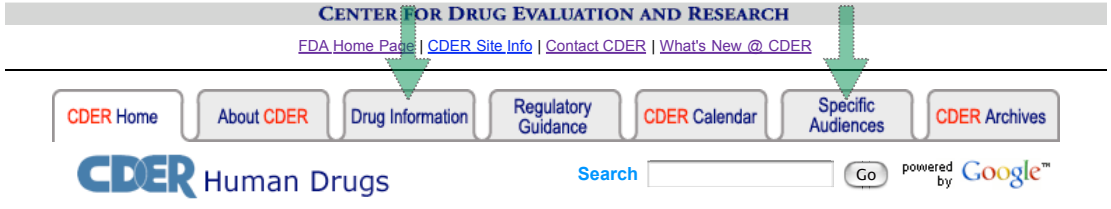
Drugs@FDA

CDERLearn

healthfinder

MEDLINEplus Health Information

CDER Human Drugs



News from CDER

- May 11. FDA warns the public about the sale of counterfeit Lipitor, Viagra, and an unapproved product promoted as "generic Evista" at pharmacies in Mexican border towns. FDA Talk Paper.
- May 5. FDA approves Requip (ropinirole) to treat moderate to severe Restless Legs Syndrome (RLS). FDA Talk Paper.
- April 28. Famotidine Injection - Recall of one lot of Famotidine Injection, 20 mg/2 mL due to a lack of sterility assurance. MedWatch Safety Info.
- April 28. Eli Lilly and FDA notify healthcare professionals of the stopping of enrollment in a randomized, double-blind, placebo-controlled trial of Xigris in pediatric patients with severe sepsis. Xigris is not indicated for use in pediatric severe sepsis. MedWatch Safety Info.
- April 14. FDA approves first-time generic Niacin Extended-Release to treat hypercholesterolemia. The reference listed drug is Niaspan.
- April 14. FDA approves first-time generic Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets as an antihistamine/decongestant. The reference listed drug is Allegra-D 12 Hour.
- April 11. FDA issues a Public Health Advisory for antipsychotic drugs used for treatment of behavioral disorders in elderly patients. FDA Talk Paper. Public Health Advisory.
- April 11. FDA approves new drug Retisert (fluocinolone acetonide intravitreal implant) 0.59 mg. to treat chronic non-infectious uveitis affecting the posterior segment of the eye.
- April 7. FDA announces a series of changes to the class of marketed non-steroidal anti-inflammatory drugs (NSAIDs). FDA Press Release. Public Health Advisory.
- Previous News Items

Drug Safety

About FDA's New Drug Safety Initiative

Safety Information for Patients & Healthcare Professionals

- Drug Specific Information

Consumer Information

Let Us Hear from You

Featured Links

- The FDA Process for Approving Generic Drugs (online tutorial)
- Genomics at FDA

Bioterrorism:

Drug Preparedness and Response

- Stay Informed -

Subscribe to Daily/ Weekly Updates

Quick Info Links

- Drugs@FDA
- Drug Information Pathfinder
- Drug Shortages
- Inactive Ingredient Database
- MedWatch
- National Drug Code Directory
- Orange Book
- Postmarketing Study Commitments
- Advisory Committees
- Bioterrorism
- CDERLearn (Online Courses)
- Drug Application Process
- FDA Patient Safety News with Videos
- Guidances
- Jobs at CDER
- Oncology Tools
- Pediatrics
- Pharmaceutical cGMPs: A Risk-Based Approach
- Small Business
- Therapeutic Biological Products

MedWatch

Safety Alerts for FDA Regulated Products

FDA regulation

Products Regulated by FDA

- Allergy Therapies
- Animal Drugs and Food
- Aquaculture
- Bioengineered Food
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- Blood
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- Tattoos
- Tissue for Transplantation
- Vaccines
- Whole-Body CT Scans
- Xenotransplantation

MedWatch

Drugs@FDA

CDERLearn

healthfinder®

MEDLINEplus Health Information

Drug Specific Information

FDA is in the process of updating its drug safety information and making it available to consumers in a new, user friendly format. Under the new format, clicking on a drug takes you to a "core page" with links to all information on that drug available on the FDA site. If you click on a drug whose information is not yet in the new format, you will reach a single information page on that product.

Search by Drug Name: GO

Viagra®	
Brand Name:	Viagra®
Active Ingredient:	sildenafil citrate
Strength(s):	25mg, 50mg & 100mg
Dosage Form(s):	Oral tablet
Company Name:	Pfizer Inc.
Availability:	Prescription only
*Date Approved by FDA:	March 27, 1998
**Approval by FDA does not mean that the drug is available for consumers at this time.*	

+ Additional information including a PDF file of the approved label

FDA regulation

Products Regulated by FDA

- Allergy Therapies
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MedWatch

Drugs@FDA

CDERLearn

healthfinder®

MEDLINEplus Health Information

CDERLearn

Welcome to CDERLearn, the web page for educational tutorials offered by the Center for Drug Evaluation and Research. CDER's primary mission is to make certain that safe and effective drugs are available to the American people. There is, however, a strategic initiative to inform and educate people about the safe use of medicine, the drug regulatory process, the vital role health care professionals play to assist FDA in fulfilling its duties, and many other important issues. Online training is one way to share FDA expertise with many more people than face-to-face classroom sessions would allow, and we will offer additional CDER courses in the future.

CDERLearn

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Course List

- Drug Review and Related Activities in the United States
- Field Investigators: Adverse Drug Effects (ADE) Investigators (2000)
- The FDA Process for Approving Generic Drugs

News @ FDA

FDA news

News

- Congressional Testimony
- Meetings
- New Reports and Publications
- Press Releases & Talk Papers
- Product Approvals
- Product Recalls, Alerts and Warnings
- Public Calendar
- Public Speeches by FDA Officials
- Warning Letters

Approvals of FDA-Regulated Products

FDA's regulatory approaches to marketing approval of the products it regulates are as varied as the products themselves. These differences are dictated by the laws FDA enforces and the relative risks that the products pose to consumers.

Some products -- such as new drugs and complex medical devices -- must be proven safe and effective before companies can put them on the market. The agency also must approve new food additives before they can be used in foods. Other products -- such as x-ray machines and microwave ovens -- must measure up to performance standards. And some products -- such as cosmetics and dietary supplements -- can generally be marketed with no prior approval.

At the heart of all FDA's medical product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great -- especially for products used to treat serious, life-threatening conditions.

FDA reviews the results of laboratory, animal and human clinical testing done by companies to determine if the product they want to put on the market is safe and effective. FDA does not develop or test products itself. The Agency does this pre-market review for new human drugs and biologics (such as vaccines, blood products, biotechnology products and gene therapy), complex medical devices, food and color additives, infant formulas, and animal drugs.

FDA has streamlined its review process for medical products in recent years to help speed important new treatments to patients. For example, the average review time for an innovative new drug is now only 6 months, and some have been approved even faster.

Drugs

- Latest
- Archives

Medical Devices

- Latest
- Archives

Therapeutic Biologicals

Other Biologicals

- Latest
- Archives

Animal Drugs

Food Additives

CDER Human Drugs

FDA news

News

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- Warning Letters

Recalls, Market Withdrawals and Safety Alerts

Recalls, Withdrawals and Alerts in the Last 60 Days:

This list includes the most significant product actions of the last 60 days, based on the extent of distribution and the degree of health risk. The recalls on the list are mainly Class I. A record of *all* recalls can be found in the FDA Enforcement Report.

Jilbert Dairy Recalls Vanilla Supreme Ice Cream Because of Possible Health Risks *(May 11, 2005)*

Consumer Alert: Undeclared Sulfites in Preserved Fruit (Apricot) *(May 10, 2005)*

MRL, Inc. a Welch Allyn Company Issues a Voluntary Worldwide Recall of Selected AED20 Automatic External Defibrillators *(May 10, 2005)*

LifeScan, Inc. Announces Worldwide Correction Concerning Certain Blood Glucose Meters *(May 10, 2005)*

FDA Public Health Notification: MRI-Caused Injuries in Patients with Implanted Neurological Stimulators *(May 10, 2005)*

FDA Warns Consumers About Counterfeit Drugs Purchased in Mexico *(May 10, 2005)*

Allergy Alert - Undeclared Dairy in Cloud Nine® Premium Dark Chocolate Bar *(May 6, 2005)*

Quik'n Tasty Foods Inc. Recalls Po Boy (Lunchmeat, Ham, and Cheese Sandwich) Because of Health Risk *(May 6, 2005)*

YTS Group Issues Allergy Alert on Undeclared Eggs in Certain YTS Vegetarian Food Products *(May 6, 2005)*

Tan Nam Tofu Company Issues Allergy Alert on Undeclared Milk in Tan Nam Fresh Soymilk *(May 6, 2005)*

Lion Pavilion LTD Issues Allergy Alert on Undeclared Sulfites *(May 5, 2005)*

Walong Marketing, Inc. Issues Allergy Alert on Undeclared Sulfites in Product *(May 4, 2005)*

Edwards Fine Foods Issues Recall and Allergy Alert on Undeclared Peanuts in Edwards *Oreo* Pie Slices *(April 29, 2005)*

MedWatch
Safety Information and Adverse Event Reporting

Enforcement Report
Recalls, Product Seizures, Court Actions

XML RSS Recalls News Feed

Industry Guidance

Recalls, Withdrawals and Safety Alerts Archives

Patient Safety News

Biologics
Blood Products, Vaccines, Allergenics

Medical Devices

Veterinary Products

Drug Shortages

Background and Definitions

FDA Recall Policies

Model Press Releases

Recalls.gov

FDA news

News

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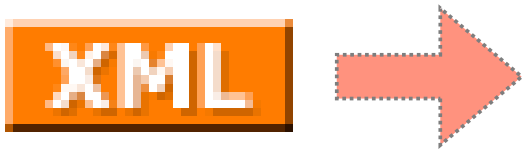
- Meetings
- New Reports and Publications
- Press Releases & Talk Papers
- Product Approvals
- Product Recalls, Alerts and Warnings
- Public Calendar
- Public Speeches by FDA Officials
- Warning Letters



Jilbert Dairy Recalls Vanilla Supreme Ice Cream Because of Possi... Yesterday, 02:57 PM

Jilbert Dairy is recalling Vanilla Supreme ice cream because it has the potential to be contaminated with Listeria Monocytogenes. Read more...

Consumer Alert: Undeclared Sulfites in Preserved Fruit (Apricot) Wednesday, 08:35 AM

State Agriculture Commissioner alerted consumers that Sino Bestfood, Inc. is recalling preserved fruit (apricot) because they may contain undeclared sulfites. Read more...

MRL, Inc. Issues a Voluntary Worldwide Recall of Selected AED2... Wednesday, 08:35 AM

The AED20 may display an error message during use resulting in failure of the device to analyze the patient's ECG and deliver the appropriate therapy. Read more...

Allergy Alert - Undeclared Dairy in Cloud Nine® Premium Dark Cho... Monday, 10:28 AM

These products are manufactured on equipment that is also used for dairy products, and there may be residual dairy protein in the product. Read more...

Quik'n Tasty Foods Inc. Recalls Po Boy (Lunchmeat, Ham, and Che... Monday, 10:28 AM

Quik'n Tasty Foods Inc. is recalling Po Boy (Lunchmeat, Ham and Cheese sandwiches) because it has the potential to be contaminated with Listeria monocytogenes. Read more...

YTS Group Issues Allergy Alert on Undeclared Eggs in Certain YTS... Monday, 07:20 AM

YTS Group is recalling certain YTS vegetarian food products because they may contain undeclared eggs. Read more...

Tan Nam Tofu Company Issues Allergy Alert on Undeclared Milk in ... Monday, 07:20 AM

Tan Nam Tofu Company is recalling its "Tan Nam Fresh Soymilk" product because the labels do not declare the presence of cow's milk. Read more...

Lion Pavilion LTD Issues Allergy Alert on Undeclared Sulfites May 6, 06:08 AM

People who have an allergy or severe sensitivity to sulfites run the risk of serious or life threatening allergic reaction if they consume this product. Read more...

Walong Marketing, Inc. Issues Allergy Alert on Undeclared Sulfites i... May 6, 06:08 AM

People who have an allergy or severe sensitivity to sulfites run the risk of serious or life threatening allergic reaction if they consume this product. Read more...

Amerisource Health Services Recalls One Lot of Famotadine Injection Apr 29, 04:00 PM

Lack of sterility assurance can represent a serious hazard to health that can lead to life threatening injuries and death. Read more...

Edwards Fine Foods Issues Recall and Allergy Alert on Undeclared ... Apr 29, 07:07 AM

Edwards Oreo Singles 2pack Frozen Pie Slices with a date code of Y84282 because the product may contain undeclared

Hot topics @ FDA

What's hot?

Hot Topics

- Hot Topics Home Page
- Bioterrorism Act
- Buying Medicines Online
- Cell Phones
- Counterfeit Drugs
- Counterterrorism
- Flu Information
- Imported Drugs
- Losing Weight
- PPA

Hot Topics

Drugs

- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - Public Health Advisory
  - Bextra
  - Celebrex
  - Naproxyn
  - Vioxx
- Buying Medicines Online
- Accutane
- Antidepressant Use in Children, Adolescents, and Adults
- Celexa
- Cialis
- Cipro
- Counterfeit Drugs
- Fen-Phen
- Foreign Rx Drugs
- Imported Drugs
- Levitra
- Oxycontin
- Phenylpropanolamine (PPA)
- Protonix
- Tequin
- Viagra

Foods

- Hurricane and Food Safety
- Bioengineered Foods
- Color Additives
- Foodborne Illness
- HACCP
- Holiday Food Safety
- Konjac Candy Recalls
- Mercury in Fish

Dietary Supplements

- General Information
- Ephedra

Medical Devices

- Decorative Contact Lenses
- Breast Implants
- Device User Fees
- LASIK Eye Surgery
- Tampons

Radiation Protection

- Whole Body CT Scans
- Wireless (Cell) Phones

Biological Products

- Blood
- Gene Therapy
- Vaccines

Miscellaneous

- Buying Medical Products Online
- Poison Ivy
- Heart Health
- Flu Information
- Losing Weight
- Halloween Safety Tips
- Antibiotic Resistance
- Counterterrorism
- Bioterrorism Act
- BSE (Mad Cow Disease)
- Cosmetics
- Diabetes Information
- SARS
- Tattoos
- West Nile Virus
- Monkeypox
- Quitting Smoking

News from FDA

- Agency-wide
- Food
- Drugs
- Medical Devices
- Biologics
- Animal Feed &Drugs
- Radiation Protection
- Cosmetics
- Toxicological Research
- Regulatory Affairs

What's hot?

Hot Topics

- Hot Topics Home Page
- Bioterrorism Act
- Buying Medicines Online
- Cell Phones
- Counterfeit Drugs
- Counterterrorism
- Flu Information
- Imported Drugs
- Losing Weight
- PPA

Federal Citizen Information Center Pueblo, Colorado

Adverse Events Associated With the Use of Non-Steroidal Anti-Inflammatory Drugs and COX-2 Inhibitors

The Food and Drug Administration has obtained and is evaluating new and sometimes conflicting scientific data on adverse events associated with the use of several non-steroidal anti-inflammatory drugs (NSAIDs) and COX-2 inhibitors. New data indicates an increased risk of major fatal and non-fatal heart attacks in clinical trial participants taking these drugs. At this time, the National Institutes of Health has suspended clinical trials involving the use of non-steroidal anti-inflammatory drugs (NSAIDs), such as naproxen or Aleve™, and the COX-2 inhibitor celecoxib (Celebrex™). FDA advises patients who are currently taking over-the-counter naproxen products to carefully follow the instructions on the label. Additional resources are listed below.

http://www.pueblo.gsa.gov/

What's hot?

Buying Medicines and Medical Products Online

Hot Topics

- Hot Topics Home Page
- Bioterrorism Act
- Buying Medicines Online
- Cell Phones
- Counterfeit Drugs
- Counterterrorism
- Flu Information
- Imported Drugs
- Losing Weight
- PPA

Tips and Warnings for Consumers

With hundreds of drug-dispensing Websites in business, how can consumers tell which sites are legitimate ones, especially when it is very easy to set up a site that is very professional looking and promises deep discounts or a minimum of hassles?

If you buy medical products online, be aware of the following dangers:

- Purchasing a medication from an illegal Website puts you at risk. You may receive a contaminated or counterfeit product, the wrong product, an incorrect dose, or no product at all.
- Taking an unsafe or inappropriate medication puts you at risk for dangerous drug interactions and other serious health consequences.
- Getting a prescription drug by filling out a questionnaire without seeing a doctor poses serious health risks. A questionnaire does not provide sufficient information for a health-care professional to determine if that drug is for you or safe to use, if another treatment is more appropriate, or if you have an underlying medical condition where using that drug may be harmful. The American Medical Association has determined that this practice is generally substandard medical care. FDA agrees.

FDA offers these tips to consumers who buy health products online:

- Check with the National Association of Boards of Pharmacy (www.nabp.net, (847) 698-6227) to determine whether a Website is a licensed pharmacy in good standing.
- Don't buy from sites that offer to prescribe a prescription drug for the first time without a physical exam, sell a prescription drug without a prescription, or sell drugs not approved by FDA.
- Don't do business with sites that have no access to a registered pharmacist to answer questions.
- Avoid sites that do not identify with whom you are dealing and do not provide a U.S. address and phone number to contact if there's a problem.
- Look for easy-to-find and understand privacy and security policies. Don't provide any personally identifiable information (social security number, credit card, and health history) unless you are confident that the site will protect them. Make sure the site does not share your information with others without your permission.
- Don't purchase from foreign Websites at this time because generally it will be illegal to import the drugs bought from these sites, the risks are greater, and there is very little the U.S. government can do if you get ripped off.
- Beware of sites that advertise a "new cure" for a serious disorder or a quick cure-all for a wide range of ailments.
- Be careful of sites that use impressive-sounding terminology to disguise a lack of good science or those that claim the government, the medical profession, or research scientists have conspired to suppress a product.
- Steer clear of sites that include undocumented case histories claiming "amazing" results.
- Talk to your health-care professional before using any medications for the first time.

Consumers who suspect that a site is illegal can report it to FDA.

Notify FDA about problem Websites
(**Note:** The Federal Trade Commission handles complaints about spam. To report spam problems, go to the FTC spam reporting page.)

More Consumer Information

Buying Medical Products Over the Internet *New!*

Some Web Pharmacies Pose Safety Risks (GAO Report, June 2004) Report Highlights

Internet Drug Sales (FDA Congressional Testimony, March 18, 2004)

Guide to Healthy Web Surfing

Consumer Alert on Importing Prescription Drugs

Imported Drugs Raise Safety Concerns

What You Should Know About Buying Foreign Medicines (Brochure) (pdf version)

Should You Buy Cipro, Other Antibiotics from Online Sources?

Beware of Buying Diagnostic Tests Online

Waging War on Internet Health Fraud

Buying Medical Devices Online

Buying Medical Devices Online

FEDERAL TRADE COMMISSION
FOR THE CONSUMER

From: "Angelina Stephens" <LenaOdell@rushmore.com>
Subject: **Re: Guaranted 35%-70% Discount On All Medications.**
Date: May 13, 2005 2:27:30 AM PDT
To: ash@salilab.org
Reply-To: "Angelina Stephens" <LenaOdell@rushmore.com>
1 Attachment, 5.1 KB Save Slideshow

ED-Drugs

Save up to 95% on your Meds

We believe ordering medication should be as simple as ordering anything else on the Internet.

Private, Secure, and Easy!

Viagra	Cialic	Levitra
30Pills $59.99	30Pills $119.99	30Pills $84.99
Propecia	Soma	Ultram
30Pills $49.99	30Pills $59.99	30Pills $49.99

WORLDWIDE DISCREET SHIPPING!

Click Here, NO PRESCRIPTION REQUIRED!

http://www.nabp.net

http://www.ftc.gov

What's hot?

Hot Topics

- Hot Topics Home Page
- Bioterrorism Act
- Buying Medicines Online
- Cell Phones
- Counterfeit Drugs
- Counterterrorism
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- Losing Weight
- PPA

CDER Human Drugs

Antidepressant Use in Children, Adolescents, and Adults

Food and Drug Administration (FDA) asks manufacturers of all antidepressant drugs to include in their labeling a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents, and additional information about the results of pediatric studies.

+ Current and background information on the topic

http://www.fda.gov/cder/

FDA Wide Web

http://www.fda.gov/

http://www.fda.gov/medwatch/

Drugs@FDA

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

CDER

http://www.fda.gov/cder/

CDERLearn

http://www.fda.gov/cder/learn/CDERLearn/

United States Code

http://www.access.gpo.gov/

http://www.ftc.gov

http://www.pueblo.gsa.gov/

http://www.nabp.net

http://www.healthfinder.gov/

MEDLINEplus Health Information

http://www.medlineplus.gov/

Next hour... pharmacist-explorer

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

(back to year 2000)

from image google search for word "pharmacists"

CV disorders & pain killers?

year 2000

Situation

Several patients are returning to the pharmacy with signs of CV disorders after have been taking a pain killers that inhibit COX-2

Action

Use all available information from scientific driven web sites and explore the FDA web site to access existing information.

Reaction

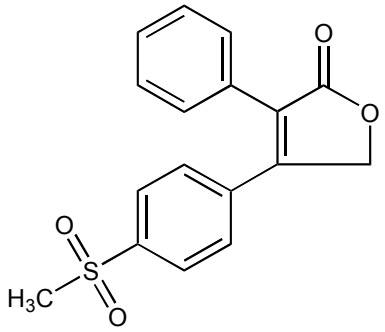
Report any finding to the FDA web site (MedWatch)

100 years of NSAIDs

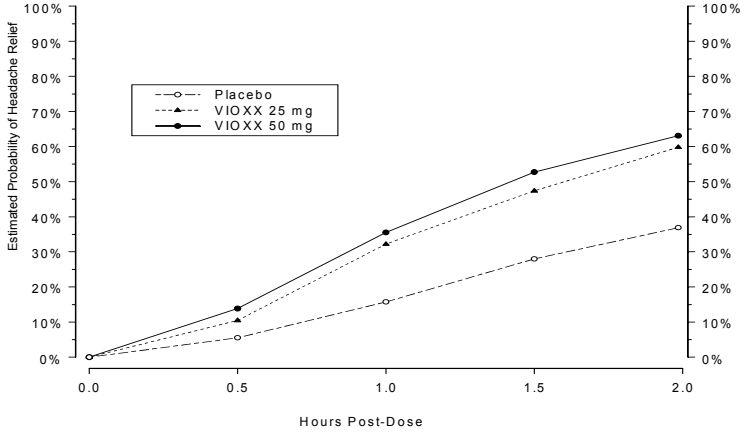
- 1899 "Aspirin" first synthesized
- 1938 First endoscopic evidence of gastric mucosal damage by aspirin
- 1970's New and safer NSAIDs are developed
- 1992 COX-2 discovered
- 1998 First COX-2 aproved
- 2001 First large and simple safety trials

Non-selective NSAIDs are widely used in both over-the-counter (OTC) and prescription settings. As prescription drugs, many are approved for short-term use in the treatment of pain and primary dysmenorrhea (menstrual discomfort), and for longer-term use to treat the signs and symptoms of osteoarthritis and rheumatoid arthritis.

CV disorders & pain killers?
VIOXX® approved label 1998



Rofecoxib



Clinical Adverse Experiences occurring in ≥ 2.0% of Patients Treated with VIOXX

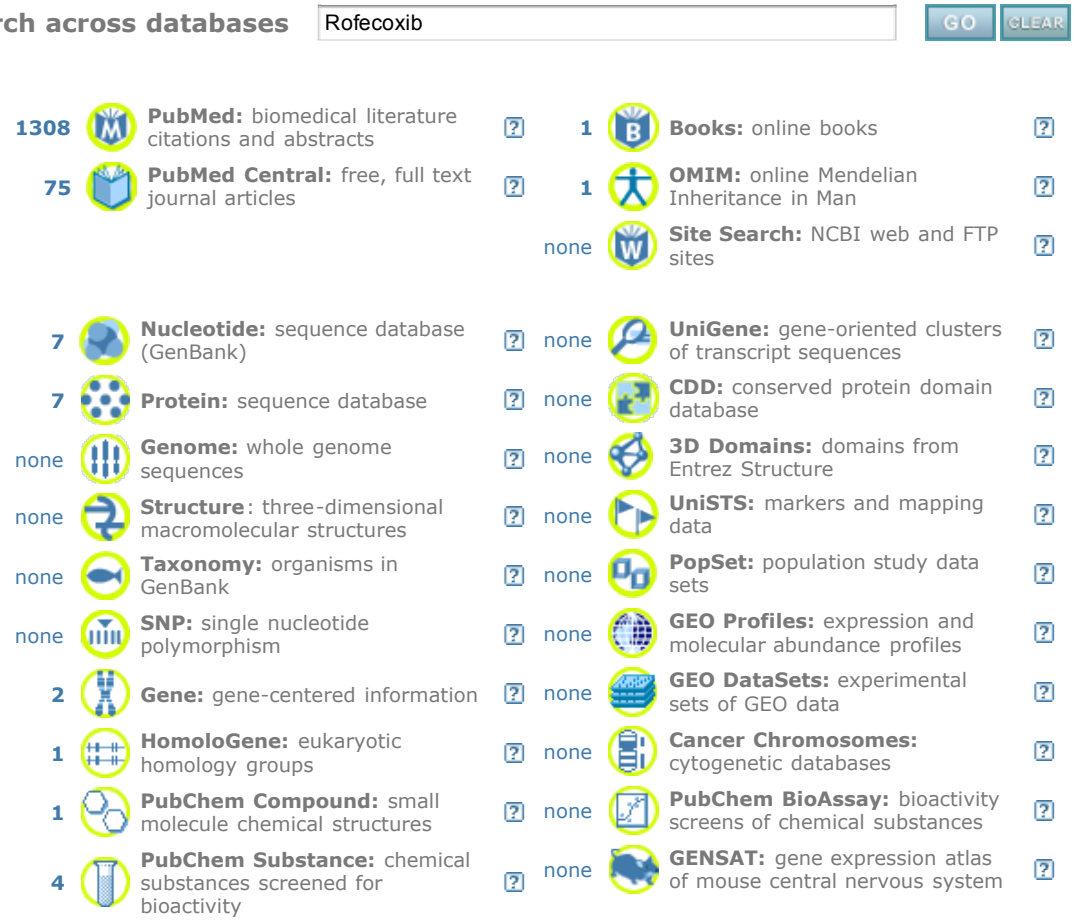
	Placebo	VIOXX 12.5 or 25 mg daily	Ibuprofen 2400 mg daily	Diclofenac 150 mg daily
	(N = 783)	(N = 2829)	(N = 847)	(N = 498)
Body As A Whole/Site Unspecified				
Abdominal Pain	4.1	3.4	4.6	5.8
Asthenia/Fatigue	1.0	2.2	2.0	2.6
Dizziness	2.2	3.0	2.7	3.4
Influenza-Like Disease	3.1	2.9	1.5	3.2
Lower Extremity Edema	1.1	3.7	3.8	3.4
Upper Respiratory Infection	7.8	8.5	5.8	8.2
Cardiovascular System				
Hypertension	1.3	3.5	3.0	1.6
Digestive System				
Diarrhea	6.8	6.5	7.1	10.6
Dyspepsia	2.7	3.5	4.7	4.0
Epigastric Discomfort	2.8	3.8	9.2	5.4
Heartburn	3.6	4.2	5.2	4.6
Nausea	2.9	5.2	7.1	7.4
Eyes, Ears, Nose, And Throat				
Sinusitis	2.0	2.7	1.8	2.4
Musculoskeletal System				
Back Pain	1.9	2.5	1.4	2.8
Nervous System				
Headache	7.5	4.7	6.1	8.0
Respiratory System				
Bronchitis	0.8	2.0	1.4	3.2
Urogenital System				
Urinary Tract Infection	2.7	2.8	2.5	3.6

CV disorders & pain killers?

NCBI search

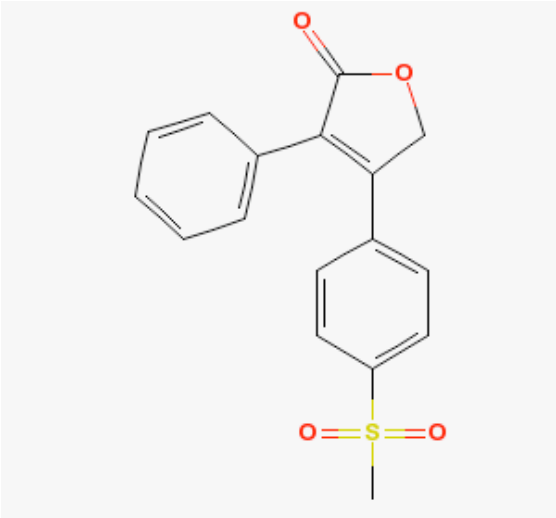
CV disorders & pain killers?

NCBI search



CV disorders & pain killers?

NCBI search



rofecoxib

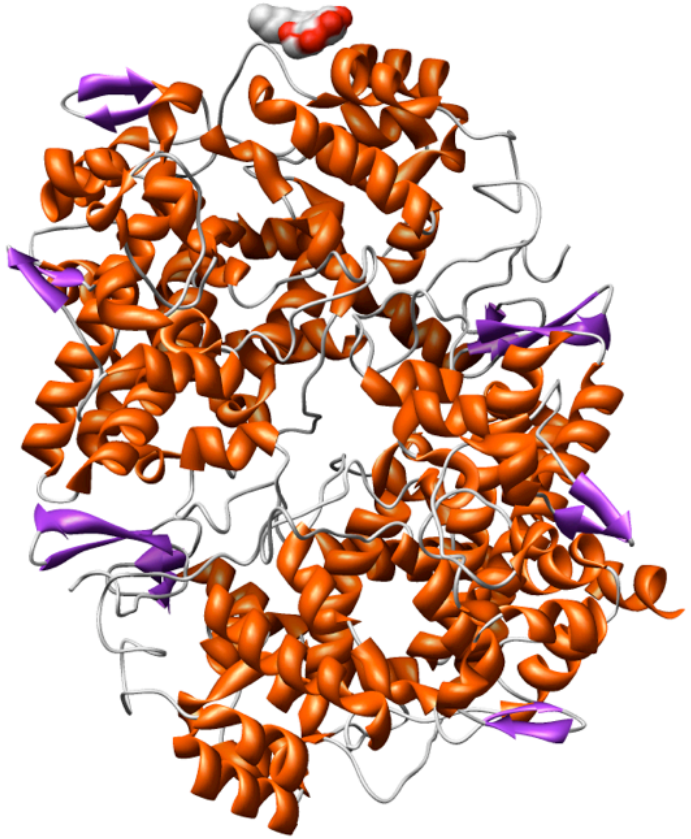
Pharmacological Action:
Anti-Inflammatory Agents, Non-Steroidal
Cyclooxygenase Inhibitors

rofecoxib
Vioxx
Vioxx (trademark)
CHEMBANK1837
CHEMID162011907
MK 966
MK 996
NSC720256
MK 0966

Molecular Weight: 314.357 g/mol
Molecular Formula: $C_{17}H_{14}O_4S$

XLogP: 3.019

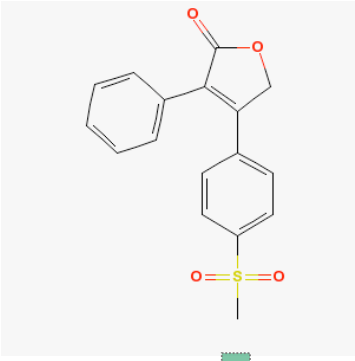
Hydrogen Bond Donor Count: 0
Hydrogen Bond Acceptor Count: 4
Rotatable Bond Count: 3



Protein structure of COX-2 with Arachidonic Acid

CV disorders & pain killers?

NCBI search



NCBI | PubChem | National Library of Medicine NLM

HOME | SEARCH | SITE MAP | PubMed | Entrez | Structure | GenBank | PubChem | Help

PubChem Text Search

Search Compound Name, Synonym or ID:

Search

Advanced Text Search

PubChem Chemical Structure Search

Search SMILES or Formula: CS(=O)(=O)C1=CC=C(C=C1)C2=C(C(=O)OC2)C3=CC=CC=C3

or Select Structure File: Choose File no file selected

Specify Search Type: Similar compounds, score >= 90%

Output: Result limit (unique structures): 200

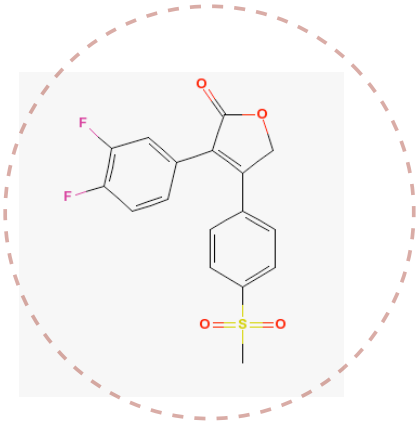
Search

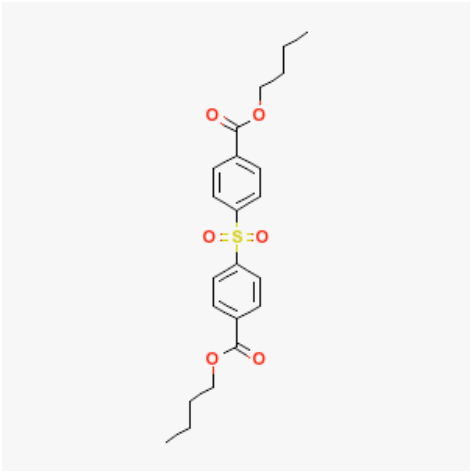
Advanced Structure Search

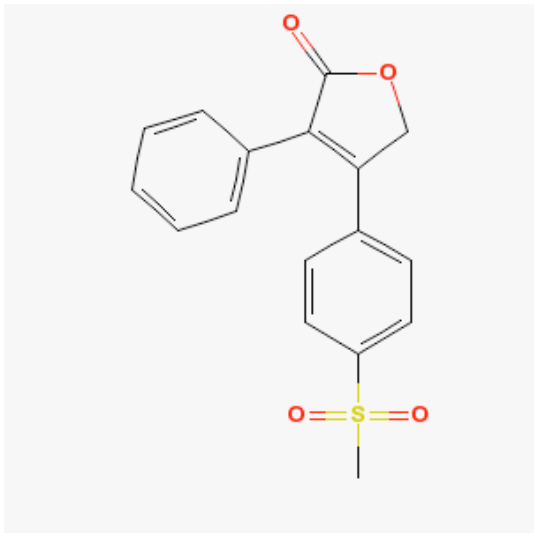
CV disorders & pain killers?
NCBI search

PubChem

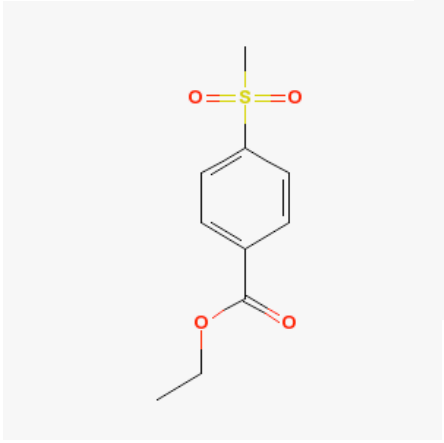
National Library of Medicine NLM

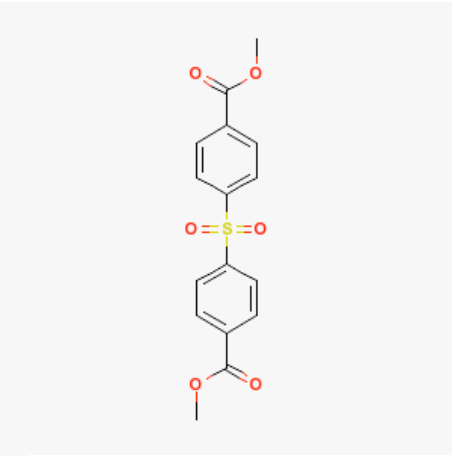






Merck Frosst Tricyclic





CV disorders & pain killers?
NCBI search

NCBI Map Viewer

Map Viewer Home

Map Viewer Help
Human Maps Help
FTP
Data As Table View

Maps & Options

Compress Map

Region Shown:
1q25.3
1q31.1
Go

out
zoom
in

You are here:
Ideogram

default
master

Homo sapiens **Build 35.1**

BLAST The Human Genome

Chromosome: [1] 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 X Y MT

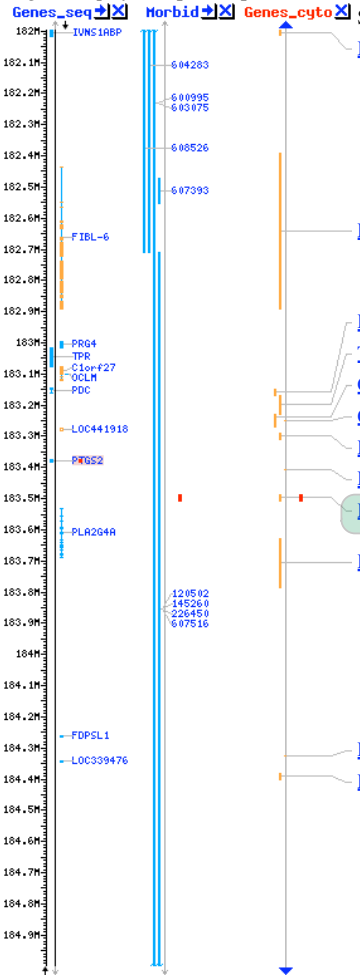
Query: PTGS2 [clear]

Master Map: Genes On Cytogenetic

Summary of Maps

Maps & Options

Region Displayed: **1q25.3-1q31.1**



Symbol	LinkOut	Cyto	Description
IVNS1ABP	sv pr dl ev mm hm	1q25.1-q31.1	influenza virus NS1A binding protein
FIBL-6	OMIM sv pr dl ev mm hm	1q25.3-q31.1	hemicentin
PRG4	OMIM sv pr dl ev mm hm	1q25-q31	proteoglycan 4, (megakaryocyte stimulating factor, articular su
TPR	OMIM sv pr dl ev mm hm	1q25	translocated promoter region (to activated MET oncogene)
C1orf27	sv pr dl ev mm hm	1q25	chromosome 1 open reading frame 27
OCLM	OMIM sv pr dl ev mm	1q31.1	oculomedin
PDC	OMIM sv pr dl ev mm hm	1q25.2	phosducin
LOC441918	sv dl ev mm	1q31.1	similar to Zinc finger protein 132
PTGS2	OMIM sv pr dl ev mm hm	1q25.2-q25.3	prostaglandin-endoperoxide synthase 2 (prostaglandin G/H syr
PLA2G4A	OMIM sv pr dl ev mm hm	1q25	phospholipase A2, group IVA (cytosolic, calcium-dependent)
FDPSL1	sv dl ev mm	1q24-q31	farnesyl diphosphate synthase-like 1 (farnesyl pyrophosphate s
LOC339476	sv pr dl ev mm	1q31.1	hypothetical protein LOC339476

CV disorders & pain killers?
NCBI search

OMIM
Online Mendelian Inheritance in Man

Johns Hopkins University

PTGS1 and PTGS2 are expressed in cells involved in inflammatory processes. Dramatic induction of PTGS2 mRNA in normal peripheral blood monocytes has been documented in response to lipopolysaccharide (LPS) and phorbol myristate acetate (PMA). This induction is partially inhibited by pretreatment with dexamethasone. In contrast, PTGS1 shows minimal induction with LPS and PMA. Tazawa et al. (1994) isolated the entire PGHS2 gene and its 5-prime flanking region and showed that the gene contains 10 exons, is 7.5 kb long, and is located on chromosome 1. By comparison, the murine and human PGHS1 genes comprise 11 exons and 10 introns and are approximately 22 kb long (Kraemer et al., 1992).

The antiinflammatory glucocorticoids are potent inhibitors of cyclooxygenase, a key regulator of prostaglandin synthesis. To investigate the mechanism of this inhibition, O'Banion et al. (1991, 1992) cloned a 4.1-kb cDNA that confers cyclooxygenase activity to transfected cells. The mRNA of this cyclooxygenase was unique for its long 3-prime untranslated region containing many AUUUA repeats. The levels of the 4.1-kb cyclooxygenase mRNA was rapidly increased by serum or interleukin-1-beta in mouse fibroblasts and human monocytes, respectively, and decreased by glucocorticoids, whereas levels of the 2.8-kb cyclooxygenase mRNA did not change. The 2.8-kb cyclooxygenase (PGHS1) is constitutive, whereas the 4.1-kb species is regulated and is probably a major mediator of inflammation.

CV disorders & pain killers?
MedWatch (<2000)

VIOXX (rofecoxib) Suspension
[October 28, 1999: Merck]

New labeling includes a patient package insert. Contact the company for a copy of the patient package insert.

COUMADIN (wafarin sodium) Tablets & Injection
[February 17, 2000: DuPont]

PRECAUTIONS:
EXOGENOUS FACTORS: factors that may be responsible for INCREASED PT/INR response under the "Specific Drugs Table" - three drugs added - "capecitabine, celecoxib, **rofecoxib**"

CV disorders & pain killers?
MedWatch (<2000)

VIOXX (rofecoxib) Tablets
[March 17, 2000: Merck]

PRECAUTIONS:
Drug Interactions: In single and multiple dose studies in healthy subjects receiving both warfarin and rofecoxib, prothrombin time (measured as INR) was increased by approximately 8% to 11%.

ADVERSE REACTIONS:

"The following serious adverse events have been reported rarely (less than 0.1%) in patients taking Vioxx, regardless of causality. Cases reported only in the post-marketing experience are indicated in italics."
"Cardiovascular:" cerebrovascular accident, congsetive heart failure, deep venous thrombosis, myocardial infarction, pulmonary embolism, transient ischemic attack, unstable angina"

Anything to say?

Interacting with FDA

- Advisory Committees
- Contact FDA
- Dockets
  - View Pending Regulations
  - Comment on Proposed Dockets
- Electronic Regulatory Submissions
- FDA-Private Sector Partnerships
- Field Offices
- Freedom of Information
- Grants
- Leveraging
- Ombudsman
- MedWatch
- Online Forms
- Petition FDA
- Product Code Builder
- Register for FDA Meetings
- Reporting Problems with FDA Products
- Technology Transfer

Food and Drug Administration MEDWATCH

A

MedWatch Online Voluntary Submission Form 3500

A. PATIENT INFORMATION

Clear Section [HELP]

1. **Patient Identifier** (In confidence)
2. **Age at Time of Event:** or **Date of Birth**: (MM/DD/YYYY)
3. **Sex** Female Male
4. **Weight** lbs. or kgs.

Clear Section [HELP]

Anything to say?

Interacting with FDA

- Advisory Committees
- Contact FDA
- Dockets
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- Technology Transfer

B

MedWatch Online Voluntary Submission Form 3500

B. ADVERSE EVENT OR PRODUCT PROBLEM

Clear Section [HELP]

1. ☐ **Adverse Event** and/or ☐ **Product Problem** (e.g., defects/malfunctions)

2. **Outcomes Attributed to Adverse Event** (Check all that apply)

- ☐ Death
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability
- ☐ Congenital Anomaly
- ☐ Required Intervention to Prevent Permanent Impairment/damage
- ☐ Other

3. **Date of Event**
If necessary, use Section B5 to explain or clarify dates.
(MM/DD/YYYY)

4. **Date of This Report**
05/13/2005 (MM/DD/YYYY)

5. **Describe Event or Problem** *up to a total of 6400 characters allowed*

6. **Relevant Tests/Laboratory Data,** Including Dates
up to a total of 1000 characters allowed

7. **Other Relevant History, Including Preexisting Medical Conditions** (e.g. allergies, race,pregnancy, smoking and alcohol use,hepatic/renal dysfunction,etc.)
up to a total of 500 characters allowed

Clear Section [HELP]

Previous Section | View/Print Submission as a PDF | Next Section

Anything to say?

Interacting with FDA

- Advisory Committees
- Contact FDA
- Dockets
  - View Pending Regulations
  - Comment on Proposed Dockets
- Electronic Regulatory Submissions
- FDA-Private Sector Partnerships
- Field Offices
- Freedom of Information
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- Reporting Problems with FDA Products
- Technology Transfer

C

MedWatch Online Voluntary Submission Form 3500

C. SUSPECT MEDICATION(S) Clear Section [HELP]

1. **Name (Give labeled strength & mfr/labeler, if known)**

	(Product Name)	(Label Strength)	(Mfr/Labeler)
#1			
#2			

2. **Dose/Frequency/Route Used**

#1 / /

#2 / /

3. **Therapy Dates** (If unknown, give duration) from/to (or best estimate) *If necessary, use Section B5 to explain or clarify dates.*

	From	To
#1		-
#2		-

4. **Diagnosis for Use** (separate indications with commas)

#1

#2

5. **Event Abated After Use Stopped or Dose Reduced**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #** (if known)

#1

#2

7. **Exp. Date** (if known)If necessary, use *Section B5 to explain or clarify dates.*

#1

#2

8. **Event Reappeared After Reintroduction**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC #**(For product problems only)

10. **Concomitant Medical Products and Therapy Dates** (Exclude treatment of event)

Anything to say?

Interacting with FDA

- Advisory Committees
- Contact FDA
- Dockets
  - View Pending Regulations
  - Comment on Proposed Dockets
- Electronic Regulatory Submissions
- FDA-Private Sector Partnerships
- Field Offices
- Freedom of Information
- Grants
- Leveraging
- Ombudsman
- MedWatch
- Online Forms
- Petition FDA
- Product Code Builder
- Register for FDA Meetings
- Reporting Problems with FDA Products
- Technology Transfer

Food and Drug Administration
MEDWATCH

D

MedWatch Online Voluntary Submission Form 3500

D. SUSPECT MEDICAL DEVICES

Clear Section [HELP]

1. **Brand Name**
2. **Type of Device**
3. **Manufacturer Name, City & State**
   Please use no more than 3 lines.
4.
   - **Model #**
   - **Catalog #**
   - **Serial #**
   - **Lot #**
   - **Expiration Date** (MM/DD/YYYY)
     If necessary, use Section B5 to explain or clarify dates.
   - **Other #**
5. **Operator of Device** ☐ Health Professional ☐ Lay User/Patient ☐ Other
6. **If Implanted, Give Date** (MM/DD/YYYY)
   If necessary, use Section B5 to explain or clarify dates
7. **If Explanted, Give Date** (MM/DD/YYYY)
   If necessary, use Section B5 to explain or clarify dates
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**
   Please use no more than 4 lines.
10. **Device Available for Evaluation?** (Do not send to FDA)
    ☐ Yes ☐ No ☐ Returned to Manufacturer on
11. **Concomitant Medical Products** and Therapy Dates (Exclude treatment of event)
    up to a total of 1000 characters allowed

Anything to say?

Interacting with FDA

- Advisory Committees
- Contact FDA
- Dockets
  - View Pending Regulations
  - Comment on Proposed Dockets
- Electronic Regulatory Submissions
- FDA-Private Sector Partnerships
- Field Offices
- Freedom of Information
- Grants
- Leveraging
- Ombudsman
- MedWatch
- Online Forms
- Petition FDA
- Product Code Builder
- Register for FDA Meetings
- Reporting Problems with FDA Products
- Technology Transfer

Food and Drug Administration
MEDWATCH

E

MedWatch Online Voluntary Submission Form 3500

E. REPORTER (See Confidentiality Section) Clear Section [HELP]

1. Name & Address

Name * (required)

Street Address * (required)

Include facility/department/mailcode as appropriate.

City * (required)

State/Territory

Postal/Zip Code * (required)

Country United States

Phone

E-mail

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Also reported to** ☐ Manufacturer ☐ User Facility ☐ Distributor

5. **If you do NOT want your identity disclosed to the manufacturer, check here.** ☐

Clear Section [HELP]

CV disorders & pain killers?
year 2005

OMIM
Online Mendelian Inheritance in Man
Johns Hopkins University

Egan et al. (2004) reported that estrogen acts on estrogen receptor subtype alpha (133430) to upregulate the production of atheroprotective prostacyclin (PGI2) by activation of COX2. This mechanism restrained both oxidant stress and platelet activation that contribute to atherogenesis in female mice. Deletion of the Pgi2 receptor removed the atheroprotective effect of estrogen in ovariectomized female mice. **Egan et al. (2004) concluded that this suggested that chronic treatment of patients with selective inhibitors of COX2 could undermine protection from cardiovascular disease in premenopausal females.**

Kothapalli et al. (2004) investigated the antimitogenic effect of high density lipoprotein (HDL) on the inhibition of S-phase entry of murine aortic smooth muscle cells, which they found to be mediated by apolipoprotein E (APOE; 107741). They also demonstrated that specific inhibition of Cox2 blocks the antimitogenic effects of HDL and Apoe, that both HDL and Apoe induce Cox2 gene expression, and that the prostacyclin receptor IP (600022) is required for the antimitogenic effects of HDL and Apoe. **Kothapalli et al. (2004) concluded that the COX2 gene is a target of APOE signaling, linking HDL and APOE to IP action, and suggested that this mechanism may contribute to the cardioprotective effect of HDL and APOE.**

CV disorders & pain killers?

VIOXX® approved label 08/19/2004

Drugs@FDA

In VIGOR, a study in 8076 patients (mean age 58; VIOXX n=4047, naproxen n=4029) with a median duration of exposure of 9 months, the risk of developing a serious cardiovascular thrombotic event was significantly higher in patients treated with VIOXX 50 mg once daily (n=45) as compared to patients treated with naproxen 500 mg twice daily (n=19). In VIGOR, mortality due to cardiovascular thrombotic events (7 vs 6, VIOXX vs naproxen, respectively) was similar between the treatment groups. (See CLINICAL STUDIES, *Special Studies*, *VIGOR*, *Other Safety Findings: Cardiovascular Safety*.) In a

Drugs@FDA

Safety of Vioxx

Merck & Co., Inc. today announced a voluntary withdrawal of Vioxx from the U.S. market due to safety concerns. Vioxx is a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) that was approved by FDA in May 1999 for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. It is also approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children.

The Agency was informed by Merck & Co., Inc. on September 27, 2004, that the Data Safety Monitoring Board for an ongoing long-term study of Vioxx (APPROVe) had recommended that the study be stopped early for safety reasons. The study was being conducted in patients at risk for developing recurrent colon polyps. The study showed an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx compared to placebo, particularly those who had been taking the drug for longer than 18 months. Based on this new safety information, Merck and FDA officials met the next day, September 28, 2004, and during that meeting FDA was informed that Merck was voluntarily withdrawing Vioxx from the market place.

Objectives...

The lecture pretended that...

- you know how-to navigate the FDA web site
- you get an idea on what it is useful for
- you get minimally bored

The lecture **did not** pretend to...

- be exhaustive
- be general