



Web Pages and Projects at FDA's Center for Drug Evaluation and Research (CDER)

**Monica Unger, MLS
Division of Information Services
www.fda.gov/cder**



CDER Forum for International Drug Regulatory Authorities



CDER Division of Information Services Mission Statement

- **We advance the exchange of information and knowledge among our customers, ultimately improving public health and the quality of life.**





CDER's Web Site **www.fda.gov/cder**

- **Created in 1996**
- Contains approximately 98,000 documents
- Average of 538,000 page hits per day
- Drugs@FDA search page is the #2 page among all FDA Web sites.



CDER Forum for International Drug Regulatory Authorities



CDER's Web Site **www.fda.gov/cder**

- **Original focus: regulated industry**
 - Guidance documents
 - Drug approvals and other regulatory actions



CDER Forum for International Drug Regulatory Authorities



CDER's Web Site www.fda.gov/cder

- **Expanded focus - a leading source of drug and regulatory information for:**
 - Health professionals
 - Patients and consumers
 - International regulators



CDER Forum for International Drug Regulatory Authorities

The screenshot shows the CDER website homepage. At the top, the FDA logo and "U.S. Food and Drug Administration" are displayed, along with the Department of Health and Human Services logo. Below this is the "CENTER FOR DRUG EVALUATION AND RESEARCH" and a navigation bar with links: "FDA Home Page", "CDER Site Info", "Contact CDER", and "What's New @ CDER". A search bar is present with the text "Search" and "Go" and "powered by Google". A horizontal menu contains: "CDER Home", "About CDER", "Drug Information", "Regulatory Guidance", "CDER Calendar", "Specific Audiences", and "CDER Archives". The main content area is titled "CDER Human Drugs" and is divided into three columns. The left column is "News from CDER" with three bullet points. The middle column is "Drug Safety" with sub-sections: "About FDA's New Drug Safety Initiative", "Safety Information for Patients and Healthcare Professionals" (with a link to "Drug Specific Information"), "Consumer Education/Information" (with a link to "Let Us Hear from You"), and "Featured Links" (with a link to "CDER 2004 Report to the"). The right column is "Quick Info Links" with a list of links: "Hurricane Katrina After a Hurricane: Safe Use of Drugs", "Insect Repellent Use and Safety in Children", "Insulin Use", "Drugs@FDA", "Drug Information Pathfinder", "Drug Shortages", "Inactive Ingredient Database", "MedWatch", "National Drug Code Directory", and "Orange Book". Arrows point to the "CDER Home" link, the "Drug Safety" header, the "Hurricane Katrina" link, and the "Drugs@FDA" link.

CDER's Web Site www.fda.gov/cder

related to the use of Herceptin (trastuzumab). [MedWatch Safety Info.](#)

• August 29. Custom RX Compounding Pharmacy and FDA announce a nationwide recall of Trypan Blue 0.06% Ophthalmic Solution. [MedWatch Safety Info.](#)

• August 26. FDA takes action on Plan B. [FDA Statement. Plan B Information.](#)

• August 12. FDA announces a strengthened risk management program to enhance safe use of Isotretinoin (Accutane) for treating severe acne. [Accutane Information.](#)

• [Previous News Items](#)

Featured Links

- [CDER 2004 Report to the Nation](#): Improving Public Health Through Human Drugs
- [The FDA Process for Approving Generic Drugs](#) (online tutorial)
- [Genomics at FDA](#)

Bioterrorism:

[Drug Preparedness and Response](#)

- Stay Informed -

[Subscribe to Daily/Weekly Updates](#)

You can receive CDER "What's New" in a daily or weekly e-mail message.

- [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](#)

Food and Drug Administration
MEDWATCH

Safety Alerts for FDA Regulated Products



Health Professional and Consumer Information

- **The CDER Web presents information for patients, health professionals, and other caregivers, including:**
 - **Drug Safety Information**
 - **Drug Shortages**
 - **Oncology Tools**
 - **Consumer Information**



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Index to Drug-Specific Information

Information for a drug will be in one of three different formats:

- **Patient Information Sheet** (with and without FDA Alerts)
- **Consumer Information Sheet** (for drugs approved since 1998. These will all be eventually converted to Patient Information Sheets)
- **Drug Information Page** (may include a Patient or Consumer Information Sheet, approval information, FDA press releases, questions and answers about a drug, and other related information)

Search the Page by Drug Name:

A B C D E E G H I J K L M N O P Q R S T U V W X Y Z

A

[Abilify](#) (aripiprazole)
[Accutane](#) (isotretinoin)
[Aciphex](#) (rabeprazole)
[Actonel](#) (risedronate)
[AcuTect](#) (technetium Tc 99m apcitide) complex
[Actos](#) (pioglitazone)
[Adderall](#) (amphetamine salts)
[Agenerase](#) (amprenavir)

F

[Factive](#) (gemifloxacin mesylate)
[Faslodex](#) (fulvestrant)
[Fentanyl](#)
[Ferlecit](#) (sodium ferric gluconate complex)
[Fluoxetine](#)
[Fluvoxamine](#)
[Foradil](#) (formoterol fumarate)

R

[Radiogardase](#) (prussian blue)
[Ramelteon](#)
[Rapamune](#) (sirolimus)
[Raptiva](#) (efalizumab)
[Refludan](#) (lepirudin recombinant)
[Relenza](#) (zanamivir)
[Remeron](#) (mirtazapine)
[Reminyl](#) (galantamine)

The Medication Errors Page

Medication Errors

- [Introduction](#)
- [Drug Products Associated with Medication Errors](#) UPDATED (4/26/2005)
- [Medication Errors Reports and Articles](#)
- [Name Differentiation Project](#)
- [Federal Regulations and Guidances](#)
- [How to Report a Medication Error](#)
- [Other Resources](#)

Introduction

FDA receives medication error reports on marketed human drugs (including prescription drugs, generic drugs, and over-the-counter drugs) and nonvaccine biological products and devices. The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication; product labeling, packaging, and nomenclature; compounding, dispensing, distribution, administration, education, monitoring, and use."

Drug Shortages Page


U.S. Food and Drug Administration


CENTER FOR DRUG EVALUATION AND RESEARCH

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Drug Shortages

- [Introduction](#)
- [FAQs](#)
- [Current Drug Shortages \(8/12/2005\)](#)
- [Resolved Drug Shortages \(8/4/2005\)](#)
- [Drugs to be Discontinued \(8/29/2005\)](#)
- [Additional Communications \(5/4/2005\)](#)
- [Drug Shortage Manual of Policies and Procedures \(MaPP\)](#)
- [Medical Necessity Guidance Document](#)
- [How to Report a Drug Shortage](#)
- [Practical Steps for Practitioners Facing Shortage Situations](#)
- [More Information on Drug Shortages, Product Recalls and Warnings](#)
- [Other Sites](#)
- [Comments on this Web Page](#)

Drug Shortages Email Alert: To receive email notification of drug products added to the Current Drug Shortages, and Resolved Drug Shortages lists, link to [http://www.fda.gov/cder/shortages](#)

Drug Shortages: Current Drug Shortages Table

Current Drug Shortages

Drug Name	Company Information	Reason for Shortage	Related Information
BICNU (carmustine) Injection Posted 5/11/2005	Bristol-Myers Squibb 1-800-631-5244	Manufacturing pending	BMS is working to resolve this shortage and anticipates resolution soon - healthcare providers may call BMS for additional information regarding availability. BMS Statement
Celestone Soluspan (Betamethasone Injection) updated 9/16/2004	Schering-Plough Corp. 2000 Galloping Hill Rd. Kenilworth, NJ 07033-0530 908-298-4000 800-526-4099 www.sch-plough.com	Manufacturing issues	Additional Information , (updated 9/16/2004)
Maxipime (cefepime)	Elan Pharmaceuticals	Manufacturing delays	You may contact Elan at 1-800-859-8586 for additional information



Oncology Tools

- **Developed by a staff pediatric oncologist in collaboration with Division of Information Services**
- **Collection of FDA information that addresses cancer-related medical and regulatory issues**



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Oncology Tools

Food and Drug Administration
Center for Drug Evaluation and Research

Oncology Tools



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Approved Oncology Drugs

Disease Summaries

Regulatory Tools

Oncology Reference Tools

Patient Liaison Program

Additional Resources

FDA Review Divisions

CDER Home

[French/Francais](#) [German/Deutsch](#) [Dutch/Nederlands](#) [Japanese](#) [Arabic](#)

Welcome to the FDA Oncology Tools web site! Oncology Tools contains a variety of information related to cancer and approved cancer drug therapies. You may take a [quick tour of the information here](#), select a category from the menu on the left or from the brief descriptions below. View [what is new](#) for approvals, upcoming meetings, and on this site.

Rather than grouping all drug product information together, this web page is a first effort at pulling together information by disease category which we hope will make this information easier to find and use. This is a pilot project, and we encourage you to give us lots of feedback about what you like and don't like about the page and how it can be made more useful to you. We'll be using your comments to improve this page and to determine whether to expand this approach to other disease categories. [Comments](#).

Consumer Education Materials

Consumer Education: What You Should Know About Buying and Using Drug Products

FDA is committed to providing consumers with information on prescription, generic, and over-the-counter drug products. The Center for Drug Evaluation and Research has developed the following public education materials to help you make informed decisions about using medicines.



FDA CDER Consumer Education Email Alert:

To receive email notification of new consumer educational materials on the safe and effective use of medicines, link to <http://list.nih.gov/cgi-bin/wa?SUBED1=fda-cder-consumer-ed&A=1> and complete the listserv form.

Subjects

- [Antibiotics and Antibiotic Resistance](#)
- [Buying Medicine and Medical Products Over the Internet](#)
- [Buying Medicine from Outside the United States](#)
- [Counterfeit Medicine](#)
- [Ensuring Safe Use of Medicine](#), including:
 - General use of prescription and over-the-counter medicine
 - Safe use of medicine for seniors
- [Generic Drugs](#)
- [Misuse of Prescription Pain Relievers](#)
- [Over-the-Counter Medicine](#), including:
 - Choosing the right over-the-counter medicine (OTCs)
 - [The Over-the-Counter Medicine Label](#)

Consumer Education Materials

Consumer Education: Ensuring Safe Use of Medicine

By being an informed consumer and being involved in your health care, you can decrease the risks and get the most benefits from your medicines. The following materials will help you, working with your health care professionals, to make informed choices when using medicines.

To obtain printed copies of any of these materials, please email your request by title to: dpapubs@cder.fda.gov. You can also call 301-827-1243 or 1-888-INFO-FDA.

The following links are text documents. You can also view the graphic versions (if available) by going to the "[All Graphics and Other Media](#)" page.

- ["Be An Active Member of Your Health Care Team."](#) This 12 page pamphlet describes how to become an active member of your health care team and to work with your teammates to make medicine use SAFER. It also includes an expanded question guide to help you gather information about your medicines with your health care team. (Done in cooperation with the Council on Family Health)
 - **En Español** ["Sea Miembro Activo del Equipo de Cuidados de la Salud."](#) This 12 page pamphlet describes how to become an active member of your health care team and to work with your teammates to make medicine use SAFER. It also includes a question guide to help you gather information about your medicines with your health care team. (Done in cooperation with the Council

Consumer Education Materials: Graphic versions

Title "Think It Through: Managing the Benefits and Risks of Medicines."



- [text-HTML](#)
- [PDF](#) (low resolution, view version)
- [PDF](#) (high resolution, print version)

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Title "Information: Your best medicine."



- [text-HTML](#)
- [PDF](#) (low resolution, view version)
- [PDF](#) (high resolution, print version)



Regulatory Information

Database Searches:

- **Drugs@FDA**
- **Inactive Ingredient Search**
- **Postmarketing Study Commitments**
- **Bioresearch Monitoring Information System (BMIS)**
- **Clinical Investigator Inspection List (CLIL)**



CDER Forum for International Drug Regulatory Authorities



Regulatory Information

- **A Risk-Based Approach to Pharmaceutical Current Good Manufacturing Practices**
- **Process Analytical Technology (PAT)**
- **Small Business Assistance**
- **Electronic Submissions and Review**
- **Human Drug Advisory Committees**



CDER Forum for International Drug Regulatory Authorities

Drugs@FDA

<http://www.fda.gov/cder/drugsatfda>

- A Catalog of FDA Approved Drug Products
- Regulatory and consumer information on innovator and generic drug products
- Links to labels, approval letters and reviews
- Approval history information including action dates and supplement types
- Identifies generics and other equivalents for innovator drugs based on therapeutic equivalence
- Provides a downloadable file of Drugs@FDA data

Drugs@FDA



Drugs@FDA [FAQ](#) | [Instructions](#) | [Glossary](#) | [Contact Us](#) | [CDER Home](#)

[Drugs@FDA Demo New!!](#) | [What's New in Drugs@FDA](#)

A Catalog of FDA Approved Drug Products

- Approved and tentatively approved prescription, over-the-counter, and discontinued drugs
- Drug approval letters, labels, and review packages

Search by Drug Name or Active Ingredient

Enter at least three characters:

Browse by Drug Name

A	B	C	D	E	F	G	H	I
J	K	L	M	N	O	P	Q	R
S	T	U	V	W	X	Y	Z	0-9

Advanced Search

- Application Number (NDA, ANDA, BLA)
- Action Dates of Application Approvals and Supplements

Drugs@FDA

Drugs@FDA [FAQ](#) | [Instructions](#) | [Glossary](#) | [Contact Us](#) | [CDER Home](#)

[Drugs@FDA Demo New!!](#) | [What's New in Drugs@FDA](#)

[Start Over](#)

Search Results for 'prozac'

Products listed on this page may not be equivalent to one another.

Click on a drug name for more information:

Drug Name	Active Ingredients
PROZAC	FLUOXETINE HYDROCHLORIDE
PROZAC WEEKLY	FLUOXETINE HYDROCHLORIDE

Drugs@FDA

Click on a drug name or application number to view drug details: 

Drug Name and FDA Application Number	Dosage Form/Route	Strength	Marketing Status	Company
PROZAC (NDA # 018936)	CAPSULE; ORAL	Multiple Strengths	Prescription	LILLY
PROZAC (NDA # 020101)	SOLUTION; ORAL	EQ 20MG BASE/5ML	Prescription	LILLY
PROZAC (NDA # 020974)	TABLET; ORAL	EQ 10MG BASE	Prescription	LILLY

Drugs@FDA

Drugs@FDA

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Drugs@FDA Demo **New!** | [What's New in Drugs@FDA](#)

[Start Over](#)

[Back to Search Results](#)

[Back to Overview](#)

Drug Details

Drug Name(s)	PROZAC (Brand Name Drug)
FDA Application No.	(NDA) 018936
Active Ingredient(s)	FLUOXETINE HYDROCHLORIDE
Company	LILLY

- [Therapeutic Equivalents](#)
- [Approval History and Related Documents](#)

- [Label Information](#)
- [More Information from FDA](#)

Products on Application (NDA) #018936

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 20MG BASE	CAPSULE; ORAL	Prescription	No	AB

Drugs@FDA – Drug Details Page

Products on Application (NDA) #018936

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 20MG BASE	CAPSULE; ORAL	Prescription	No	AB
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 40MG BASE	CAPSULE; ORAL	Prescription	Yes	AB
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 60MG BASE	CAPSULE; ORAL	Discontinued	No	None
PROZAC	FLUOXETINE HYDROCHLORIDE	EQ 10MG BASE	CAPSULE; ORAL	Prescription	No	AB
SARAFEM	FLUOXETINE HYDROCHLORIDE	EQ 10MG BASE	CAPSULE; ORAL	Prescription	No	None
SARAFEM	FLUOXETINE HYDROCHLORIDE	EQ 20MG BASE	CAPSULE; ORAL	Prescription	Yes	None



Drugs@FDA

Coming Soon

■ Reports by Month:

- All Approvals
- All Original NDAs
- All Original ANDAs
- Supplements to NDAs and BLAs
- Tentative Approvals



Inactive Ingredient Search



U.S. Food and Drug Administration - Center for Drug Evaluation and Research

Inactive Ingredient Search for Approved Drug Products

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Type in all or part of an inactive ingredient name (must be at least 3 characters long).



Drug questions email: drugproducts@cder.fda.gov

[Privacy Statement](#)

Inactive Ingredient Search



U.S. Food and Drug Administration - Center for Drug Evaluation and Research

Inactive Ingredient Search for Approved Drug Products

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Search Results for: "purple"



<u>INACTIVE</u> <u>INGREDIENT</u>	<u>ROUTE; DOSAGE FORM</u>	<u>CAS</u> <u>NUMBER</u>	<u>MAXIMUM</u> <u>POTENCY</u>
DYE FDC PURPLE LB588	ORAL; TABLET		0.2MG
DYE FDC PURPLE LB-694	ORAL; TABLET		0.25MG
DYE PURPLE LAKE	ORAL; TABLET		

Postmarketing Study Commitments Search



U.S. Food and Drug Administration - Center for Drug Evaluation and Research

Postmarketing Study Commitments

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Postmarketing commitment studies occur after a drug or biological product has been approved by FDA. For more information, please read: "[Report to Congress: Reports on Postmarketing Studies \(FDAMA 130\)](#)" and the [Draft Guidance for Industry](#).

Center: Both CBER and CDER CBER CDER

Applicant:

Product:

NDA/ANDA/BLA Number:

Commitment Status: [Commitment Status Definitions](#)

Commitment Required Under: [Approval](#)
 [Policy Rule](#)
 [Research Equity Act](#)
 [n/dd/yyyy](#)

NDA/ANDA/BLA Approval Date:

Postmarketing Study Commitments Search

Applicant	LUITPOLD PHARMACEUTICALS INC
Product	VENOFER (IRON SUCROSE) 100MG INJECTION, IRON SUCROSE
NDA/BLA Number	21135
NDA/BLA Approval Date	11/06/2000
Annual Report Due Date	11/06/2003
Annual Report Received	12/18/2002

Commitment Number 1

Commitment Description	Examine the worldwide safety database for Venofer for occurrence of adverse events in pediatric patients by age group (neonates, infants, children, adolescents). Attempt to obtain further information on the 5 reported cases of necrotizing enterocolitis in infants, including examination of the safety database for other similar cases. No study of Venofer in neonates and infants is requested at this time. However, you should address possible need for and risks involved with Venofer use in very young pediatric patients.
Current Status	Fulfilled



Bioresearch Monitoring Information System (BMIS) Search

- In 2005 CDER launched a version of the BMIS file that is searchable on the Web.
- A downloadable file is also available.



CDER Forum for International Drug Regulatory Authorities



Clinical Investigator Inspection List (CLIL)

- In 2005 we added a Web search for the Clinical Investigator Inspection List
- A downloadable file is also available.



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A Risk-Based Approach to Pharmaceutical Current Good Manufacturing Practices



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Pharmaceutical cGMPs for the 21st Century - A Risk-Based Approach

Final Report - Fall 2004

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

September 2004

[This Report is also available in PDF](#)

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- [Executive Summary — Key Accomplishments](#)
- [Adoption of Quality Systems Model for Agency Operations](#)
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Process Analytical Technology (PAT) Initiatives

Process Analytical Technology (PAT) Initiative

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Introduction

The goal of PAT is to understand and control the manufacturing process, which is consistent with our current drug quality system: *quality cannot be tested into products; it should be built-in or should be by design.*

Drug Approval Application Process

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- [New Drug Application](#)
- [Abbreviated New Drug Application for Generic Drug Products](#) UPDATED
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 - [Institutional Review Boards and Protection of Human Subjects in Clinical Trials](#)
- [Laws, Regulations, Policies and Procedures](#)
- [Drug Application Regulatory Compliance](#)
- [Drug Application Forms and Electronic Submissions](#) UPDATED
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- [Economic Assistance and Incentives for Drug Development](#)
 - [Economic Assistance, Pre-Approval](#)
 - [Economic Incentives Post-Approval](#)
 - [Economic Assistance Pre-Approval and Post-Approval](#)



What's New for Small Pharmaceutical Businesses: To receive email notification of new information (Federal Register notices, guidances, etc.) from Small Business Assistance in CDER, send an email to cdersba@listmanager.fda.gov. In the subject field type **subscribe**. You may leave the body of the message blank. To remove your name from the list, simply send an email to the above address and enter **unsubscribe** in the subject field.



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Human Drug Advisory Committees

- [Introduction](#)
- [Advisory Committee Meeting Transcripts and Other Meeting Documents, Contacts, Rosters, and Charters](#) UPDATED (9/10/2004)
- [CDER Advisory Committee Staff](#)
- [Calendar of CDER Advisory Committee Meetings](#)
- [List of Advisory Committees and Information Line Numbers](#)
- [2004 Tentative Meeting Schedule Ordered By Committee](#)
- [2004 FDA Advisory Committee Calendar](#) Meeting information includes center, date, time and location; agenda, presentation procedures, contact persons, and links to the *Federal Register* notice.
- [Federal Register Notices of Past FDA Advisory Committee Meetings](#)
- [Committee Nomination Information for Consumer, Patient, and Industry Representatives](#)
- [Other FDA Advisory Committees](#)



Human Drug Advisory Committee Information

- [Federal Register Notices of Future FDA Advisory Committee Meetings](#)
- [Federal Register Notices of Past FDA Advisory Committee Meetings](#)

Committee	Meeting Transcripts, Agendas, and Other Info	CDER Contacts	Committee Members	Charter
Anesthetic and Life Support Drugs	Meeting Information	Contacts	Committee Members	Charter
Anti-Infective Drugs	Meeting Information	Contacts	Committee Members <small>UPDATED (9/24/2003)</small>	Charter
Antiviral Drugs	Meeting Information	Contacts	Committee Members <small>UPDATED (9/24/2003)</small>	Charter
Arthritis Drugs	Meeting Information	Contacts	Committee Members	Charter
Cardiovascular and Renal Drugs	Meeting Information	Contacts	Committee Members	Charter



Sample Advisory Committee Page



U.S. Food and Drug Administration



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Anesthetic and Life Support Drugs Advisory Committee Meetings

- [List of Tentative Meeting Dates for All CDER Advisory Committees](#)
- [List of Committee Members](#)
- [Committee Charter](#)
- [CDER Contacts](#)

Current Year Meeting Information

- [2005 FDA Advisory Committee Calendar](#) Meeting information includes center, date, time and location, agenda, presentation procedures, contact persons, and links to the *Federal Register* notice.
- [2005 Anesthetic and Life Support Drugs Meeting Documents](#) (link to draft agendas, questions, transcripts, and other meeting information)

Previous Years Meeting Information



Thank You!

Please send questions or comments to:

webmaster@fda.hhs.gov OR

Monica Unger

monica.unger@fda.hhs.gov



CDER Forum for International Drug Regulatory Authorities