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 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's Web Site www.fda.gov/cder

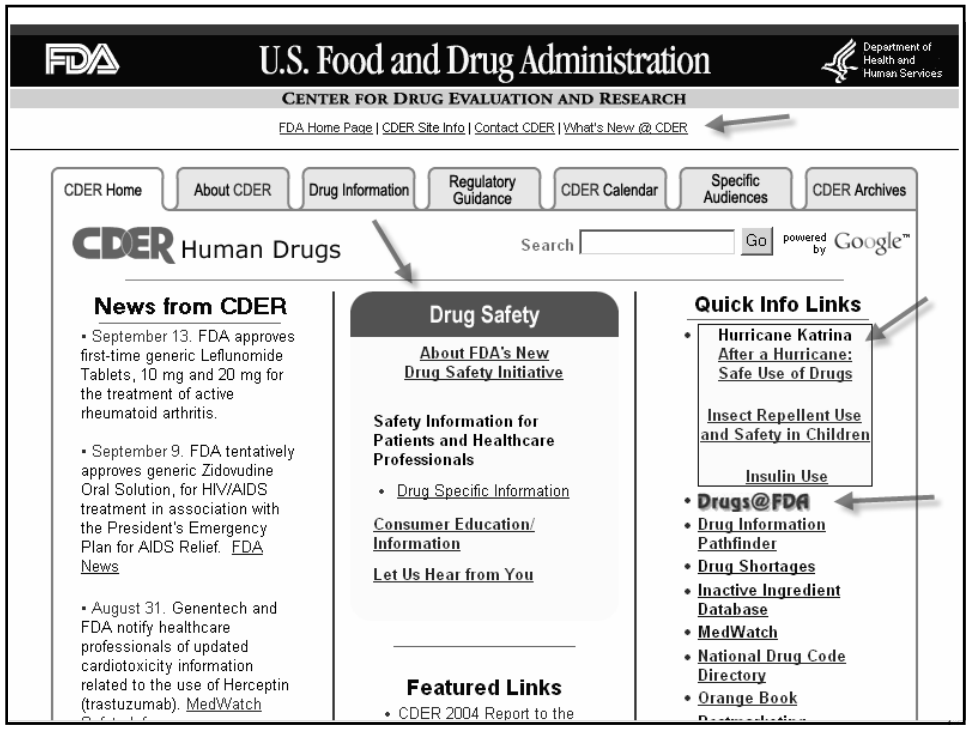
- **Original focus: regulated industry**
  - Guidance documents
  - Drug approvals and other regulatory actions

CDER Forum for International Drug Regulatory Authorities

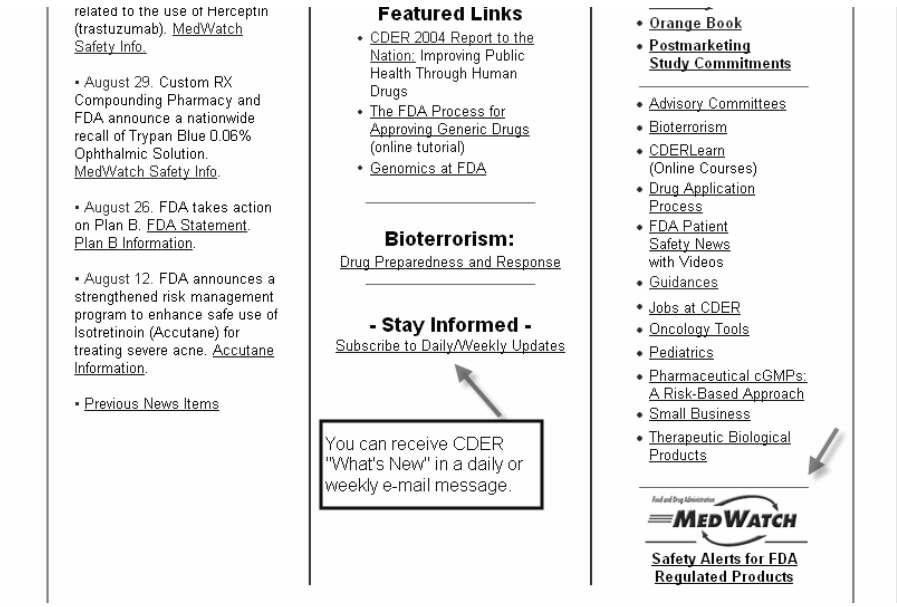
CDER's Web Site
www.fda.gov/cder

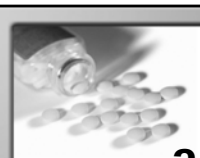
- **Expanded focus - a leading source of drug and regulatory information for:**
  - Health professionals
  - Patients and consumers
  - International regulators

CDER Forum for International Drug Regulatory Authorities



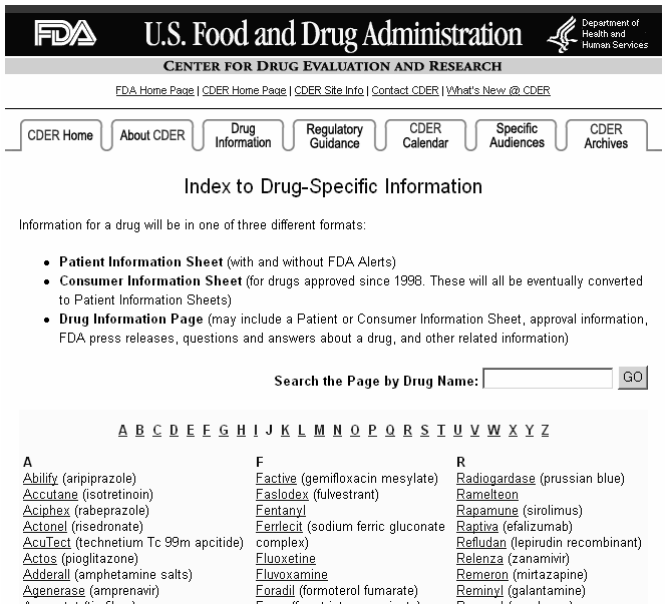
CDER's Web Site
www.fda.gov/cder





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



U.S. Food and Drug Administration

Department of Health and Human Services

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CDER Home | About CDER | Drug Information | Regulatory Guidance | CDER Calendar | Specific Audiences | CDER Archives

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: GO

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

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

F
Factive (gemifloxacin mesylate)
Faslodex (fulvestrant)
Fentanyl
Ferrlecit (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

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

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Search GO powered by Google™

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

Drug Shortages: Current Drug Shortages Table

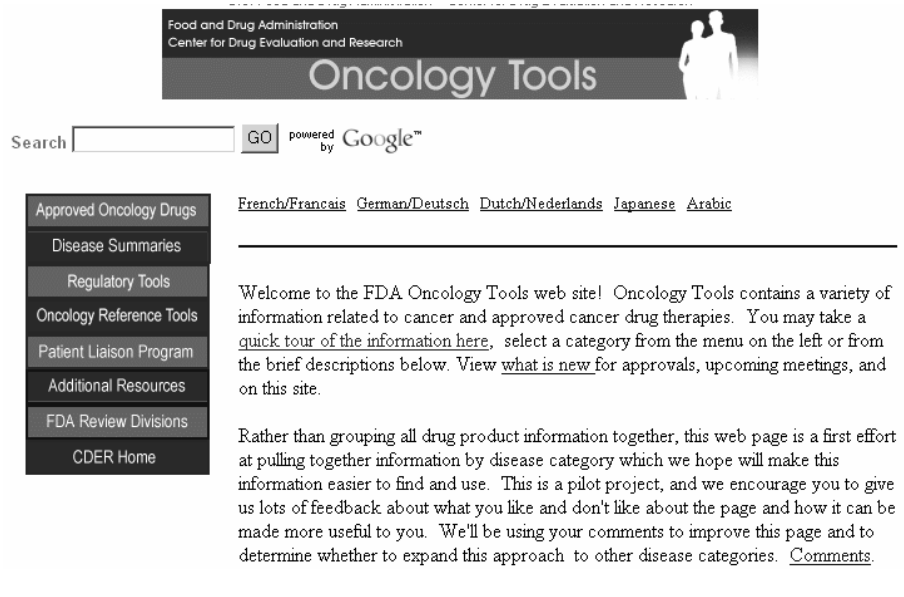
Current Drug Shortages

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**

Oncology Tools



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

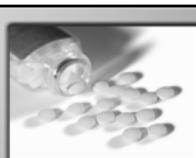
Title **"Think It Through: Managing the Benefits and Risks of Medicines."**

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

Back to Top

Title **"Information: Your best medicine."**

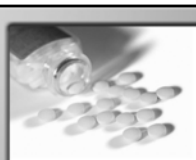
- text-HTML
- PDF (low resolution, view version)
- PDF (high resolution, print version)



Regulatory Information

Database Searches:

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



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**

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: prozac Submit Clear

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

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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

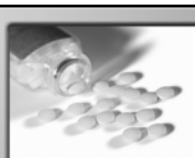
Products on Application (NDA) #018936

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

About this Database

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

purple Search Clear

Drug questions email: drugproducts@cder.fda.gov

Privacy Statement

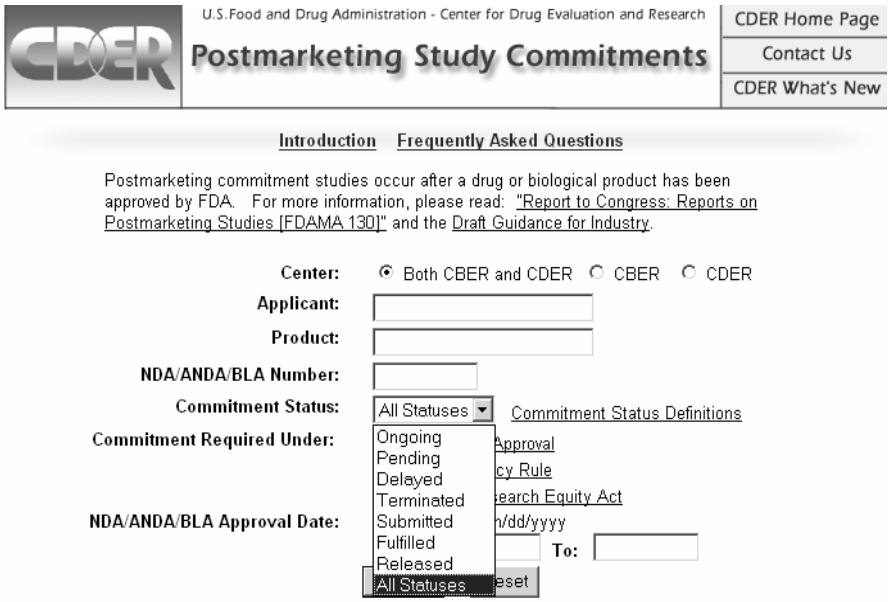
Inactive Ingredient Search

About this Database Back to Search Page

Search Results for: "purple"

INACTIVE INGREDIENT	ROUTE;DOSAGE FORM	CAS NUMBER	MAXIMUM POTENCY
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



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

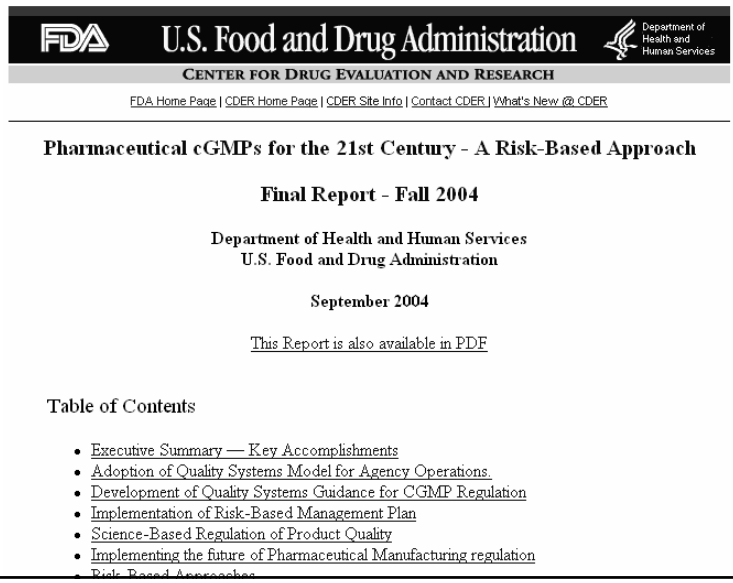
Bioresearch Monitoring Information System (BMIS) Search

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

Clinical Investigator Inspection List (CLIIL)

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

A Risk-Based Approach to Pharmaceutical Current Good Manufacturing Practices



U.S. Food and Drug Administration

Department of Health and Human Services

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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

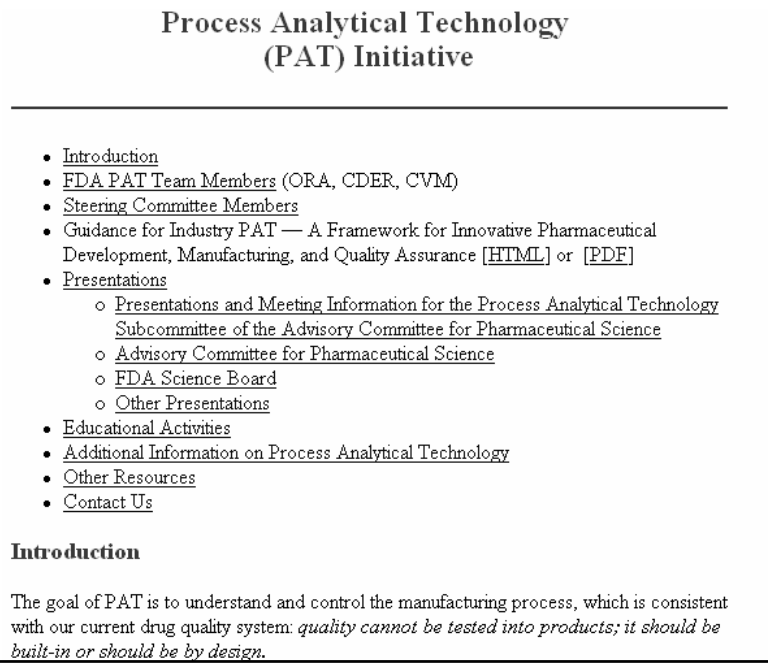
September 2004

This Report is also available in PDF

Table of Contents

- Executive Summary — Key Accomplishments
- Adoption of Quality Systems Model for Agency Operations.
- Development of Quality Systems Guidance for CGMP Regulation
- Implementation of Risk-Based Management Plan
- Science-Based Regulation of Product Quality
- Implementing the future of Pharmaceutical Manufacturing regulation
- Risk-Based Approaches

Process Analytical Technology (PAT) Initiatives

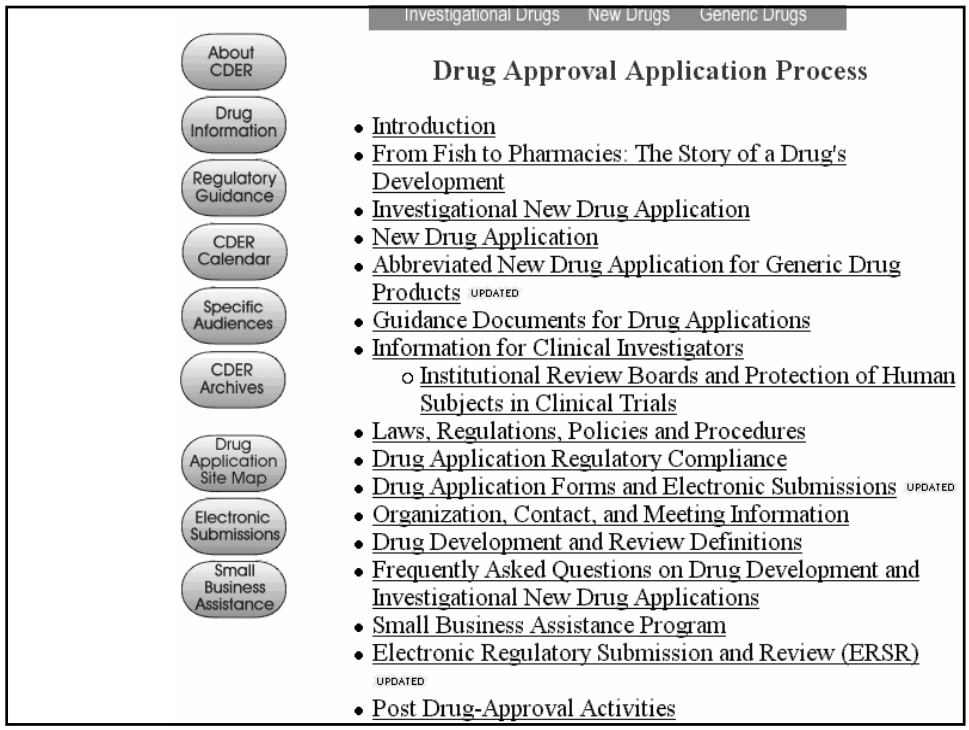


Process Analytical Technology (PAT) Initiative

- Introduction
- FDA PAT Team Members (ORA, CDER, CVM)
- Steering Committee Members
- Guidance for Industry PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance [HTML] or [PDF]
- Presentations
  - Presentations and Meeting Information for the Process Analytical Technology Subcommittee of the Advisory Committee for Pharmaceutical Science
  - Advisory Committee for Pharmaceutical Science
  - FDA Science Board
  - Other Presentations
- Educational Activities
- Additional Information on Process Analytical Technology
- Other Resources
- Contact Us

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.*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Laws, Regulations, Policies and Procedures
Drug Application Regulatory Compliance
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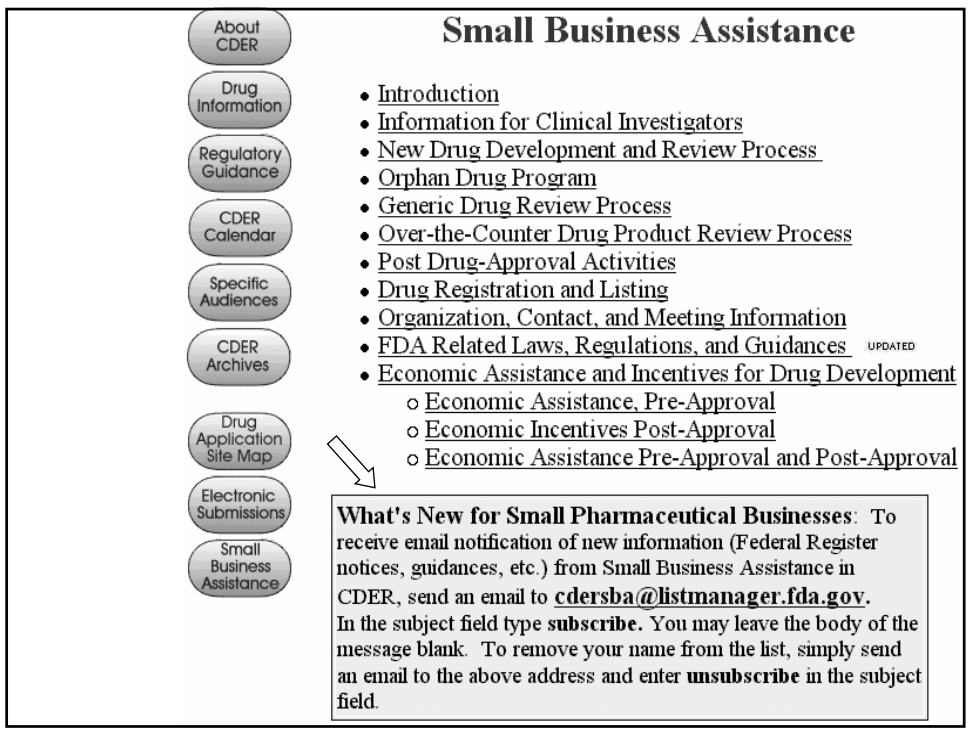
Drug Development and Review Definitions
Frequently Asked Questions on Drug Development and Investigational New Drug Applications
Small Business Assistance Program
Electronic Regulatory Submission and Review (ERSR) UPDATED
Post Drug-Approval Activities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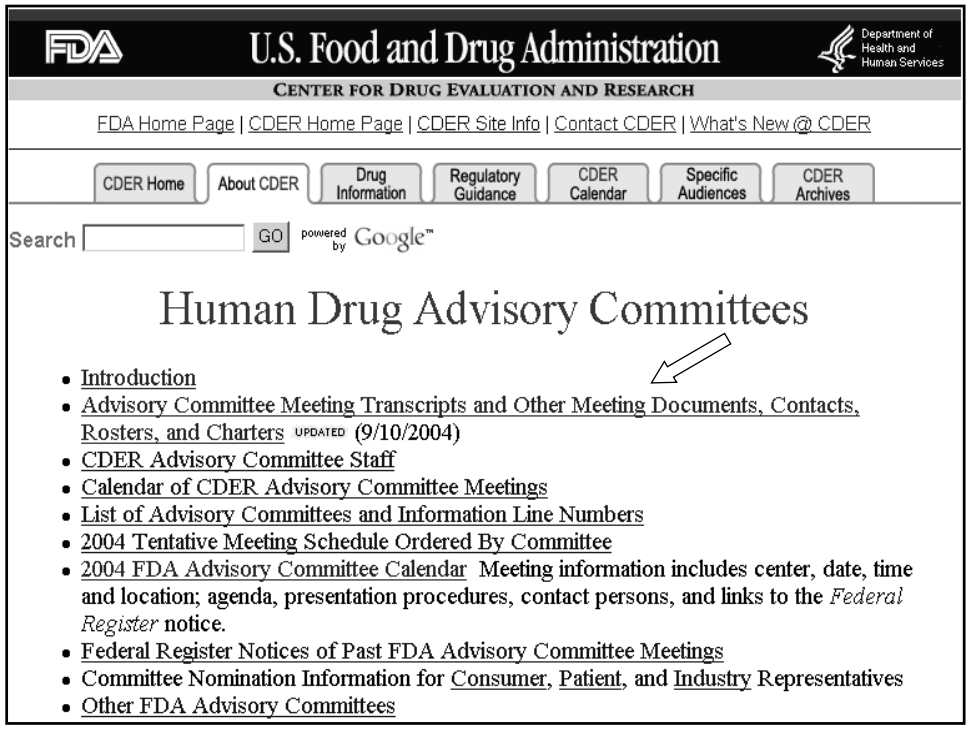
Economic Assistance, Pre-Approval
Economic Incentives Post-Approval
Economic Assistance Pre-Approval and Post-Approval
What's New for Small Pharmaceutical Businesses: To receive email notification of new information (Federal Register notices, guidances, etc.) from Small Business Assistance in CDER, send 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.

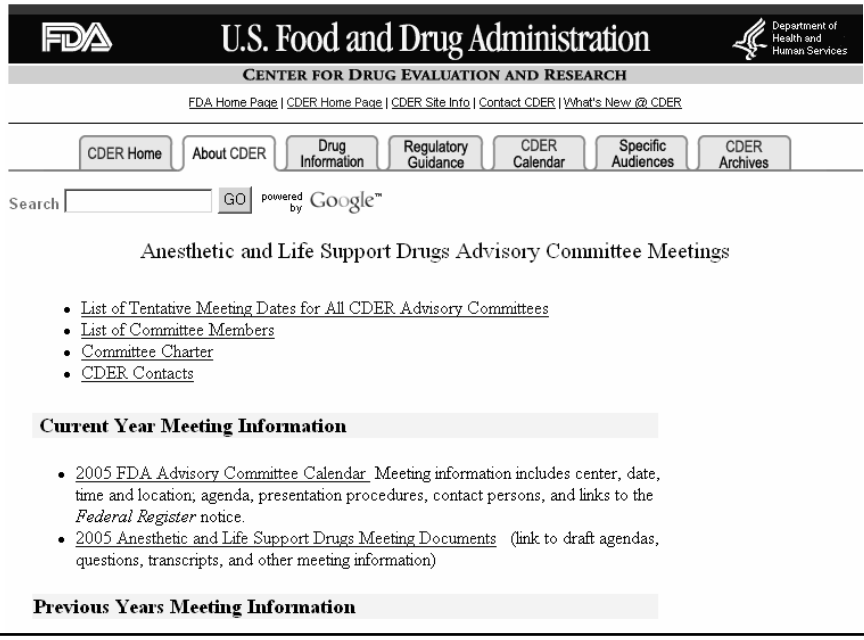


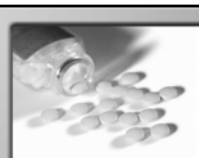
Human Drug Advisory Committee Information

- 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 UPDATED (9/24/2003)	Charter
Antiviral Drugs	Meeting Information	Contacts	Committee Members UPDATED (9/24/2003)	Charter
Arthritis Drugs	Meeting Information	Contacts	Committee Members	Charter
Cardiovascular and Renal Drugs	Meeting Information	Contacts	Committee Members	Charter

Sample Advisory Committee Page





Thank You!

Please send questions or comments to:

webmaster@fda.hhs.gov OR

Monica Unger
monica.unger@fda.hhs.gov