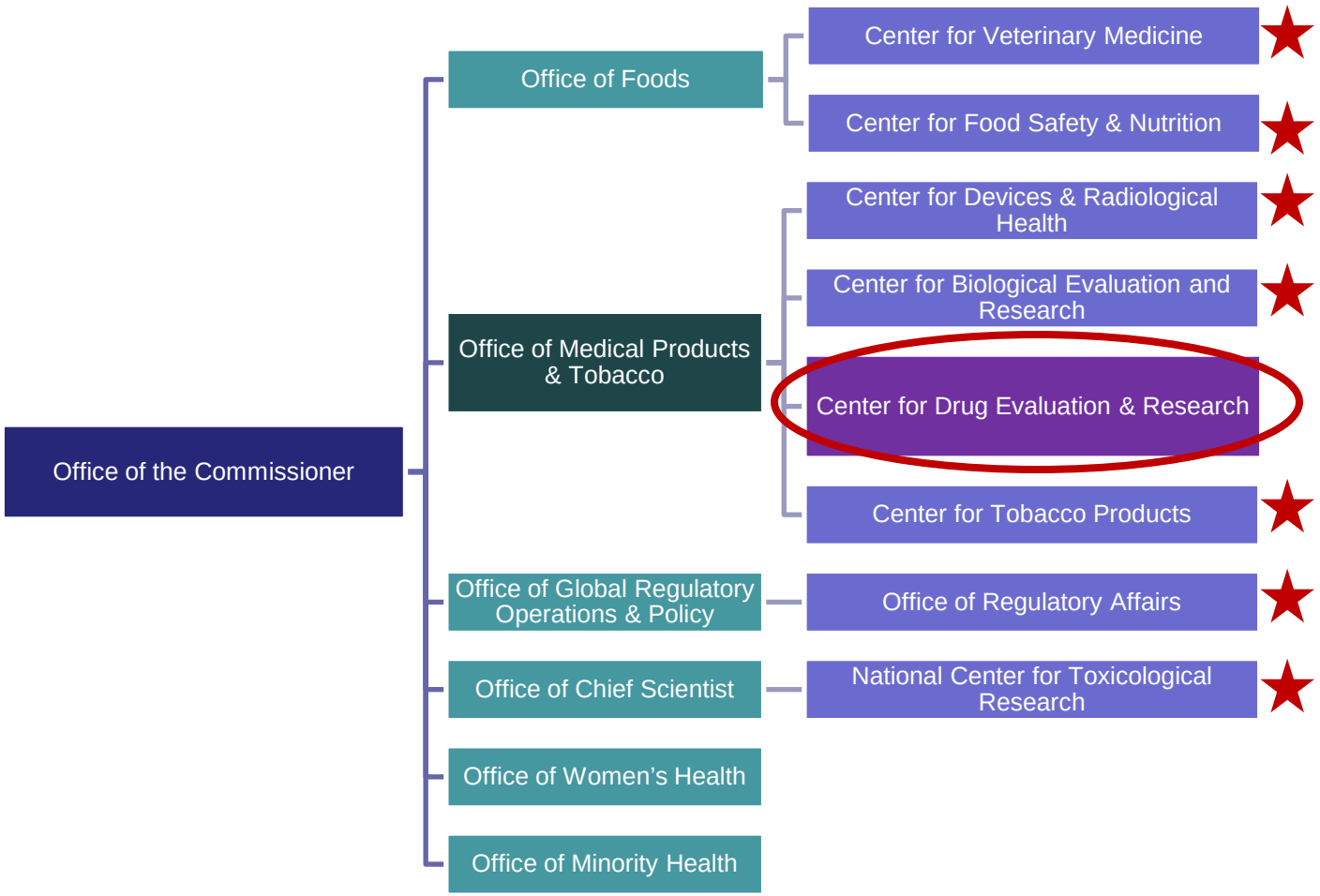
FDA Online Drug Information Resources for Students and Clinicians

Lesley R. Navin RN, MSN
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
September 2015

Objectives

- Verify FDA indications for approved drugs
- Research and retrieve safety issues for drugs
- Locate adverse event reporting information
- Identify resources that HCPs can use to stay informed of FDA actions, decisions and initiatives

US Food and Drug Administration



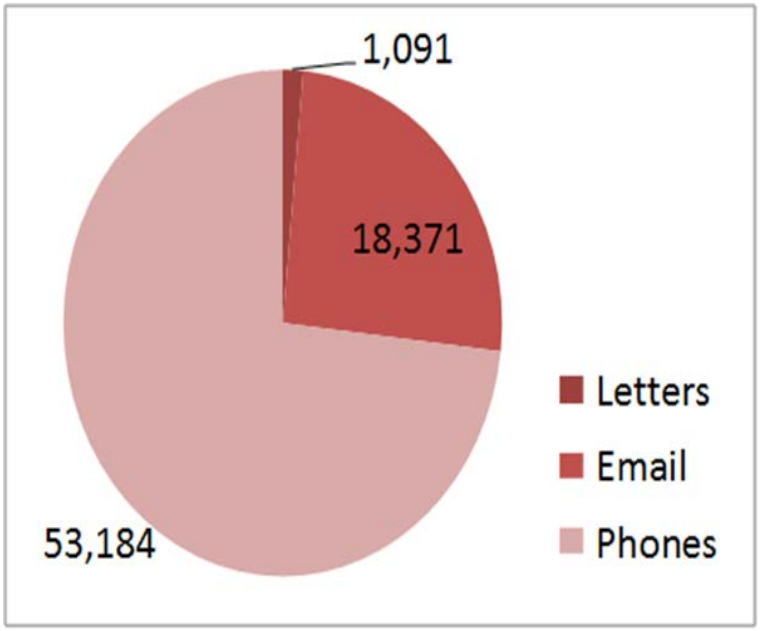
Division of Drug Information (DDI)

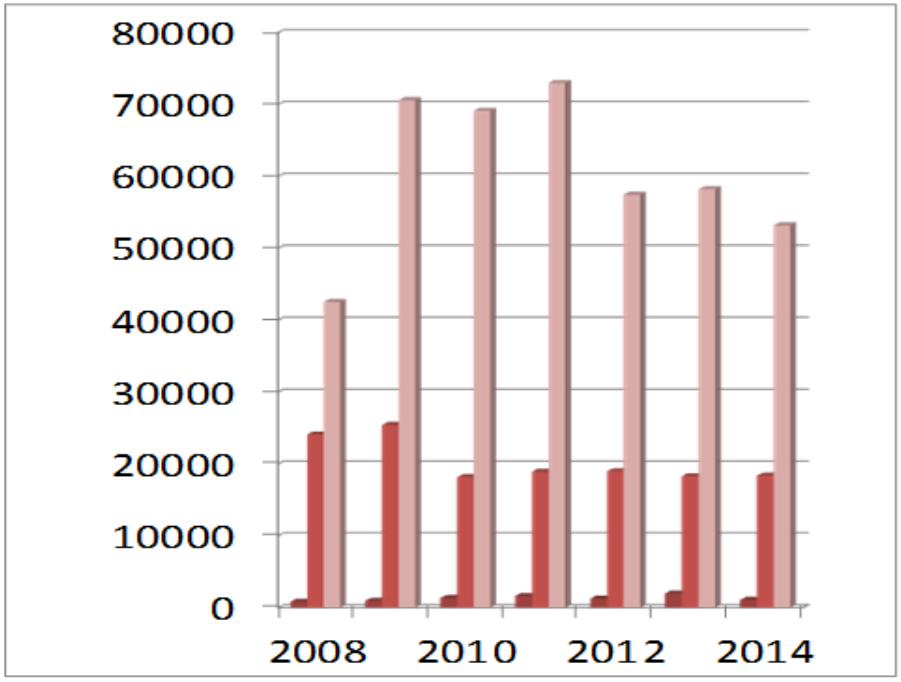
- DDI is CDERs focal point for public inquiries regarding human drug products

- The **mission** of DDI is to optimize CDER's educational and communication efforts to our global community

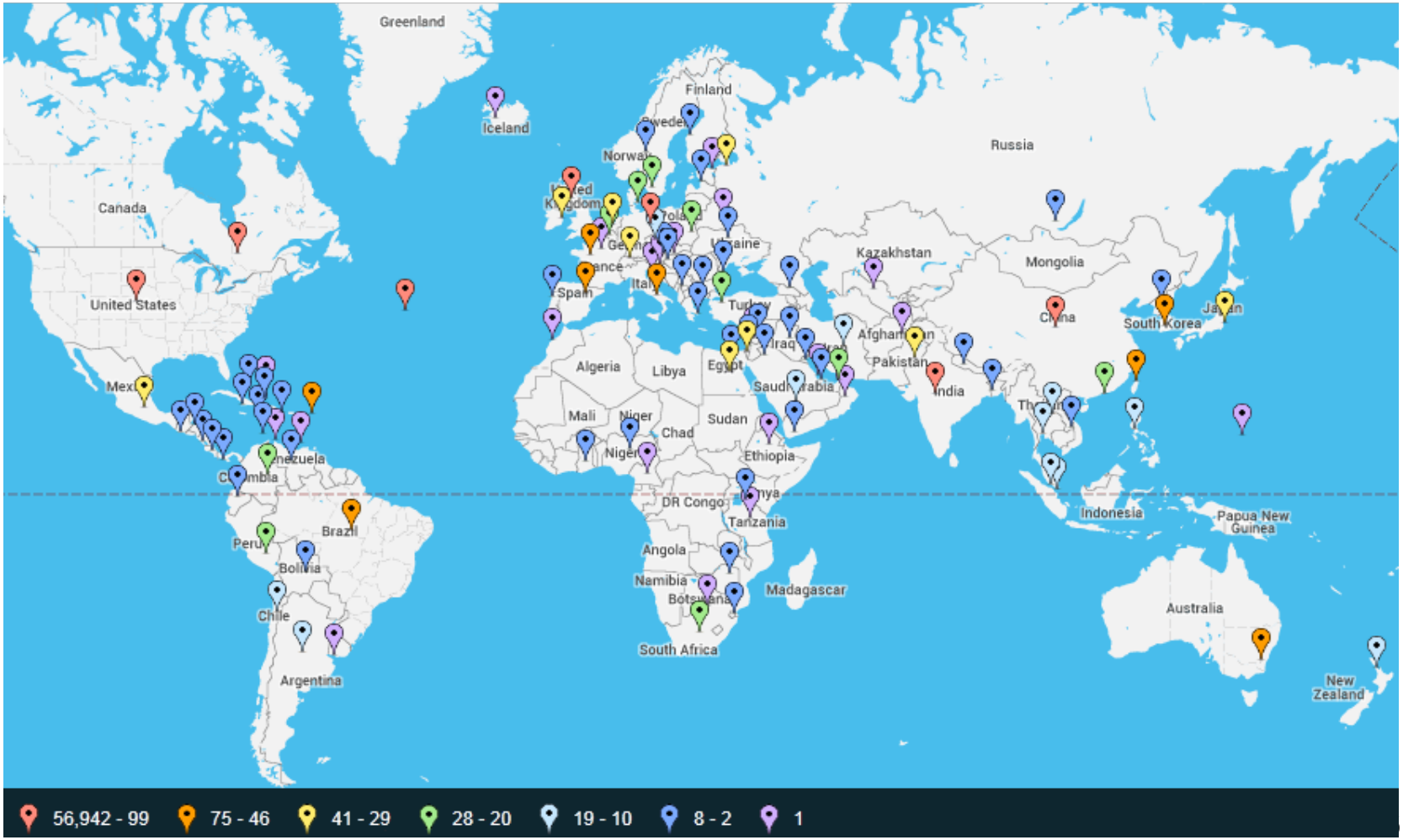
- We support the FDA mission to promote and protect public health

- DDI received 72,646 inquiries in 2014
  - Inquiry channels: phone, email, letters





DDI International Inquiries



Correspondence

- E-mails ~1,531 per month
- Phone Calls ~ 4,432 per month
- Letters ~ 91 per month

Drug Information: OUTREACH

- DDI website
- Drug Information Listserv
- Audio: FDA Drug Safety Podcasts for Healthcare Professionals
- Video: FDA Drug Info Rounds
- Twitter: @FDA_ Drug_ Info
- Publications & Presentations
- Posters & Exhibits
- Imprint Identification

AND……..

- Webinars for pharmacy, medical & nursing students
- CDERLearn Continuing Education courses
- Hosting international visitors
- Small Business Assistance
- FDA Pharmacy Student Experiential Program
- Regulatory Pharmaceutical Fellowship
- Global Alliance of Drug Information Specialists (GADIS)

About the Center for Drug Evaluation and Research

- CDER Offices and Divisions
- Drug Safety Oversight Board
- Jobs at the Center for Drug Evaluation and Research (CDER)
- Meeting Presentations (Drugs)
- CDER Exclusivity Board
- FAQs about CDER
- Reports & Budgets (CDER)
- Manual of Policies & Procedures (CDER)
- Contact CDER

Resources for You

- FDA Pharmacy Student Experiential Program
- Regulatory Pharmaceutical Fellowship
- Regulatory Pharmaceutical Fellowship (Drug Information)
- FDA Drug Info Rounds Video

Division of Drug Information (DDI)

Division Director: Mary Kremzner, PharmD, MPH
Deputy Director: Catherine Chew, PharmD
CDER Small Business and Industry Assistance (SBIA) Program Director: Brenda Stodart, PharmD

The Division of Drug Information (DDI) is CDER's focal point for public inquiries regarding human drug products. Our mission is to optimize CDER's educational and communication outreach efforts to the global community. We accomplish this by engaging in effective internal and external interactions to provide timely, accurate, and useful information through traditional and social media channels.

DDI is staffed with a team of pharmacists and other health professionals who provide expert advice and guidance regarding all aspects of the center's activities. We work with U.S. and international consumers, health care professionals, insurance companies, pharmaceutical companies, academia, law enforcement, and other government agencies.

What is DDI's Role?

- Respond to public inquiries about human drug products received by phone, email, social media and mail. On average, we respond to more than 4,432 telephone calls, 1,531 emails and 91 letters every month.
- Use social media to communicate the latest drug information.
  - Facebook - Engaging our stakeholders in two-way conversations. Follow FDA.
  - Twitter – Follow us @FDA_Drug_Info and partipate in our Twitter Chats.
  - Video podcasts – FDA Drug Info Rounds is a series of training videos for practicing clinical and community pharmacists.
  - Audio podcasts – Drug Safety Podcasts are broadcast in conjunction with the release of new drug safety communications about emerging safety information.
  - ListServ – Subscribe to receive the latest drug information by email.

Pharmacy Student Experiential Program

FDA Pharmacy Student Experiential Program

Spotlight

- Division of Drug Information (DDI) Webinars

The Food and Drug Administration is one of the nation's oldest and most respected consumer protection agencies. FDA's mission is to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after marketing.

Goals and Objectives

The FDA Pharmacy Student Experiential Program provides an opportunity to learn about the FDA's multidisciplinary processes for addressing public

FDA Databases/Resources

- Drugs @FDA
- REMS@FDA
- Orange Book
- Drug Shortages
- Drug Recalls
- Drug Safety Communications
- MedWatch

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

Frances Oldham Kelsey, Ph.D., M.D. (1914-2015)

A Pioneer in Public Health and Protection of Patients

1 2 3

Recalls & Alerts | **Approvals & Clearances** | **Report a Problem**

- MedWatch: Adverse Event Reporting
- Report a Non-Emergency
- For Industry: Reportable Food Registry
- Report an Emergency
- Report Suspected Criminal Activity
- For Industry: Drugs and Therapeutic Biologics

News & Events

- August 18, 2015 - FDA approves first treatment for sexual desire disorder
- August 17, 2015 - Federal judge approves consent decree with Iowa drug and dietary supplement maker, Iowa Select Herbs
- August 04, 2015 - Federal judge enters permanent injunction against Wisconsin dietary supplement manufacturers

Newsroom | Meetings | Testimonies | Speeches

For Consumers
Updates and information for staying safe and healthy

For Patients
Learn about other treatments, drug/device approvals, public meetings and more

For Health Professionals
Medical product safety information, adverse event/problem reporting and more

For Scientists & Researchers
NCTR, pediatrics, clinical trials, Critical Path Initiative and more

For Industry
Guidance, registration and listing, pay user fees, import programs and more

FDA Voice Blog

August 18, 2015
Kicking off the PDUFA VI Reauthorization Process

August 11, 2015
Frances Oldham Kelsey, Ph.D., M.D.: A Pioneer in Public Health and Protection of Patients

More FDA Voice Blog Posts

Drugs

6th Annual Coalition Against Major Diseases/FDA workshop
White Oak Campus, October 15, 2015; register now

Navigate the Drugs Section

Emergency Preparedness
Bioterrorism, drug preparedness and natural disaster response

Drug Approvals and Databases
Drug-Related Databases from FDA; Information on Drug Approvals

Drug Safety and Availability
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News & Events
What's New on This Site, Drug Approval Listing, Meetings and Conferences

Science & Research (Drugs)
Research by FDA Staff to Evaluate and Enhance the Safety of Drug Products

Resources for You
For Consumers, Health Professionals, Industry

Spotlight

- Find Information about a Drug
- Search Drugs@FDA
- Orange Book Search
- National Drug Code Directory
- Drug Shortages

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- Recalls, Market Withdrawals, & Safety Alerts

Approvals & Clearances

- This Week's Drug Approvals
- Drug and Biologic Approval and IND Activity Reports
- Search Drug Approvals by Month Using Drugs@FDA

Stay Informed

Resources for You

- Consumers
- Healthcare Professionals
- Industry
- About the Center for Drug Evaluation and Research
- Buying Medicines Over the Internet
- Counterfeit Medicine
- CDERLearn
- Report a Problem

News and Announcements

- FDA Drug Safety Communication: FDA requests label changes and single-use packaging for some over-the-counter topical antiseptic products to decrease risk of infection
- FDA approves Imbruvica for rare blood cancer
- FDA approves first generic versions of Aciphex delayed-release tablets to treat GERD

More News and Announcements

Drug Safety

- Buying & Using Medicine Safely
- Drug Safety Communications
- Index to Drug-Specific Information
- Medication Guides
- Medication Health Fraud
- Postmarket Drug Safety Information for Patients and Providers

Program Areas

- Advisory Committees
- Generic Drugs
- Guidances (Drugs)
- General Information on Manufacturing and Product Quality

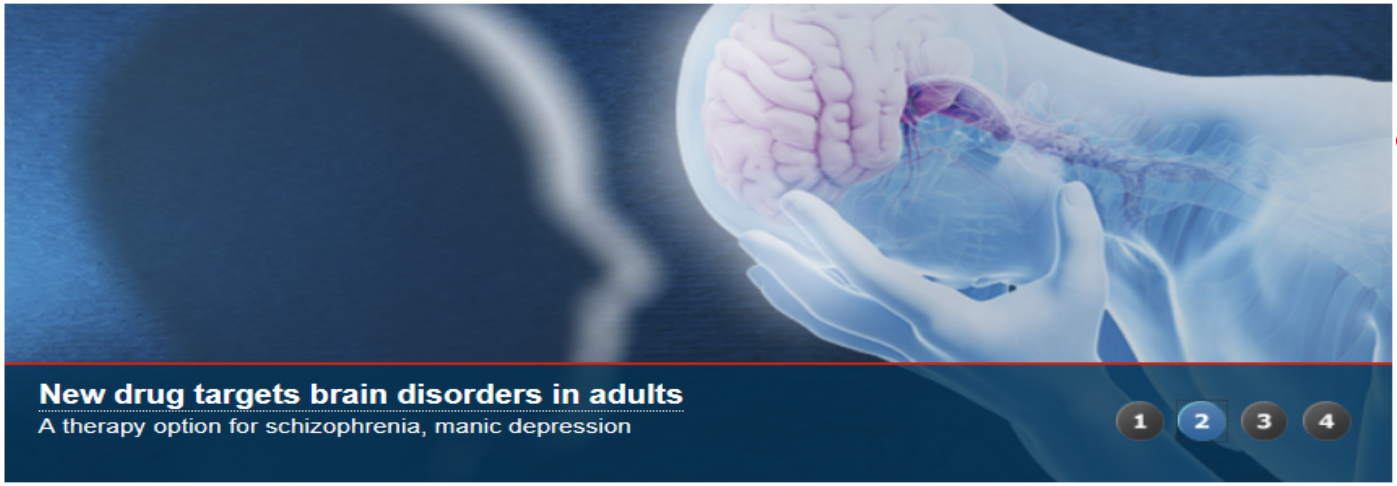
- What's New Related to Drugs
- Email Alerts, News Feeds, Podcasts, Webinars and Videos on Drug Topics
- Meeting Presentations

Contact FDA

Toll Free
(855) 543-3784, or
(301) 796-3400
druginfo@fda.hhs.gov

Human Drug Information
Division of Drug Information
(CDER)
Office of Communications
Feedback Form
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

Drugs



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Drugs@FDA

FDA Approved Drug Products

FAQ | Instructions | Glossary | Contact Us

Drugs@FDA Demo | What's New in Drugs@FDA

Search by Drug Name, Active Ingredient, or Application Number

Enter at least three characters: LAMOTRIGINE Submit Clear Advanced Search

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

Drug Approval Reports by Month

Disclaimer

FDA/Center for Drug Evaluation and Research
Office of Communications
Division of Online Communications
Update Frequency: Daily

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

Drugs@FDA

FDA Approved Drug Products

FAQ | Instructions | Glossary | Contact Us

Start Over

Search Results for 'lamotrigine'

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

Click on a drug name for more information:
Click on a column header to re-sort the table:

Drug Name	Active Ingredients
LAMICTAL	LAMOTRIGINE
LAMICTAL CD	LAMOTRIGINE
LAMICTAL ODT	LAMOTRIGINE
LAMICTAL XR	LAMOTRIGINE
LAMOTRIGINE	LAMOTRIGINE

Back to Top | Back to Previous Page | Back to Drugs@FDA Home

Disclaimer

FDA/Center for Drug Evaluation and Research
Office of Communications
Division of Online Communications
Update Frequency: Daily

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Drugs@FDA

FDA Approved Drug Products

FAQ | Instructions | Glossary | Contact Us

Start Over | Back to Search Results

Overview

Drug Name	LAMICTAL XR
Active Ingredient(s)	• LAMOTRIGINE
Form(s) and Strength(s) Available	• TABLET, EXTENDED RELEASE; ORAL: 100MG ; 200MG ; 250MG ; 25MG ; 300MG ; 50MG

Details about drugs are organized by FDA Application Number (NDA or ANDA or BLA).

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

Click on a column header to re-sort the table:

Drug Name and FDA Application Number	Label Info New!	Dosage Form/Route	Strength	Marketing Status	Company
LAMICTAL XR (NDA # 022115)	Label Available	TABLET, EXTENDED RELEASE; ORAL	Multiple Strengths	Prescription	SMITHKLINE BEECHAM
LAMICTAL XR (NDA # 022509)	Label Available	TABLET, EXTENDED RELEASE; ORAL	Multiple Strengths	Prescription	SMITHKLINE BEECHAM

Back to Top | Back to Previous Page | Back to Drugs@FDA Home

Drugs@FDA
FDA Approved Drug Products

Label and Approval History

Drug Name(s)	LAMICTAL XR
FDA Application No.	(NDA) 022115
Active Ingredient(s)	LAMOTRIGINE
Company	GLAXOSMITHKLINE LLC

Go to Approval History

Label Information

What information does a label include?
Note: Not all labels are available in electronic format from FDA.

View the label approved on 03/24/2015 (PDF) for NDA no. 022115

- To see older, previously-approved labels, go to the "Approval History" section of this page. Older labels are for historical information only and should not be used for clinical purposes.

Approval History

NDA 022115

Note: Not all reviews are available in electronic format from FDA.
Older labels are for historical information only, and should not be used for clinical purposes.
Approval dates can only be verified from 1984 to the present.

Click on a column header to re-sort the table:

Download data

Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
03/24/2015	018	Labeling Revision	Label (PDF) Letter (PDF)	
03/24/2015	011	Labeling Revision	Label (PDF) Letter (PDF)	
12/30/2014	014	Labeling Revision	Label (PDF) Letter (PDF)	
12/30/2014	004	Labeling Revision	Label (PDF) Letter (PDF)	
06/10/2014	019	Labeling Revision	Label (PDF) Letter (PDF)	
12/20/2013	003	Labeling Revision	Label (PDF) Letter (PDF)	
08/01/2012	017	Labeling Revision	Label (PDF) Letter (PDF)	
11/29/2011	016	Labeling Revision	Label (PDF) Letter (PDF)	
08/04/2011	013	Labeling Revision	Label (PDF) Letter (PDF)	
06/21/2011	015	Manufacturing Change or Addition	Label (PDF) Letter (PDF)	This supplement type does not usually require new labeling.
04/25/2011	006	Patient Population Altered	Label (PDF) Letter (PDF)	
10/24/2010	010	Labeling Revision	Label (PDF)	
10/24/2010	009	Labeling Revision	Label (PDF)	
04/14/2010	005	Labeling Revision	Label (PDF) Letter (PDF)	
04/14/2010	001	Manufacturing Change or Addition	Label (PDF) Letter (PDF)	This supplement type does not usually require new labeling.
05/29/2009	000	Approval	Label (PDF) Letter (PDF) Review Summary Review (PDF)	

Drug Approval Package

Lamictal XR (Lamotrigine) Extended-Release Tablets
Company: SmithKline Beecham Corporation
Application No.: 022115
Approval Date: 5/29/2009

Persons with disabilities having problems accessing the PDF files below may call (301) 796-3634 for assistance.

- Approval Letter(s) (PDF)
- Summary Review (PDF)
- Risk Evaluation and Mitigation Strategy (REMS) (PDF)
- Officer/Employee List (PDF)
- Other Action Letters (PDF)
- Printed Labeling (PDF)
- Medical Review(s) (PDF)
- Chemistry Review(s) (PDF)
- Enviornmental Assessment(s) (PDF)
- Statistical Review(s) (PDF)
- Clinical Pharmacology Biopharmaceutics Review(s) (PDF)
- Risk Assessment and Risk Mitigation Review(s) (PDF)
- Proprietary Name Review(s) (PDF)
- Other Review(s) (PDF)
- Administrative Document(s) & Correspondence (PDF)

Date created: February16, 2010

Back to Top Drugs@FDA

Vision impaired people having problems accessing certain pages of a PDF file may call (301) 796-3634 for assistance.

Note: Documents in PDF format require the Adobe Acrobat Reader®.

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Drugs

Navigate the Drugs Section

Emergency Preparedness
Bioterrorism, drug preparedness and natural disaster response

Drug Approvals and Databases
Drug-Related Databases from FDA; Information on Drug Approvals

Drug Safety and Availability
Medication Guides, Drug Shortages, Drug Safety Communications and Other Safety Announcements

Development & Approval Process (Drugs)
Conducting Clinical Trials, Types of Drug Applications, Forms and Submissions Requirements, Labeling Initiatives,

Guidance, Compliance & Regulatory Information
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News & Events
What's New on This Site, Drug Approval Listing, Meetings and Conferences

Science & Research (Drugs)
Research by FDA Staff to Evaluate and Enhance the Safety of Drug Products

Resources for You
For Consumers, Health Professionals, Industry

Spotlight

- Find Information about a Drug
- Search Drugs@FDA
- Orange Book Search
- National Drug Code Directory
- Drug Shortages

Recalls & Alerts

- Drug Recalls
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
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Approvals & Clearances

- This Week's Drug Approvals
- Drug and Biologic Approval and IND Activity Reports
- Search Drug Approvals by Month Using Drugs@FDA

Stay Informed

Approved Risk Evaluation and Mitigation Strategies (REMS)

REMS@FDA

Contact Us | REMS Basics | Get Email Alerts | Data Files

The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

The table below provides links to currently approved individual and shared system REMS.

Information on historical and released REMS: downloadable data files.

Filter by Keyword (e.g. REMS name, active ingredient, element):

Clear Filter

Download This List

Name	Last Updated	Medication Guide*	Communication Plan	ETASU	Implementation System
Actemra (*tocilizumab*), injection, solution; injection, solution, concentrate BLA #125276 BLA #125472	10/21/2013		✓		
Adasuve (*loxapine*), aerosol, powder NDA #22549	12/09/2013		✓	✓	✓
Addyi (*flibanserin*), tablet NDA #022526	08/18/2015			✓	✓
Adempas (*riociguat*), tablet, film coated NDA #204819	06/11/2014	✓		✓	✓

Approved Risk Evaluation and Mitigation Strategies (REMS)

REMS@FDA

Contact Us | REMS Basics | Get Email Alerts | Data Files

Actemra *(tocilizumab)*

BLA #125276 BLA #125472

REMS last update: 10/21/2013

View the Actemra Prescribing Information at DailyMed for BLA 125276 (injection, solution, concentrate)

View Actemra's Regulatory Information at Drugs@FDA for BLA 125276 (injection, solution, concentrate)
View Actemra's Regulatory Information at Drugs@FDA for BLA 125472 (injection, solution)

What do participants need to know?

Healthcare providers should read the relevant Medication Guide or communication materials included in the product-specific approved RE
about the risk(s).

The REMS includes a REMS Document. In addition, the REMS includes the following materials intended for patients and healthcare providers:

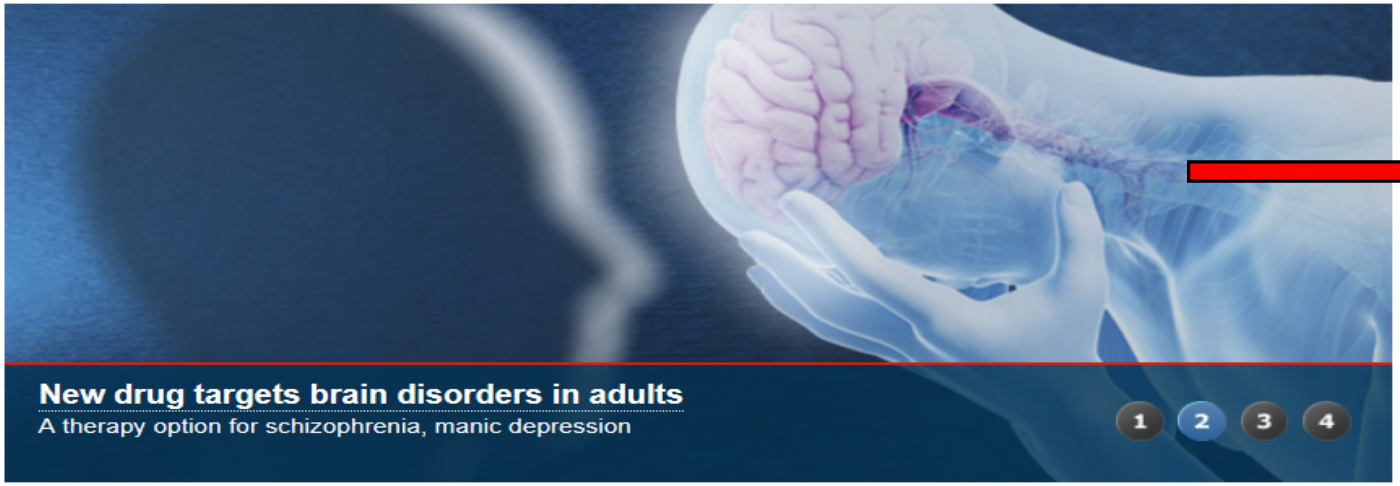
Download This List

Material Name	Category	Target Audience
Dear Healthcare Provider Letter (PDF)	Communication	Prescriber
Prescriber Education Slide Deck (PDF)	Training	Prescriber
REMS document (PDF)		
REMS full (PDF)		
REMS journal information piece for emergency medicine physicians (PDF)	Communication	Prescriber
REMS journal information piece for gastroenterologists (PDF)	Communication	Prescriber
REMS journal information piece for infectious disease specialists (PDF)	Communication	Prescriber
REMS journal information piece for internists and internal medicine (PDF)	Communication	Prescriber
REMS journal information piece for neurologists (PDF)	Communication	Prescriber
REMS journal information piece for oncologists (PDF)	Communication	Prescriber

« ‹ 1 2 › »

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Drugs



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Stay Informed

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Current through July 2015

To provide timely consumer information on generic drugs, the Electronic Orange Book is updated daily as new generic approvals occur.

Publications
FAQ

- Search by Active Ingredient
- Search by Proprietary Name
- Search by Patent
- Search by Applicant Holder
- Search by Application Number

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Drug questions email: druginfo@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Science
Office of Generic Drugs

Page Last Updated: 05/17/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search by Proprietary Name:
LAMICTAL (Type in part or all of name)

Select the list you would like to search:

- (•) Rx (Prescription Drug Products)
- ( ) OTC (Over-the-Counter Drug Products)
- ( ) Disc (Discontinued Drug Products)

Submit Clear

Return to the Electronic Orange Book Home Page!

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Proprietary Name Search Results from "OB_Rx" table for query on "LAMICTAL."

Displaying records 1 to 17 of 17

Download data

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
N020764	AB	Yes	LAMOTRIGINE	TABLET, CHEWABLE; ORAL	25MG	LAMICTAL CD	GLAXOSMITHKLINE LLC
N020764	AB	No	LAMOTRIGINE	TABLET, CHEWABLE; ORAL	2MG	LAMICTAL CD	GLAXOSMITHKLINE LLC
N020764	AB	No	LAMOTRIGINE	TABLET, CHEWABLE; ORAL	5MG	LAMICTAL CD	GLAXOSMITHKLINE LLC
N022115	AB	No	LAMOTRIGINE	TABLET, EXTENDED RELEASE; ORAL	100MG	LAMICTAL XR	GLAXOSMITHKLINE LLC
N022115	AB	No	LAMOTRIGINE	TABLET, EXTENDED RELEASE; ORAL	200MG	LAMICTAL XR	GLAXOSMITHKLINE LLC
N022115	AB	No	LAMOTRIGINE	TABLET, EXTENDED RELEASE; ORAL	250MG	LAMICTAL XR	GLAXOSMITHKLINE LLC
N022115	AB	No	LAMOTRIGINE	TABLET, EXTENDED RELEASE; ORAL	25MG	LAMICTAL XR	GLAXOSMITHKLINE LLC
N022115	AB	No	LAMOTRIGINE	TABLET, EXTENDED RELEASE; ORAL	300MG	LAMICTAL XR	GLAXOSMITHKLINE LLC
N022115	AB	Yes	LAMOTRIGINE	TABLET, EXTENDED RELEASE; ORAL	50MG	LAMICTAL XR	GLAXOSMITHKLINE LLC

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "020764."

Active Ingredient:	LAMOTRIGINE
Dosage Form;Route:	TABLET, CHEWABLE; ORAL
Proprietary Name:	LAMICTAL CD
Applicant:	GLAXOSMITHKLINE
Strength:	5MG
Application Number:	N020764
Product Number:	001
Approval Date:	Aug 24, 1998
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	LAMOTRIGINE
Dosage Form;Route:	TABLET, CHEWABLE; ORAL
Proprietary Name:	LAMICTAL CD
Applicant:	GLAXOSMITHKLINE
Strength:	25MG
Application Number:	N020764

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Patent and Exclusivity Search Results from query on Appl No 020764 Product 001 in the OB_Rx list.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N020764	001	M - 159	May 18, 2018

View a list of all patent use codes
View a list of all exclusivity codes

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through July 2015
Patent and Generic Drug Product Data Last Updated September 18, 2015

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Conducting Clinical Trials, Types of Drug Applications, Forms and Submissions Requirements, Labeling Initiatives,

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Guidance for Industry, Warning Letters, Postmarket Surveillance Programs, Rules and Regulations

News & Events
What's New on This Site, Drug Approval Listing, Meetings and Conferences

Science & Research (Drugs)
Research by FDA Staff to Evaluate and Enhance the Safety of Drug Products

Resources for You
For Consumers, Health Professionals, Industry

Spotlight

- Find Information about a Drug
- Search Drugs@FDA
- Orange Book Search
- National Drug Code Directory
- Drug Shortages

Recalls & Alerts

- Drug Recalls
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Recalls, Market Withdrawals, & Safety Alerts

Approvals & Clearances

- This Week's Drug Approvals
- Drug and Biologic Approval and IND Activity Reports
- Search Drug Approvals by Month Using Drugs@FDA

Stay Informed

Drug Shortages

Drug Shortages: Additional News and Information

Frequently Asked Questions About the Drug Shortages Program

Resources for You

- Drug Shortages Infographic
- Drug Shortage Manual of Policies and Procedures (MaPP) (PDF - 1.1MB)
- American Society of Health-System Pharmacists: Drug Shortages
- American Society of Health-System Pharmacists: Guideline on Managing Drug Shortages
- FDA Drug Shortages RSS Feed (XML - 14KB)
- Sign up for Drug Shortages E-mail Notifications

Drug Shortages

Search the Drug Shortages Database

Upgraded Drug Shortages app for Android devices adds alert feature

The Food and Drug Administration released Drug Shortages 2 mobile application for Android devices. Android device users are able to receive notifications when there is new or updated information about a shortage of a drug product or about a drug within selected therapeutic categories.

Designed for Android devices, Drug Shortages 2 sends alerts when the Agency adds or updates shortage information about a drug product or about a drug within selected therapeutic categories. We are currently working on notifications for the iOS version of the Drug Shortage mobile app, which will be available soon.

Download the Drug Shortages 2 app for Android devices

Download the Drug Shortages Mobile Application

Download on the App Store | ANDROID APP ON Google play

Information for You

- Consumers: FDA Works to Lessen Drug Shortage Impact
- FDA actions reduce drug shortages but critical issues remain
- Drug Shortages: Additional News and Information
- Health Professionals: FDA Working to Lessen Patient Impact from Drug Shortages
- Industry: FDA and Manufacturers Work to Prevent Drug Shortages

Reports to Congress

- Second Annual Report on Drug Shortages for Calendar Year 2014 (PDF - 137KB)
- First Annual Report on Drug Shortages for Calendar Year 2013 (PDF - 200KB)

FDA Drug Shortages

Current and Resolved Drug Shortages and Discontinuations Reported to FDA

Report a Drug Shortage | Contact Us | FAQ | Background Info | Get Email Alerts | RSS Feed

Search by Generic Name or Active Ingredient: Enter at least three characters Submit

Current/Resolved Shortages | Discontinuations | Therapeutic Categories | New and Updated

Current and Resolved Shortages Listed by Generic Name or Active Ingredient

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 drug receives Resolved status when the Drug Shortages Staff (DSS) determines that the market is covered, based on information from all manufacturers. The market is considered covered when supply is available from at least one manufacturer to cover total market demand. However, some manufacturers may not have all presentations available. DSS monitors the supply of products with Resolved status. For the most current supply information, contact the manufacturers.

Generic Name or Active Ingredient	Status
Acetohydroxamic Acid (Lithostat) Tablets	*Currently in Shortage*
Ammonium Chloride Injection	*Currently in Shortage*
Aprepitant (Emend) Capsules	*Currently in Shortage*
Atropine Sulfate Injection	*Currently in Shortage*
Azathioprine Tablet	*Currently in Shortage*
Barium Sulfate for Suspension	*Resolved*
Bupivacaine Hydrochloride (Marcaine, Sensorcaine) Injection	*Resolved*
Caffeine Anhydrous (125mg/mL); Sodium Benzoate (125mg/mL) Injection	*Currently in Shortage*
Calcium Chloride Injection, USP	*Currently in Shortage*

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Search by Generic Name or Active Ingredient: Enter at least three characters Submit

Start Over | Back to Previous Screen

Acetohydroxamic Acid (Lithostat) Tablets

Status: Currently in Shortage

» **Date first posted**: 07/15/2014
» **Therapeutic Categories**: Renal

Mission Pharmacal (*Reverified 01/21/2015*)

Company Contact Information:
210-696-8400

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
250 mg (NDC 01780-500-01)	Unavailable - no product available for release.	API manufacturer discontinued the material.	Shortage of an active ingredient.

Drug Recalls

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. See Definitions of Market Withdrawals and Class I, II, and III recalls. All recalls (Class I, II, and III) can be found in the FDA Enforcement Report.

In July 2011, FDA began a pilot program to notify people of drug recalls before they are classified. These unclassified recalls will be published in the Enforcement Report every Wednesday, and will be listed under the heading, "Human Drug Product Recalls Pending Classification." They will be reposted with their classification once that determination has been made. Send comments or suggestions to CDERRecallPilot@fda.hhs.gov.

If you have a medicine that has been recalled, talk to your health care professional about the best course of action. Stores generally have a return and refund policy when a company has announced a recall of its products.

NOTE: The recalls on the list are generally Class I., which means there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Recalls for all FDA-regulated products
For recall notices older than 60 days, see the **Recall and Safety Alerts Archive.**

Filter by Keyword(s):

Recalls for all FDA-regulated products
For recall notices older than 60 days, see the **Recall and Safety Alerts Archive.**

Filter by Keyword(s):

Clear Filter

Date	Brand Name	Product Description	Reason/ Problem	Company	Details / Photo
09/11/2015	The One Minute Miracle Inc.	Miracle 30 & Miracle Rock 48 dietary supplements	Unapproved new drug	The One Minute Miracle Inc.	
09/09/2015	Medistat RX, LLC	Sterile Drug Products	Sterility cannot be assured	Medistat RX, LLC	
08/24/2015	Fataway Ultimate Stack, ThermoFX, MaxOut Body, Metabolic Accelerator, Burn Fat Now, Thermogenic Fat Burner, Thin and Slim Naturally, Extreme Stack, Asia Black, Black Widow 25, and Methyldrene Original 25	Dietary Supplements	These products contain the undeclared drug ingredient salicylic acid making these unapproved new drugs	Novacare, LLC	
08/24/2015	REFRESH®, FML® and Blephamide®	REFRESH® Lacri-Lube®, REFRESH P.M.®, FML® (fluorometholone ophthalmic ointment) and Blephamide®	Contains particulate matter	Allergan plc	

Resources for You

- Consumers
- Healthcare Professionals
- Industry
- About the Center for Drug Evaluation and Research
- Buying Medicines Over the Internet
- Counterfeit Medicine
- CDERLearn
- Report a Problem

News and Announcements

- FDA Drug Safety Communication: FDA requests label changes and single-use packaging for some over-the-counter topical antiseptic products to decrease risk of infection
- FDA approves Imbruvica for rare blood cancer
- FDA approves first generic versions of Aciphex delayed-release tablets to treat GERD

More News and Announcements

Drug Safety

- Buying & Using Medicine Safely
- Drug Safety Communications
- Index to Drug-Specific Information
- Medication Guides
- Medication Health Fraud
- Postmarket Drug Safety Information for Patients and Providers

Program Areas

- Advisory Committees
- Generic Drugs
- Guidances (Drugs)
- General Information on Manufacturing and Product Quality
- Regulation of Nonprescription Products

- What's New Related to Drugs
- Email Alerts, News Feeds, Podcasts, Webinars and Videos on Drug Topics
- Meeting Presentations

Contact FDA

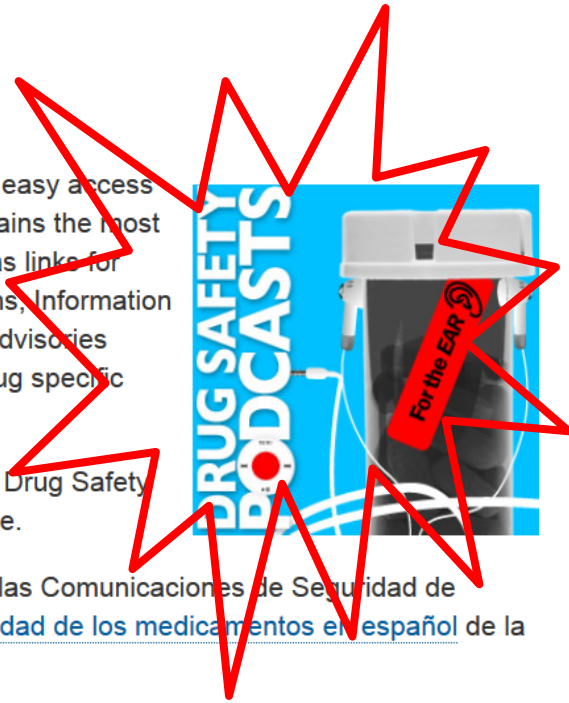
Toll Free
(855) 543-3784, or
(301) 796-3400
druginfo@fda.hhs.gov

Human Drug Information
Division of Drug Information (CDER)
Office of Communications
Feedback Form
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

Drugs

Drug Safety and Availability
Drug Alerts and Statements
Medication Guides
Drug Safety Communications
Drug Shortages
Postmarket Drug Safety Information for Patients and Providers
Information by Drug Class
Medication Errors
Drug Safety Podcasts
Safe Use Initiative
Drug Recalls
Drug Supply Chain Integrity

Drug Safety Communications



This webpage was developed to provide the public with easy access to important drug safety information. The webpage contains the most recent Drug Safety Communications from FDA as well as links for Early Communications, Follow-Up Early Communications, Information for Healthcare Professional sheets, and Public Health Advisories issued prior to January 29th, 2010. You can also find drug specific information using the Index to Drug-Specific Information.

Starting July 18, 2011, you can find Spanish language versions of the Drug Safety Communications on our Drug Safety Communications in Spanish page.

El 18 de julio de 2011, se pueden encontrar versiones en español de las Comunicaciones de Seguridad de Medicamentos en nuestra Comunicaciones de la FDA sobre la seguridad de los medicamentos en español de la página.

Current Drug Safety Communications

- FDA Drug Safety Communication: FDA modifies monitoring for neutropenia associated with schizophrenia medicine clozapine; approves new shared REMS program for all clozapine medicines
  9/15/2015

Drugs

Navigate the Drugs Section

Emergency Preparedness
Bioterrorism, drug preparedness and natural disaster response

Guidance, Compliance & Regulatory Information
Guidance for Industry, Warning Letters, Postmarket Surveillance Programs, Rules and Regulations

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Approvals & Clearances

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Subscribe to MedWatch Safety Alerts

Safety Information

Reporting Serious Problems to FDA

Search the MedWatch Section

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

Report a Problem **Safety Information** **Stay Informed**

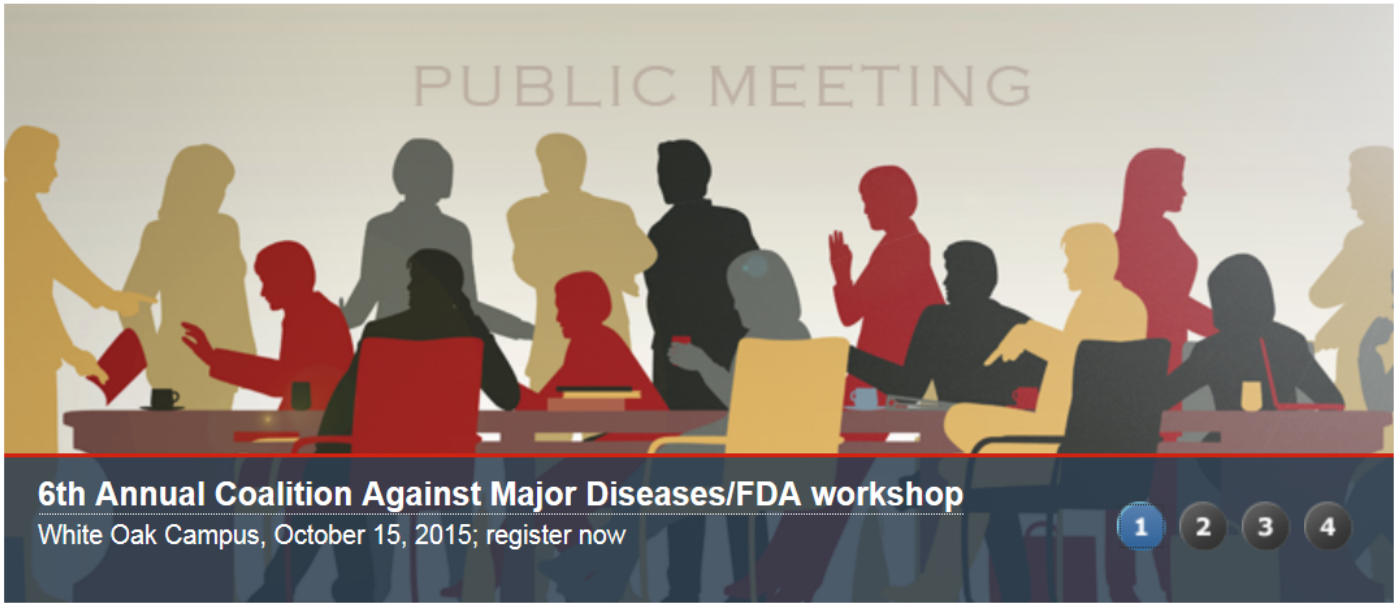
Resources for You

- 2015 Safety Alerts for Human Medical Products
- Contact Information For Voluntary Adverse Event Reporting
- MedWatchLearn - Teaching students, health professionals, and consumers how to report problems to FDA
- Medical Product Safety Educational Resources

What's New

- Freedom Driver System by SynCardia: Class I Recall - Part May Fail Causing Device to Stop Working If the device stops pumping, the patient will lose consciousness almost immediately, which can lead to serious

Drugs



6th Annual Coalition Against Major Diseases/FDA workshop
White Oak Campus, October 15, 2015; register now

1 2 3 4

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Approvals & Clearances

Web Addresses:

- CDER: http://www.fda.gov/drugs
- CDER Mailing List: http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/GetEmailUpdates/default.htm#drug
- Drug Safety Podcasts: http://www.fda.gov/DrugSafetyPodcasts
- Twitter: Follow us at FDA_Drug_Info
- FDA Drug Info Rounds: http://www.fda.gov/DrugInfoRounds

Student Web Addresses:

- FDA Pharmacy Student Experiential Program: http://www.fda.gov/pharmstudentprogram
- Regulatory Pharmaceutical Fellowship: http://www.fda.gov/RegPharmFellowship
- CDERLearn (educational tutorials): http://www.fda.gov/Training/forHealthProfessionals/default.htm
- DDI Webinars for students & HCPs: http://www.fda.gov/DDIWebinars

QUESTIONS???

Division of Drug Information

Call: 855-543-3784

301-796-3400

Email: druginfo@fda.hhs.gov

Website: www.fda.gov/aboutDDI