U.S. FOOD & DRUG ADMINISTRATION

# Overview of FDA Resources

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Center for Drug Evaluation and Research │Food and Drug Administration
Division of Drug Information │ Office of Communications

# Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be construed to represent FDA's view or policies.

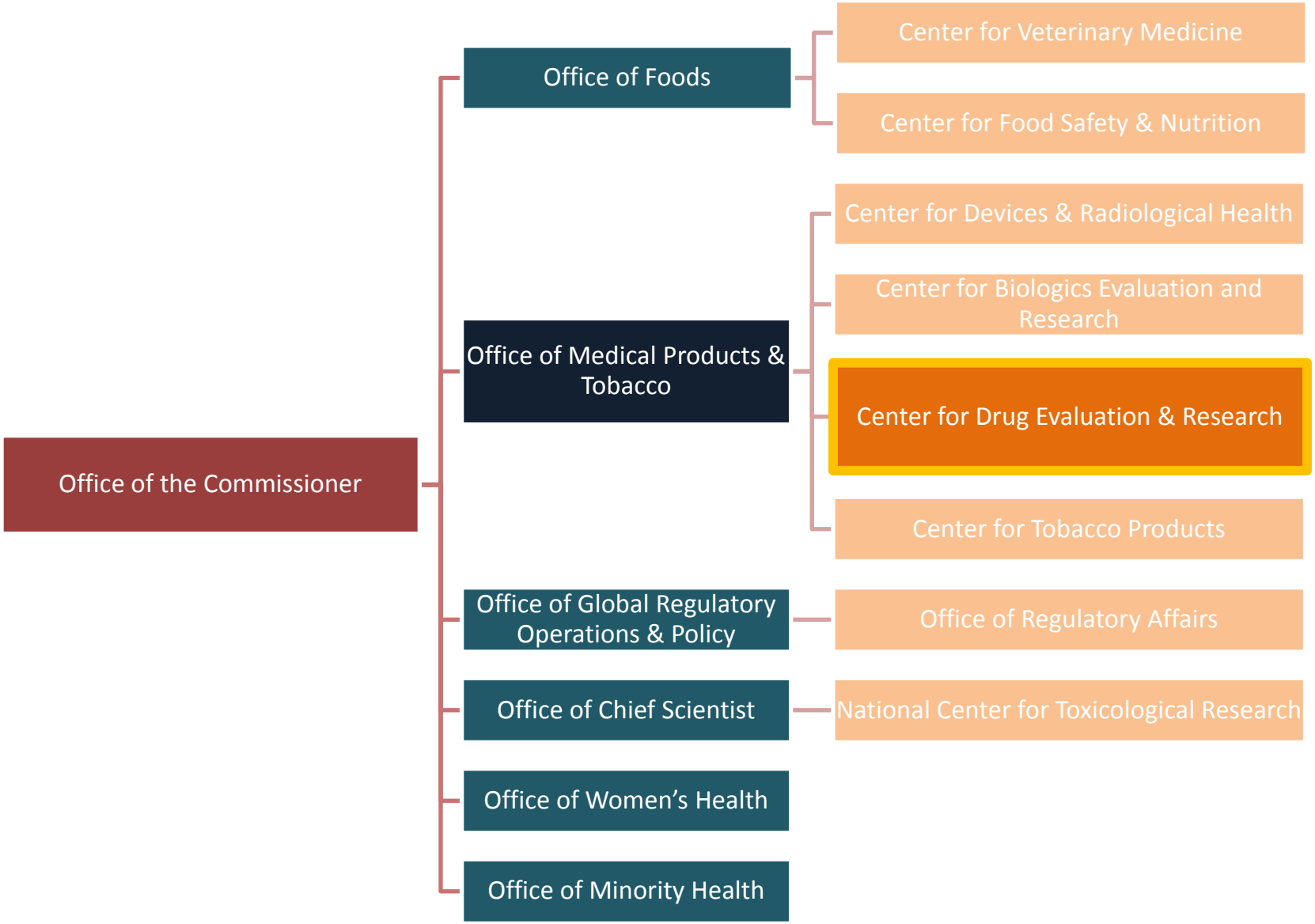
# Objectives

1. Identify FDA resources that contain information on drug safety issues

2. Locate adverse event reporting information on FDA's website

3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives

# U.S. Food and Drug Administration



# FDA: What We Do

- Mission: Promote and protect public health

- FDA's primary responsibility is to protect the American people from unsafe or mislabeled food, drugs, and other medical products and to make sure consumers have access to accurate, science-based information about the products they need and rely on every day

- FDA/CDER (Center for Drug Evaluation and Research) ensures that safe, effective and high quality drugs are available for U.S. consumers

# Division of Drug Information (DDI)

- DDI is CDER’s 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’s mission to promote and protect public health

# Objectives

1. **Identify FDA resources that contain information on drug safety issues**

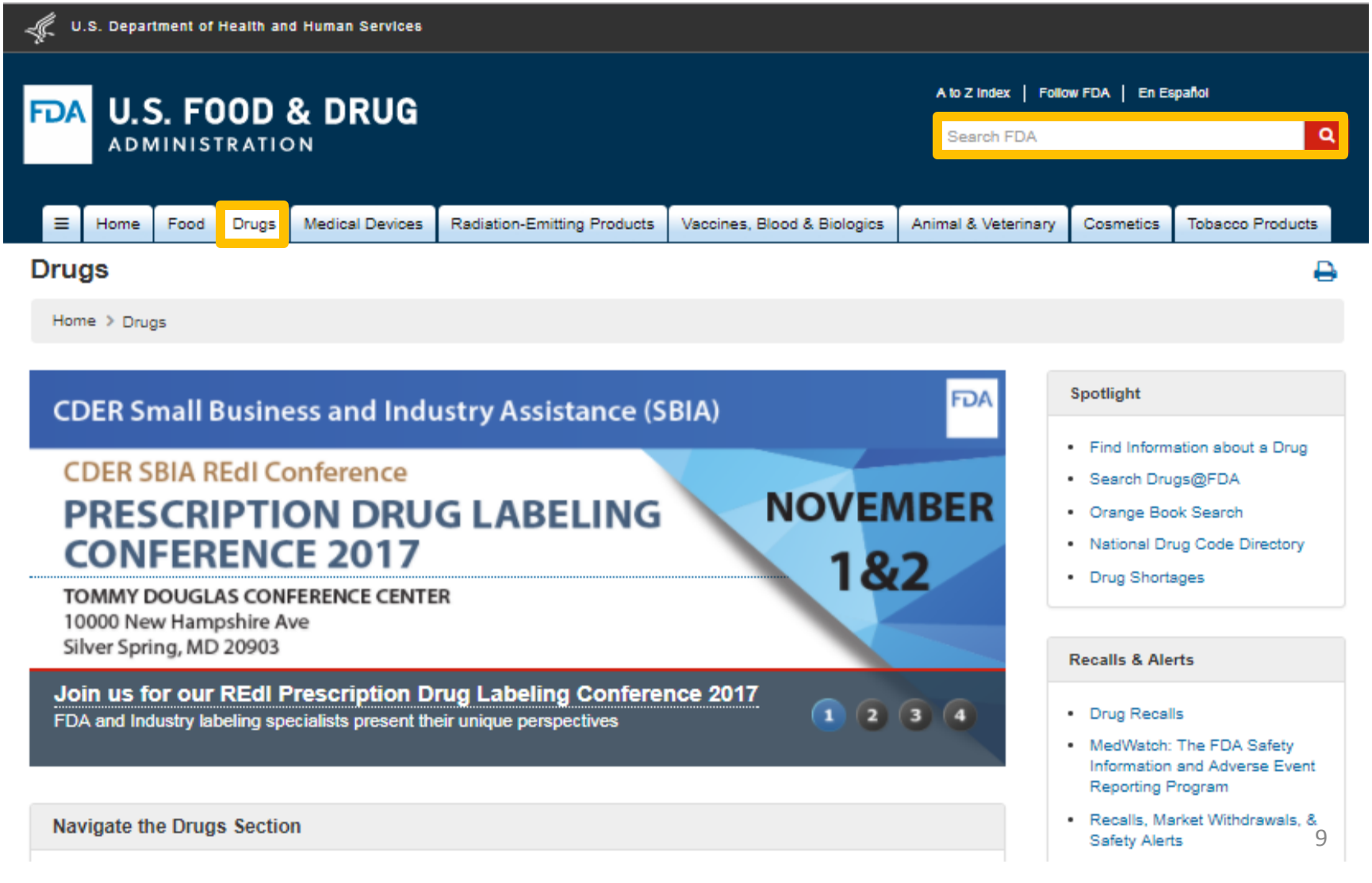
2. Locate adverse event reporting information on FDA's website

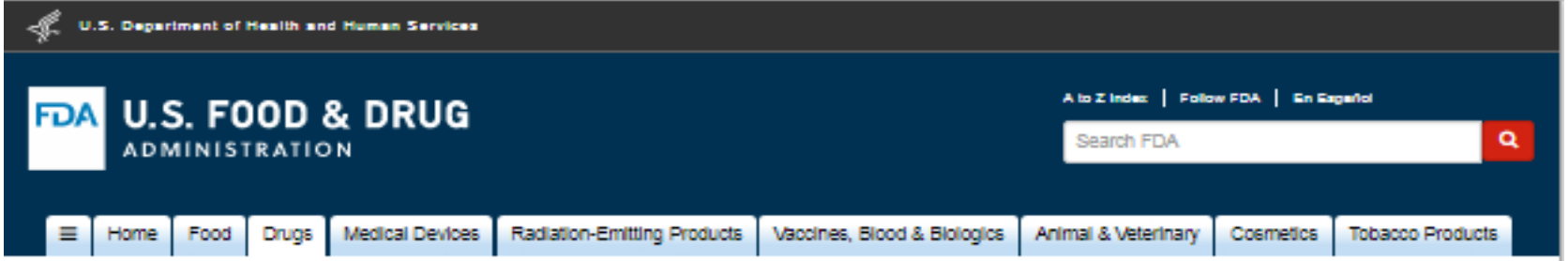
3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives

# FDA Databases/Resources

- Drugs@FDA
- National Drug Code (NDC) Directory
- Orange Book
- Purple Book
- Drug Safety Labeling Changes (SLC) Database
- Drug Shortages
- Approved Risk Evaluation and Mitigation Strategies (REMS)
- Drug Safety Communications
- MedWatch

# CDER Home Page: Where to Find Resources






# Drugs

Home > Drugs


## Navigate the Drugs Section

Emergency Preparedness
Bioterrorism, drug preparedness and natural disaster response

Drug Approvals and Databases
CDER highlights key Web sites. Web page provides quick links to everything from acronyms to wholesale distributor and third-party logistics providers reporting.

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

Development & Approval Process (Drugs)
Get to know FDA's drug development and approval process -- ensuring that drugs work and that the benefits outweigh their known risks.

Guidance, Compliance & Regulatory Information
Looking for FDA Guidance, Compliance, & Regulatory Information? Web page provides quick links to a variety of topics.

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 Approval Reports by Month Using Drugs@FDA

## Stay Informed

- What's New Related to Drugs
- Tools To Keep You Informed

## Navigate the Drugs Section

Emergency Preparedness
Bioterrorism, drug preparedness and natural disaster response

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CDER highlights key Web sites. Web page provides quick links to everything from acronyms to wholesale distributor and third-party logistics providers reporting.

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

Development & Approval Process (Drugs)
Get to know FDA's drug development and approval process -- ensuring that drugs work and that the benefits outweigh their known risks.

Guidance, Compliance & Regulatory Information
Looking for FDA Guidance, Compliance, & Regulatory Information? Web page provides quick links to a variety of topics.

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

### Resources for You

- Find Information about a Drug
- Consumers
- Healthcare Professionals
- Industry
- About the Center for Drug Evaluation and Research
- Quick Tips for Buying Medicines Over the Internet
- CDERLearn
- Report a Problem to the FDA

### News and Announcements

- Expanded Access: FDA Describes Efforts to Ease Application Process
- Reducing the Hurdles for Complex Generic Drug Development
- FDA Takes Important Steps to Stem the Tide of Opioid Misuse and Abuse

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

- Recalls, Market Withdrawals, & Safety Alerts

### Approvals & Clearances

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

### Stay Informed

- What's New Related to Drugs
- Tools To Keep You Informed
- Meetings, Conferences, and Workshops
- FDA's Drug Related Performance Measures

### 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@FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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

Home > Drug Databases > Drugs@FDA

# Drugs@FDA: FDA Approved Drug Products

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

## Search by Drug Name, Active Ingredient, or Application Number

Enter at least 3 characters LAMOTRIGINE

Search | Clear

## Search 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

# Drugs@FDA: FDA Approved Drug Products

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Home | Previous Page

## Search Results for "LAMOTRIGINE"

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

| |
|---|
| LAMICTAL |
| LAMICTAL CD |
| LAMICTAL ODT |
| LAMICTAL XR |
| LAMOTRIGINE |

# Drugs@FDA: FDA Approved Drug Products

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Home | Previous Page

New Drug Application (NDA): 020241
Company: GLAXOSMITHKLINE LLC

EMAIL

- Medication Guide

## Products on NDA 020241

CSV | Excel | Print

| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | TE Code | RLD | RS |
|---|---|---|---|---|---|---|---|
| LAMICTAL | LAMOTRIGINE | 100MG | TABLET;ORAL | Prescription | AB | Yes | No |
| LAMICTAL | LAMOTRIGINE | 150MG | TABLET;ORAL | Prescription | AB | Yes | No |
| LAMICTAL | LAMOTRIGINE | 200MG | TABLET;ORAL | Prescription | AB | Yes | No |
| LAMICTAL | LAMOTRIGINE | 250MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** | TABLET;ORAL | Discontinued | None | Yes | No |
| LAMICTAL | LAMOTRIGINE | 25MG | TABLET;ORAL | Prescription | AB | Yes | Yes |
| LAMICTAL | LAMOTRIGINE | 50MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** | TABLET;ORAL | Discontinued | None | Yes | No |

Showing 1 to 6 of 6 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 020241

Labels for NDA 020241

Therapeutic Equivalents for NDA 020241

# Drugs@FDA: FDA Approved Drug Products

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Home | Previous Page

New Drug Application (NDA): 020241
Company: GLAXOSMITHKLINE LLC

EMAIL

- Medication Guide

Products on NDA 020241

Approval Date(s) and History, Letters, Labels, Reviews for NDA 020241

Original Approvals or Tentative Approvals

CSV | Excel | Print

| Action Date | Submission | Action Type | Submission Classification | Review Priority; Orphan Status | Letters, Reviews, Labels, Patient Package Insert | Notes |
|---|---|---|---|---|---|---|
| 12/27/1994 | ORIG-1 | Approval | Type 1 - New Molecular Entity | PRIORITY | | Label is not available on this site. |

Showing 1 to 1 of 1 entries

Supplements

CSV | Excel | Print

| Action Date | Submission | Supplement Categories or Approval Type | Letters, Reviews, Labels, Patient Package Insert | Note |
|---|---|---|---|---|
| 05/18/2015 | SUPPL-53 | Efficacy-New Patient Population | Label (PDF)<br>Letter (PDF) | |
| 03/24/2015 | SUPPL-51 | Labeling-Medication Guide | Label (PDF)<br>Letter (PDF) | |
| 03/24/2015 | SUPPL-45 | Labeling | Label (PDF)<br>Letter (PDF) | |
| 12/30/2014 | SUPPL-40 | Labeling-Patient Package Insert | Label (PDF)<br>Letter (PDF) | |

# Drugs@FDA: FDA Approved Drug Products

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Home | Previous Page

**New Drug Application (NDA):** 020241
**Company:** GLAXOSMITHKLINE LLC

EMAIL

- Medication Guide

**Products on NDA 020241**

**Approval Date(s) and History, Letters, Labels, Reviews for NDA 020241**

| | | | | |
|---|---|---|---|---|
| 04/04/2003 | SUPPL-18 | Labeling | Letter (PDF) | Label is not available on this site. |
| 01/17/2003 | SUPPL-8 | Efficacy-New Indication | Label (PDF) | |
| 05/25/2001 | SUPPL-11 | Efficacy-Labeling Change With Clinical Data | Label (PDF)<br>Review (PDF) | |
| 02/23/2001 | SUPPL-15 | Labeling | | Label is not available on this site. |
| 09/08/2000 | SUPPL-14 | Labeling | | Label is not available on this site. |
| 06/12/2000 | SUPPL-12 | Manufacturing (CMC) | | Label is not available on this site. |
| 06/08/1999 | SUPPL-9 | Manufacturing (CMC) | | Label is not available on this site. |
| 05/10/1999 | SUPPL-7 | Manufacturing (CMC) | | Label is not available on this site. |
| 12/14/1998 | SUPPL-3 | Efficacy-New Indication | Label (PDF)<br>Letter (PDF)<br>Review | |
| 08/24/1998 | SUPPL-2 | Efficacy-New Indication | Label (PDF)<br>Letter (PDF)<br>Review | |
| 03/16/1998 | SUPPL-6 | Labeling | | Label is not available on this site. |
| 03/16/1998 | SUPPL-5 | Manufacturing (CMC)-Control | | Label is not available on this site. |
| 03/11/1997 | SUPPL-4 | Labeling | | Label is not available on this site. |

# Drug Approval Package



## Lamictal Chewable Dispersible Tablets (Lamotrigine)
## Company: Glaxo Wellcome, Inc.
## Application No.: 020-764 & 020-241/S002
## Approval Date: 8/24/1998

- Approval Letter & Printed Labeling (PDF) (3.6 MB)
- Medical Review(s) (PDF)
  Part 1 (2 MB)
  Part 2 (2 MB)
  Part 3 (2.8 MB)
  Part 4 (2.8 MB)
- Chemistry Review(s) (PDF) (762 KB)
- Pharmacology Review(s) & Statistical Review(s) (PDF) (2.3 MB)
- Clinical Pharmacology Biopharmaceutics Review(s) (PDF)
  Part 1 (3 MB)
  Part 2 (2.2 MB)
  Part 3 (2 MB)
  Part 4 (1 MB)
- Administrative Document(s)/Correspondence (PDF)
  Part 1 (3 MB)
  Part 2 (2.2 MB)
  Part 3 (2 MB)
  Part 4 (1 MB)

Date created: March 30, 2001; last updated: July 1, 2005

# National Drug Code (NDC) Directory


A to Z Index | Follow FDA | En Español

Search FDA

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

Home › Drug Databases › NDC

# National Drug Code Directory

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The National Drug Code (NDC) Directory is updated daily.
Current through: September 17, 2017

*Required Field

## Search the database

Choose a Search Type*: Nonproprietary Name

Search by Non Proprietary Name*: lamotrigine

(Type in part or all of Non Proprietary Name)

SEARCH CLEAR

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

# National Drug Code Directory



Current through September 17, 2017

*Records marked with (E): This information was removed from publication, because FDA has found inaccuracy in the data submitted by the firm. Data will be released for publication once complete and accurate information is submitted to FDA*

**Only the first 500 results are displayed. Consider refining your search by entering more specific terms.**

**Search Results: Nonproprietary Name**

Back to Search Page | Search Again

CSV | Excel

Display 50 records per page

Search for text in the table:

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date | Market Category | Package Description | Pharm Class | DEA |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| LAMICTAL | 0173-0526-00 | 5 mg/1 | TABLET, CHEWABLE | ORAL | NDA020764 | GlaxoSmithKline LLC | 0173-0526 | lamotrigine | LAMOTRIGINE | HUMAN PRESCRIPTION DRUG | 09-04-1998 | N/A | NDA | 100 TABLET, CHEWABLE in 1 BOTTLE (0173-0526-00) | Anti-epileptic Agent [EPC], Decreased Central Nervous System Disorganized Electrical Activity [PE], Mood Stabilizer [EPC] | N/A |
| LAMICTAL | 0173-0527-00 | 25 mg/1 | TABLET, CHEWABLE | ORAL | NDA020764 | GlaxoSmithKline LLC | 0173-0527 | lamotrigine | LAMOTRIGINE | HUMAN PRESCRIPTION DRUG | 09-03-1998 | N/A | NDA | 100 TABLET, CHEWABLE in 1 BOTTLE (0173-0527-00) | Anti-epileptic Agent [EPC], Decreased Central Nervous System Disorganized Electrical Activity [PE], Mood Stabilizer [EPC] | N/A |
| LAMICTAL | 0173-0594-02 | | KIT | | NDA020241 | GlaxoSmithKline LLC | 0173-0594 | lamotrigine | | HUMAN PRESCRIPTION DRUG | 09-29-2003 | N/A | NDA | 1 BLISTER PACK in 1 PACKAGE, COMBINATION (0173-0594-02) > 1 KIT in 1 BLISTER PACK | N/A | N/A |
| LAMICTAL | 0173-0633-02 | 25 mg/1 | TABLET | ORAL | NDA020241 | GlaxoSmithKline LLC | 0173-0633 | lamotrigine | LAMOTRIGINE | HUMAN PRESCRIPTION DRUG | 08-15-1996 | N/A | NDA | 100 TABLET in 1 BOTTLE (0173-0633-02) | Anti-epileptic Agent [EPC], Decreased Central Nervous System Disorganized Electrical Activity [PE], Mood Stabilizer [EPC] | N/A |
| LAMICTAL | 0173-0633-10 | 25 mg/1 | TABLET | ORAL | NDA020241 | GlaxoSmithKline LLC | 0173-0633 | lamotrigine | LAMOTRIGINE | HUMAN PRESCRIPTION DRUG | 08-15-1996 | N/A | NDA | 35 TABLET in 1 DOSE PACK (0173-0633-10) | Anti-epileptic Agent [EPC], Decreased Central Nervous System Disorganized Electrical Activity [PE], Mood Stabilizer [EPC] | N/A |

Drug Approvals and Databases

Approved Drugs

# National Drug Code Directory



The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act.

# Orange Book

FDA U.S. FOOD & DRUG ADMINISTRATION

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Home › Drug Databases › Orange Book Home

# Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Additional information and resources for the Orange Book

Mobile App Users: Please replace Orange Book Express with Orange Book Express 2.0

## Find Approved Drugs

Search by Proprietary Name, Active Ingredient or Application Number

Entecavir Search

Search by Applicant (Company)

Search by Dosage Form (for example: *TABLET*)

Search by Route of Administration (for example: *ORAL*)

## Find Patent Information

Search by Patent Number

View Newly Added Patents or Delisted Patents

# Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations



Home | Modify Search

## Search Results for Proprietary Name, Active Ingredient or Application Number: *Entecavir*

**21 records returned**

☑ RX ☐ OTC ☐ DISCN

Display 50 records per page

Search for text in the table:

| Mkt. Status | Active Ingredient | Proprietary Name | Appl No | Dosage Form | Route | Strength | TE Code | RLD | RS | Applicant Holder |
|---|---|---|---|---|---|---|---|---|---|---|
| RX | ENTECAVIR | BARACLUDE | N021798 | SOLUTION | ORAL | 0.05MG/ML | | RLD | RS | BRISTOL MYERS SQUIBB |
| RX | ENTECAVIR | BARACLUDE | N021797 | TABLET | ORAL | 0.5MG | AB | RLD | | BRISTOL MYERS SQUIBB |
| RX | ENTECAVIR | BARACLUDE | N021797 | TABLET | ORAL | 1MG | AB | RLD | RS | BRISTOL MYERS SQUIBB |
| RX | ENTECAVIR | ENTECAVIR | A205824 | TABLET | ORAL | 0.5MG | AB | | | ACCORD HEALTHCARE INC |
| RX | ENTECAVIR | ENTECAVIR | A206652 | TABLET | ORAL | 0.5MG | AB | | | AMNEAL PHARMACEUTICALS |
| RX | ENTECAVIR | ENTECAVIR | A206217 | TABLET | ORAL | 0.5MG | AB | | | AUROBINDO PHARMA LTD |
| RX | ENTECAVIR | ENTECAVIR | A206872 | TABLET | ORAL | 0.5MG | AB | | | CIPLA LTD |
| RX | ENTECAVIR | ENTECAVIR | A205740 | TABLET | ORAL | 0.5MG | AB | | | HETERO LABS LTD UNIT V |
| RX | ENTECAVIR | ENTECAVIR | A206294 | TABLET | ORAL | 0.5MG | AB | | | PAR PHARMACEUTICAL INC |
| RX | ENTECAVIR | ENTECAVIR | A206672 | TABLET | ORAL | 0.5MG | AB | | | SANDOZ INC |
| RX | ENTECAVIR | ENTECAVIR | A202122 | TABLET | ORAL | 0.5MG | AB | | | TEVA PHARMACEUTICALS USA |
| RX | ENTECAVIR | ENTECAVIR | A206745 | TABLET | ORAL | 0.5MG | AB | | | ZYDUS PHARMACEUTICALS USA INC |

U.S. FOOD & DRUG ADMINISTRATION

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Home › Drug Databases › Orange Book Home

# Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Download Orange Book Express 2.0

Download on the App Store | ANDROID APP ON Google play

## Additional information and resources for the Orange Book

## Mobile App Users: Please replace Orange Book Express with Orange Book Express 2.0

## Find Approved Drugs

Search by Proprietary Name, Active Ingredient or Application Number

Xiidra

Search

Search by Applicant (Company)

Search by Dosage Form (for example: *TABLET*)

Search by Route of Administration (for example: *ORAL*)

## Find Patent Information

Search by Patent Number

View Newly Added Patents or Delisted Patents

## Search Results for Proprietary Name, Active Ingredient or Application Number: *Xiidra*

**1 record returned**

☑ RX ☑ OTC ☑ DISCN

CSV | Excel

Display 50 records per page

Search for text in the table:

| Mkt. Status | Active Ingredient | Proprietary Name | Appl No | Dosage Form | Route | Strength | TE Code | RLD | RS | Applicant Holder |
|---|---|---|---|---|---|---|---|---|---|---|
| RX | LIFITEGRAST | XIIDRA | N208073 | SOLUTION/DROPS | OPHTHALMIC | 5% | | RLD | RS | SHIRE DEVELOPMENT LLC |
| Mkt. Status | Active Ingredient | Proprietary Name | Appl No | Dosage Form | Route | Strength | TE Code | RLD | RS | Applicant Holder |

Showing 1 to 1 of 1 entries

Previous 1 Next

XIIDRA (LIFITEGRAST)
5%
Marketing Status: Prescription

**Active Ingredient:** LIFITEGRAST
**Proprietary Name:** XIIDRA
**Dosage Form; Route of Administration:** SOLUTION/DROPS; OPHTHALMIC
**Strength:** 5%
**Reference Listed Drug:** Yes
**Reference Standard:** Yes
**TE Code:**
**Application Number:** N208073
**Product Number:** 001
**Approval Date:** Jul 11, 2016
**Applicant Holder Full Name:** SHIRE DEVELOPMENT LLC
**Marketing Status:** Prescription
Patent and Exclusivity Information

## Patent and Exclusivity for: N208073

Product 001
LIFITEGRAST (XIIDRA) SOLUTION/DROPS 5%

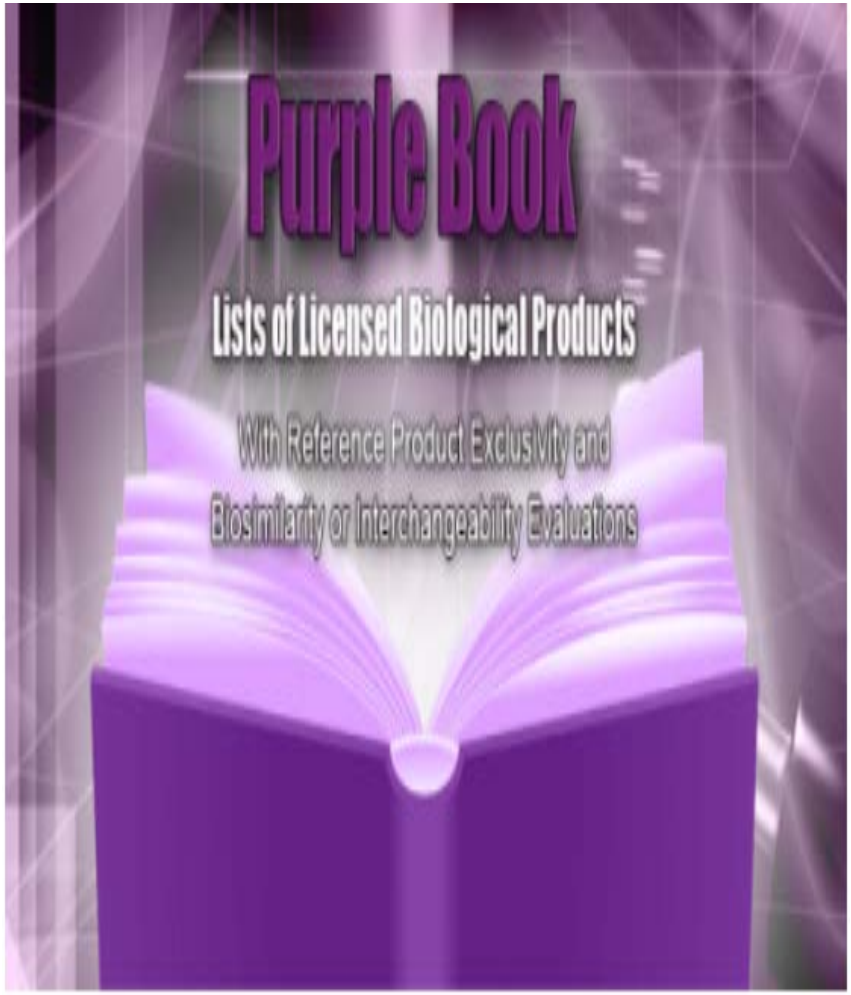
### Patent Data

| Product No | Patent No | Patent Expiration | Drug Substance Claim | Drug Product Claim | Patent Use Code | Delist Requested |
|---|---|---|---|---|---|---|
| 001 | 7314938 | Mar 10, 2025 | DS | DP | | |
| 001 | 7745460 | Nov 5, 2024 | DS | DP | U-1880 | |
| 001 | 7790743 | Nov 5, 2024 | | | U-1880 | |
| 001 | 7928122 | Nov 5, 2024 | DS | DP | | |
| 001 | 8084047 | May 17, 2026 | DS | DP | | |
| 001 | 8168655 | May 9, 2029 | | | U-1880 | |
| 001 | 8367701 | Apr 15, 2029 | | DP | U-1880 | |
| 001 | 8592450 | May 17, 2026 | | | U-1880 | |
| 001 | 8927574 | Nov 12, 2030 | | DP | | |
| 001 | 9085553 | Jul 25, 2033 | | DP | | |
| 001 | 9216174 | Nov 5, 2024 | | DP | | |
| 001 | 9353088 | Oct 21, 2030 | | DP | | |
| 001 | 9447077 | Apr 15, 2029 | | | U-1900 | |

### Exclusivity Data

| Product No | Exclusivity Code | Exclusivity Expiration |
|---|---|---|
| 001 | NCE | Jul 11, 2021 |

# Biosimilars




**The Purple Book includes :**

•A list of biological products, including any biosimilar and interchangeable biological products

•The date a biological product was licensed and whether FDA evaluated the biological product for reference product exclusivity

•Indicates whether a biological product has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product

•Biosimilar and interchangeable biological products licensed will be listed under the reference product to which biosimilarity or interchangeability was demonstrated

•Separate lists for those biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER)

# Purple Book

Center for Drug Evaluation and Research

List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

| BLA STN | PRODUCT (PROPER) NAME | PROPRIETARY NAME | DATE OF LICENSURE (mo/day/yr) | DATE OF FIRST LICENSURE (mo/day/yr) | REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr) | INTERCHANGEABLE (I)/ BIOSIMILAR (B) | WITHDRAWN |
|---|---|---|---|---|---|---|---|
| 125118 | abatacept | Orencia | 12/23/05 | | | | |
| 103575 | abciximab | ReoPro | 12/22/94 | NA | NA | | |
| 125274 | abobotulinumtoxinA | Dysport | 04/29/09 | | | | |
| 125057 | adalimumab | Humira | 12/31/02 | NA | NA | | |
| 761058 | adalimumab-adbm | Cyltezo | 08/25/17 | | | B | |
| 761024 | adalimumab-atto | Amjevita | 09/23/16 | | | B | |
| 125427 | ado-trastuzumab emtansine | Kadcyla | 02/22/13 | | | | |

# Drug Shortages

# Drug Shortages

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## 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

# FDA Drug Shortages

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## 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

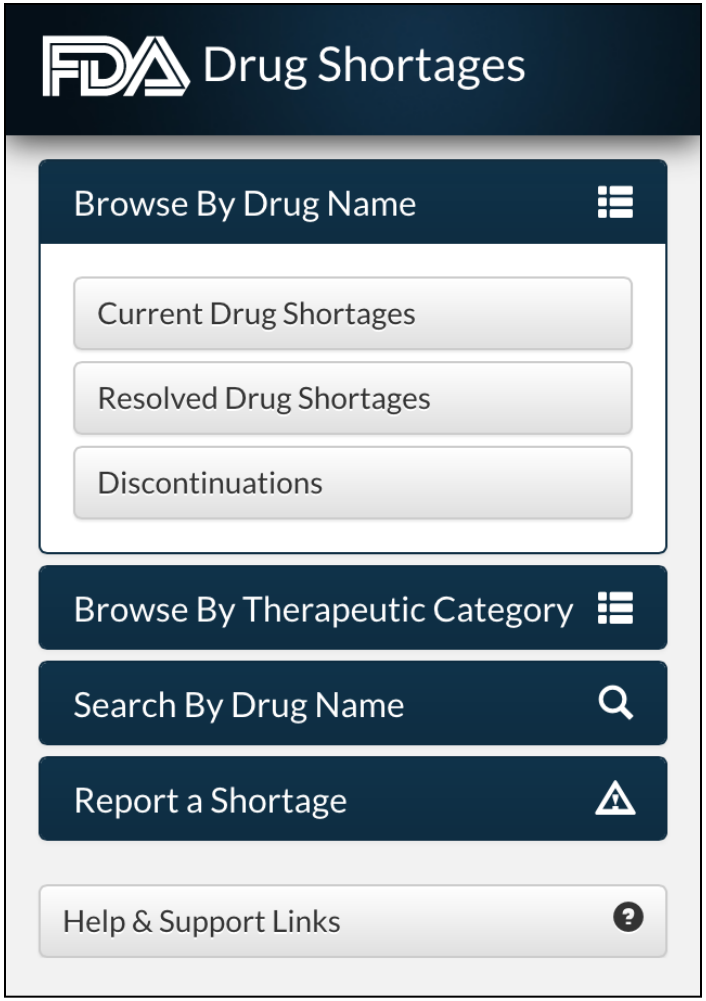
Current/Resolved Shortages | Discontinuations | Therapeutic Categories | New and Updated

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.

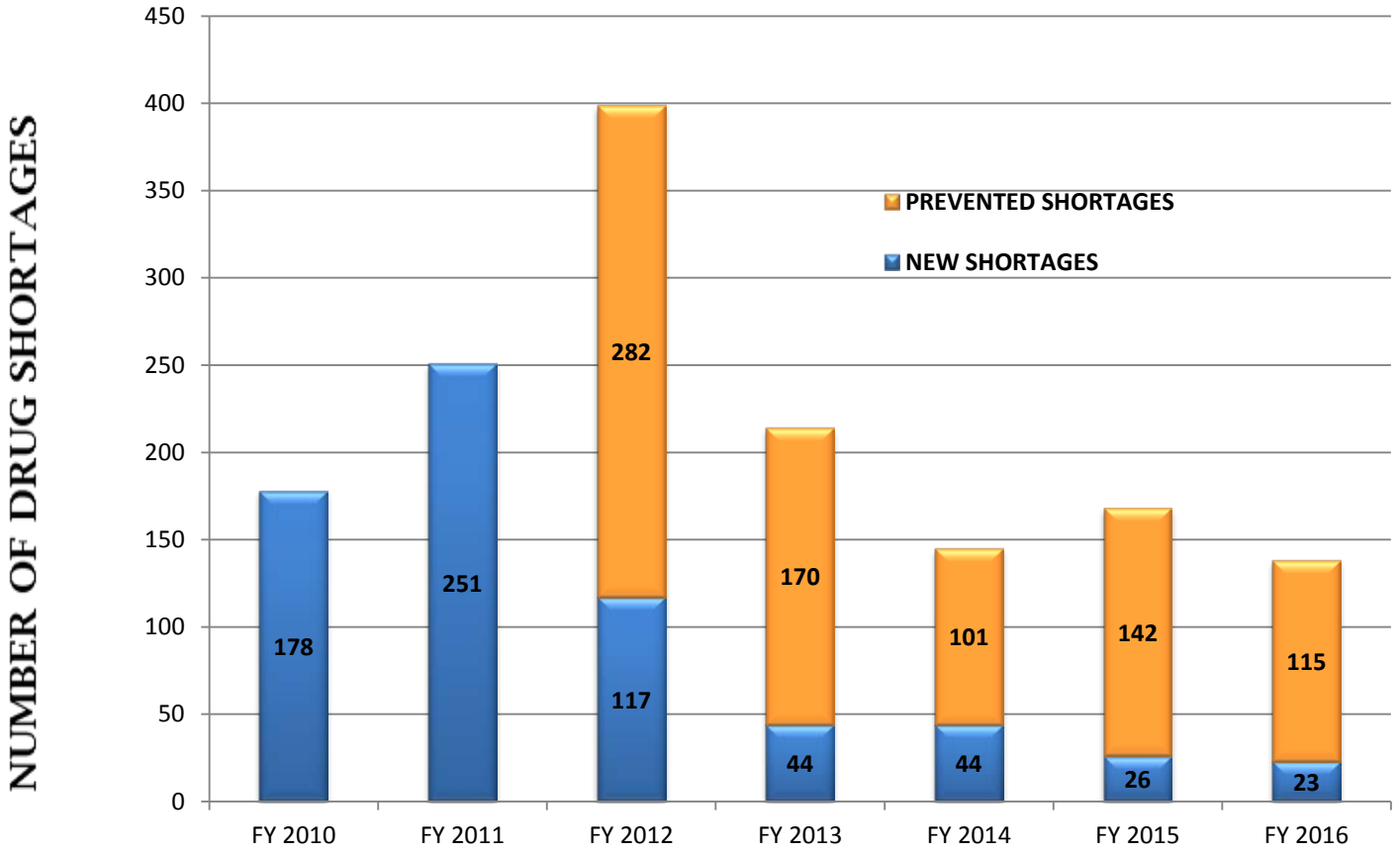
| Generic Name or Active Ingredient | Status |
|---|---|
| Acetohydroxamic Acid (Lithostat) Tablets | ***Resolved*** |
| Albuterol Sulfate Inhalation Solution (0.5%) | ***Resolved*** |
| Alitretinoin (Panretin) Gel | ***Resolved*** |
| Asparaginase Erwinia Chrysanthemi (Erwinaze) | ***Currently in Shortage*** |
| Atenolol Tablets | ***Currently in Shortage*** |

# Drug Shortages Mobile App



# Drug Shortage Data

## Drug Shortages: New vs. Prevented



# Responding to Drug Shortages

- Regulatory Discretion
  - Allows for manufacture of medically necessary products to continue
  - May require additional safety controls
    - Filters with product; extra testing at plant; 3rd party oversight of production; special instructions for safe use
- Request other firms to raise production
- Expedite reviews
  - New manufacturing sites, longer expiry date, new raw material source, changes in specifications, etc.
- In rare cases, temporary importation from unapproved sources

# Extended Use Dates Provided by Pfizer to Assist with Emergency Syringe Shortages



**UPDATE [8/17/17]** Due to the ongoing critical shortages of injectable drugs used in critical care, please see additional products with extended use dates and corresponding lot numbers in the tables below. To help ensure patient safety, these products should have been — and should continue to be — stored as per labeled conditions. As data become available, this list can continue to expand.

For more information, see the CDER Statement. Please contact CDER Drug Shortage Staff at drugshortages@fda.hhs.gov with questions regarding these tables.

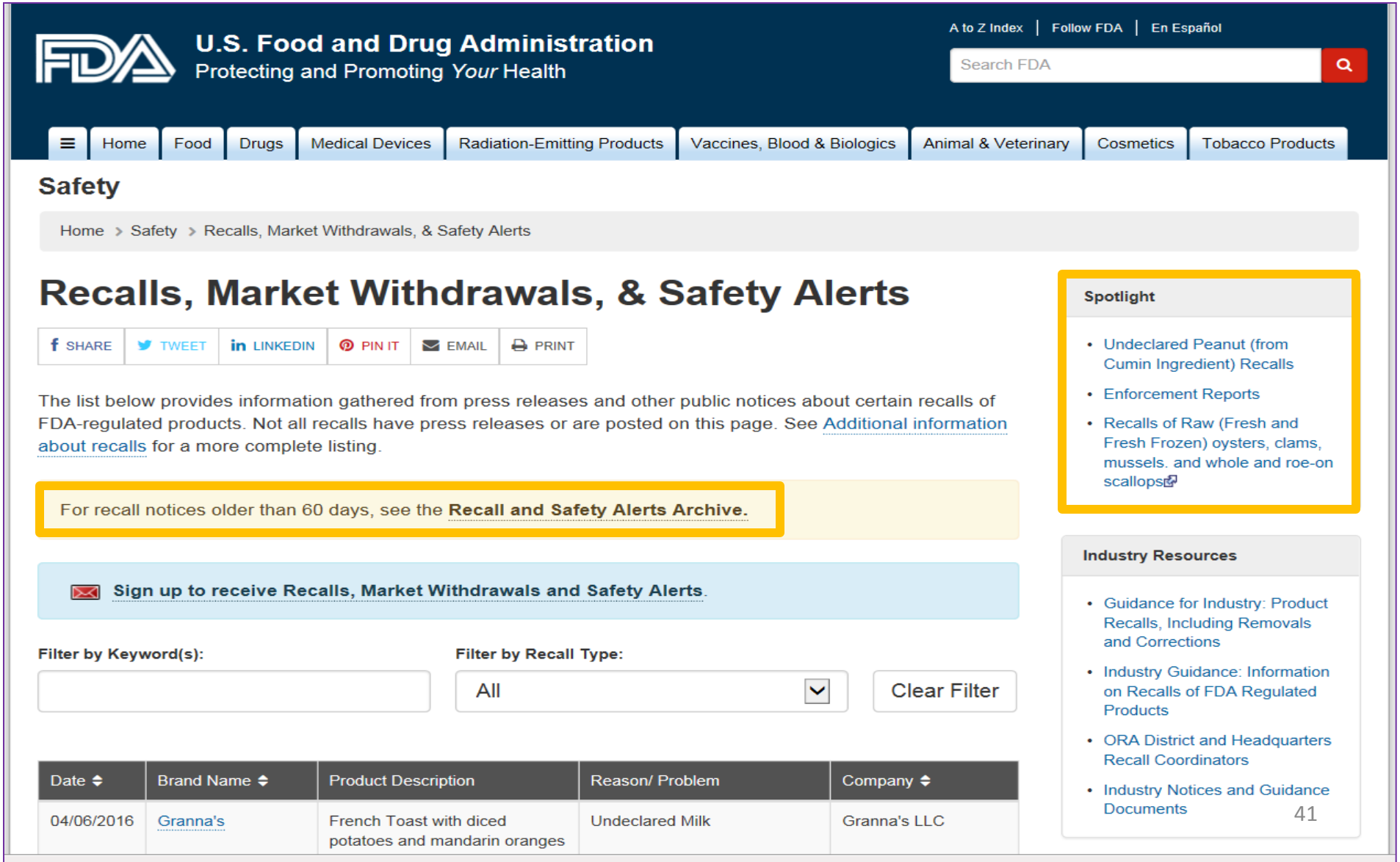
**Product and lot numbers of Sodium Bicarbonate products in glass fliptop vials eligible for use beyond the manufacturer's labeled expiration date (as of August 17, 2017).**

- **Sodium Bicarbonate Injection, USP 8.4% (1 mEq/mL); 50 mEq/50 mL Single Dose Glass Fliptop Vial (NDC 0409-6625-25) LABELLED AS NOVAPLUS**

| Product/ Lot Number | Manufacturer's Original Expiry Date | New Use Date (beyond manufacturer's original expiry date) |
|---|---|---|
| 57254EV00 | 9/1/2017 | 2/1/2018 |
| 57496EV00 | 9/1/2017 | 2/1/2018 |
| 60043EV00 | 12/1/2017 | 5/1/2018 |
| 60122EV00 | 12/1/2017 | 5/1/2018 |

# Drug Recalls

# Recalls



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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## Safety

Home > Safety > Recalls, Market Withdrawals, & Safety Alerts

## Recalls, Market Withdrawals, & Safety Alerts

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The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See Additional information about recalls for a more complete listing.

For recall notices older than 60 days, see the **Recall and Safety Alerts Archive.**

**Sign up to receive Recalls, Market Withdrawals and Safety Alerts.**

**Filter by Keyword(s):**

**Filter by Recall Type:** All

Clear Filter

| Date | Brand Name | Product Description | Reason/ Problem | Company |
|---|---|---|---|---|
| 04/06/2016 | Granna's | French Toast with diced potatoes and mandarin oranges | Undeclared Milk | Granna's LLC |

**Spotlight**

- Undeclared Peanut (from Cumin Ingredient) Recalls
- Enforcement Reports
- Recalls of Raw (Fresh and Fresh Frozen) oysters, clams, mussels. and whole and roe-on scallops

**Industry Resources**

- Guidance for Industry: Product Recalls, Including Removals and Corrections
- Industry Guidance: Information on Recalls of FDA Regulated Products
- ORA District and Headquarters Recall Coordinators
- Industry Notices and Guidance Documents

# Enforcement Reports

# Enforcement Reports

- All recalls go into **FDA's Enforcement Report** once they are classified according to the level of hazard involved

**Enforcement Report - Week of September 13, 2017**

View by Product | View by Event

Export to CSV | Print View

Showing 1 to 7 of 7 records *(filtered from 50 total records)* |< < 1 > >| Records per page: 50

For a more detailed search, go to Advanced Search

Product Type: Drugs | Classification | Recalling Firm | Clear Filter

| Product Type | Product Description | Classification | Code Information | Reason for Recall | Recalling Firm |
|---|---|---|---|---|---|
| Drugs + view details | Curcumin Emulsion 10mg/ml Injection, Sterile 10 mL Multiple Dose Vial, For Slow IV Administration, Compounded for a licensed professional or patient use by ImprimisRx, Irvine, CA | Class II | 03212017@21B Exp:6/19/2017; 0323 2017@19B Exp:6/21/2017; 03292017 @27B Exp:6/27/2017; 03292017@9B Exp:6/27/2017; 04042017@21B Exp: 7/3/2017; 04122017@22B Exp:7/11/2 017; 04132017@14B Exp:7/12/2017; 04192017@37B Exp:7/18/2017; 0419 2017@17B Exp:7/18/2017; 04242017 @18B Exp:7/23/2017 | Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier | ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr Irvine, CA 92618-4286 |
| Drugs + view details | Latanoprost PF Solution, 0.005%, Ophthalmic Drops in Sterile 5ml Bottles, Compounded for a licensed professional or patient use, imprimisRx, Irvine, CA | Class II | 0404017@32B, 10/01/2017 | Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG 40 Castor Oil was used due to a mislabeling by the supplier | ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr Irvine, CA 92618-4286 |
| Drugs | Timolol-Latanoprost PF Solution (0.5-0.005)%, Ophthalmic Drops, Sterile 5ml Bottle, Compounded for a | Class II | 04042017@34B, 10/01/2017 | Incorrect/Undeclared Excipient; non-pharmaceutical grade PEG | ImprimisRx CA, Inc., dba ImprimisRx 9257 Research Dr |

Compounding
Regulatory Policy Information
Compounding Risk Alerts
Compounding: Inspections, Recalls, and other Actions
Outsourcing Facilities

# Compounding Risk Alerts




The information provided on this webpage is intended to alert health care professionals of adverse event reports related to compounded drugs. Providing this information to health care professionals should further FDA's goal of protecting patients from unsafe, ineffective, and poor quality compounded drugs.

Please contact compounding@fda.hhs.gov if you have any questions regarding the information provided in a compounding risk alert below:

- A Case of Hemorrhagic Occlusive Retinal Vasculitis (HORV) Following Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin Formulation
- FDA alerts health care professionals of adverse events associated with Guardian's compounded triamcinolone and moxifloxacin product for intravitreal injection
- FDA investigates two serious adverse events associated with ImprimisRx's compounded curcumin emulsion product for injection

FDA encourages health care professionals to report adverse events and product quality defects associated with compounded drugs to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

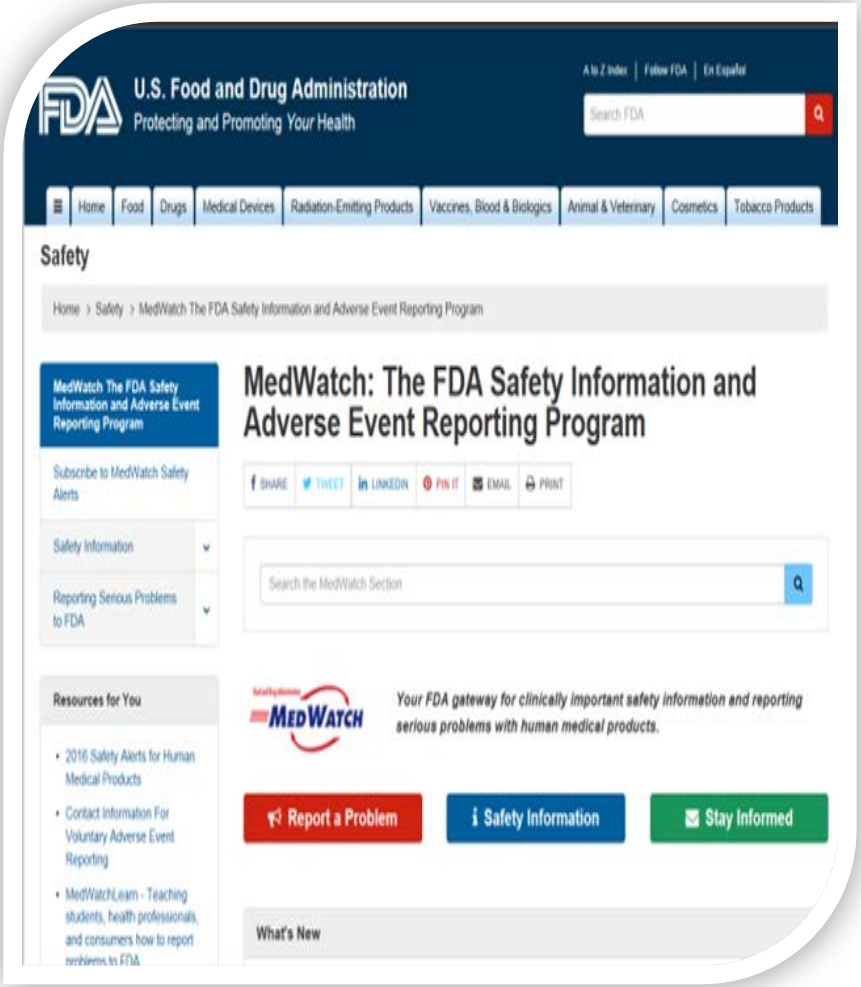
# Objectives

1. Identify FDA resources that contain information on drug safety issues

2. **Locate adverse event reporting information on FDA's website**

3. Utilize drug information resources to stay informed on FDA actions, decisions and initiatives

# MedWatch




**Report:**

- Adverse events
- Product problems
- Product use errors

**Forms:**

**Voluntary**

- Form FDA 3500
- Form FDA 3500B

**Mandatory**

- Form FDA 3500A

U.S. Department of Health and Human Services

# U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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

## Drugs

Home > Drugs


**Potassium-lowering drugs can bind to oral Rx, OTC drugs**

Separate time between doses to avoid drug-drug interactions

1 2 3 4

### Navigate the Drugs Section

### 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

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Subscribe to MedWatch Safety Alerts

Safety Information

Reporting Serious Problems to FDA

Resources for You

- 2017 Safety Alerts for Human Medical Products
- MedWatchLearn - Teaching students, health professionals, and consumers how to report problems to FDA
- Medical Product Safety Educational Resources
- Consumer-Friendly Reporting Form 3500B (PDF - 1.3MB)

# MedWatch: The FDA Safety Information and Adverse Event Reporting Program

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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**

## What's New

- Baby Organic Liquid Formula by Garden of Life: Recall - Directions For Use May Be Misinterpreted If not administered precisely following the labeled instructions, the product may present difficulties in swallowing and potentially pose a choking hazard due to the thickness of the liquid. Posted 09/08/2017

FDA U.S. FOOD & DRUG ADMINISTRATION

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

MedWatch Home | Help | OMB Paperwork Reduction Act | Your Privacy Statement

# MedWatch Online Voluntary Reporting Form

Welcome

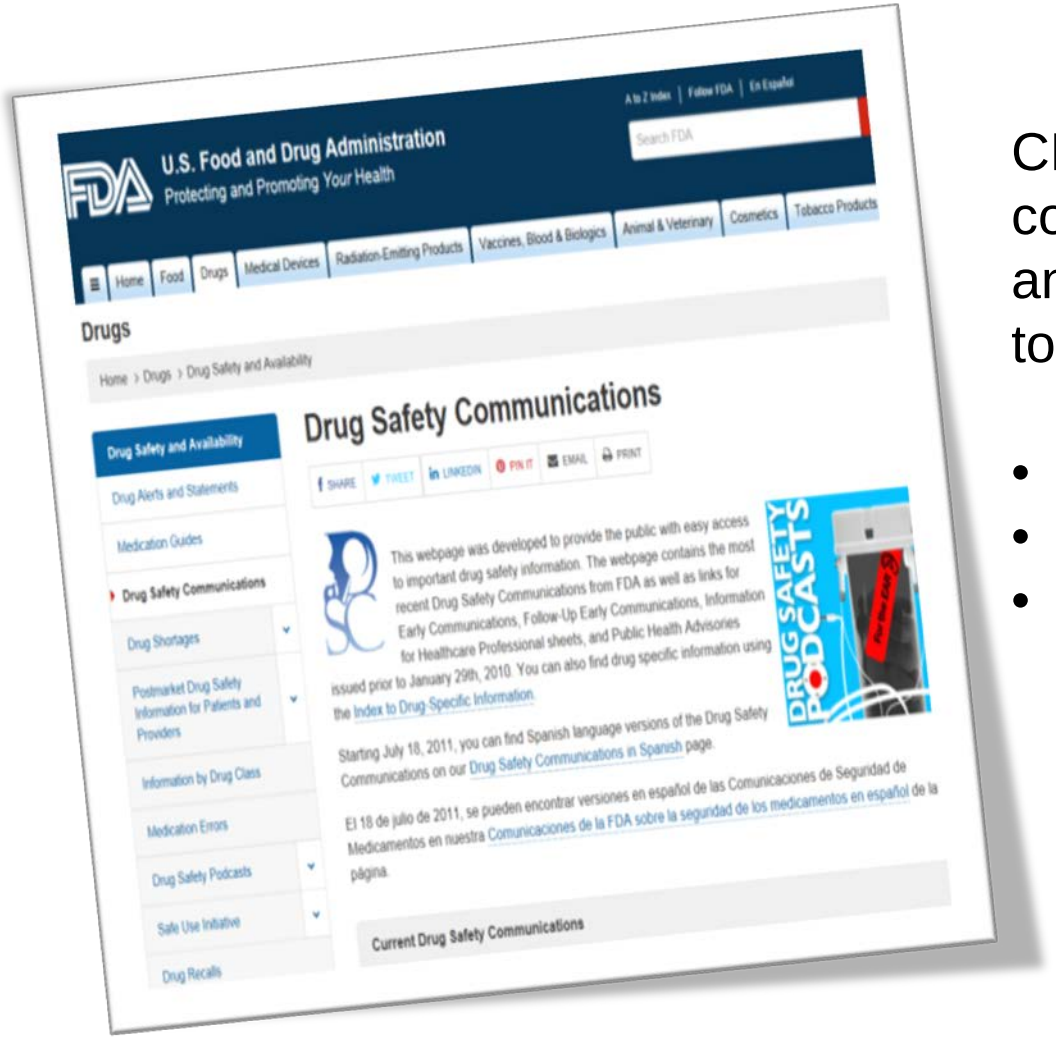
Frequently Asked Questions

Begin report as a:

Health Professional
(FDA Form 3500)

Consumer/Patient
(FDA Form 3500B)

# Drug Safety Communications (DSC)




CDER's primary tool for communicating important new and emerging safety information to the public

- New drug warnings
- Drug label changes
- Other safety information

# Drug Safety Communications

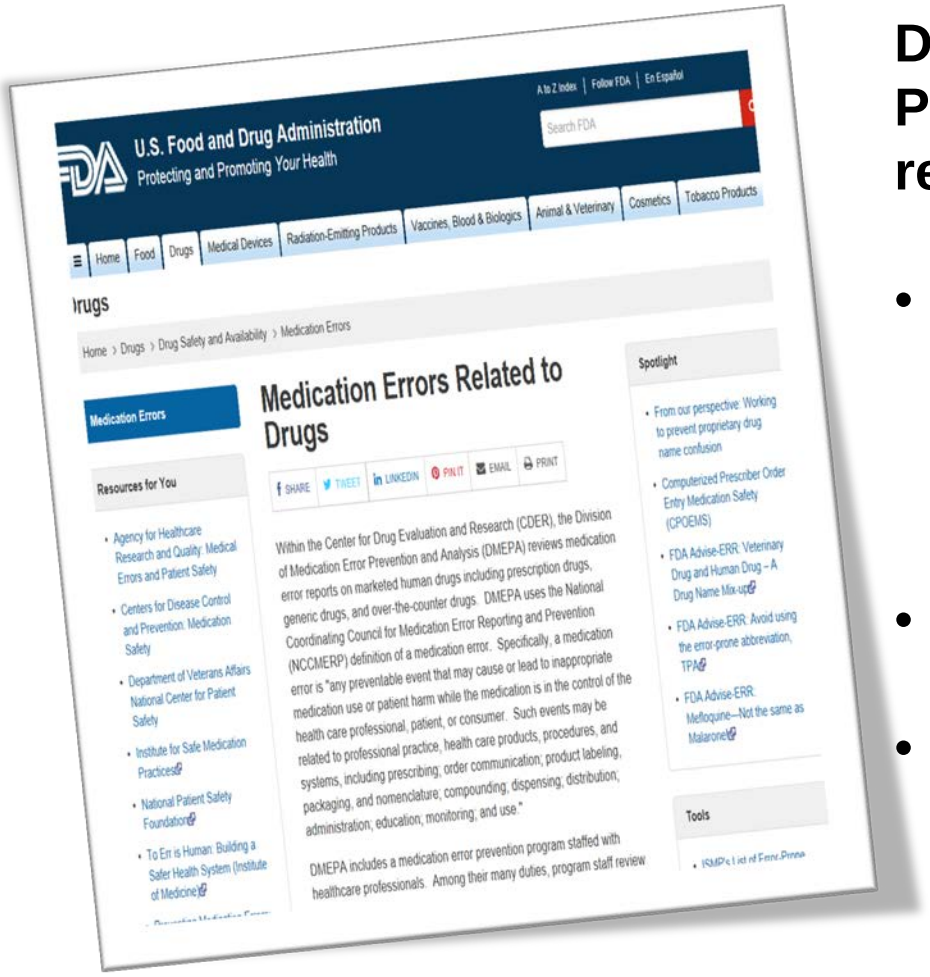
**September 2017:** FDA warns about serious liver injury with Ocaliva (obeticholic acid) for rare chronic liver disease

**September 2017:** FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks

**September 2017:** FDA recommends separating dosing of potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) from all other oral drugs

**May 2017:** FDA identifies no harmful effects to date with brain retention of gadolinium-based contrast agents for MRIs; review to continue

# Medication Errors




**Division of Medication Error Prevention and Analysis (DMEPA) reviews:**

- Medication error reports on marketed human drugs including prescription drugs, generic drugs, and OTC drugs
- MedWatch Reports
- Proprietary names, labeling, packaging, and product design prior to drug approval to help prevent medication errors

**Medication Errors**

**Resources for You**

- Agency for Healthcare Research and Quality: Medical Errors and Patient Safety
- Centers for Disease Control and Prevention: Medication Safety
- Department of Veterans Affairs National Center for Patient Safety
- Institute for Safe Medication Practices
- National Patient Safety Foundation
- To Err is Human: Building a Safer Health System (Institute of Medicine)
- Preventing Medication Errors: Quality Chasm Series
- National Coordinating Council for Medication Error Reporting and Prevention

# Medication Errors Related to Drugs



Within the Center for Drug Evaluation and Research (CDER), the Division of Medication Error Prevention and Analysis (DMEPA) reviews medication error reports on marketed human drugs including prescription drugs, generic drugs, and over-the-counter drugs. DMEPA uses the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) definition of a medication error. Specifically, a medication error is "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."

DMEPA includes a medication error prevention program staffed with healthcare professionals. Among their many duties, program staff review medication error reports sent to MedWatch, evaluate causality, and analyze the data to provide solutions to reduce the risk of medication errors to industry and others at FDA.

Additionally, DMEPA prospectively reviews proprietary names, labeling, packaging, and product design prior to drug approval to help prevent medication errors.

Although DMEPA encourages manufacturers to perform their due diligence when naming their drug products and we strive to avoid approving confusing proprietary names for drug products, there are cases of adverse

**Spotlight**

- MedWatch Online Voluntary Reporting Form
- Guidance for Industry: Safety Considerations for Product Design to Minimize Medication Errors Guidance for Industry (PDF - 212KB)
- From our perspective: Working to prevent proprietary drug name confusion
- Computerized Prescriber Order Entry Medication Safety (CPOEMS)
- Update on Phonetic and Orthographic Computer Analysis Tool

**Tools**

- ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations
- ISMP's List of Products with Drug Name Suffixes
- FDA Drug Info Rounds Video: Medication Errors
- Over-the-Counter (OTC) Dosage Delivery Devices
- Avoiding Medication Mistakes

# Objectives

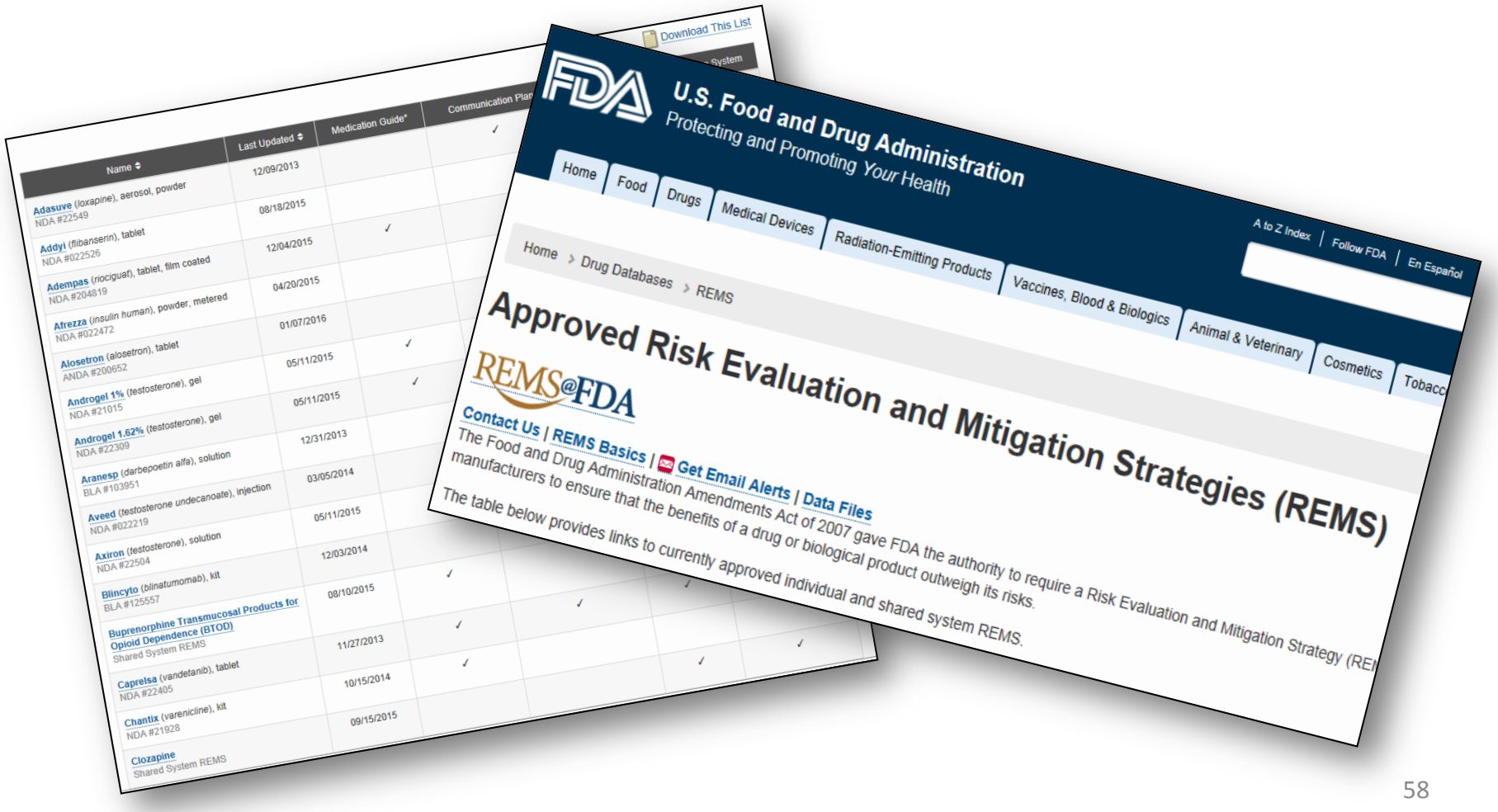
1. Identify FDA resources that contain information on drug safety issues

2. Locate adverse event reporting information on FDA's website

3. **Utilize drug information resources to stay informed on FDA actions, decisions and initiatives**

# Labeling Initiatives

# Approved Risk Evaluation and Mitigation Strategies (REMS)



# 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 Mitiga
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

Get email alerts when the site changes

Download historic REMS data in CSV format

Search by REMS, drug name, and element

Sort to find the most recently updated REMS

| Name | Last Updated | Medication Guide* | Communication Plan | ETASU | Implementation System |
|---|---|---|---|---|---|
| Actemra (*tocilizumab*), injection, solution; injection, solution, concentrate<br>BLA #125276<br>BLA #125472 | 10/21/2013 | | ✓ | | |
| Adasuve (*loxapine*), aerosol, powder<br>NDA #22549 | 12/09/2013 | | ✓ | | |
| Addyi (*flibanserin*), tablet<br>NDA #022526 | 08/18/2015 | | | | |

Click for more detailed info on each REMS

# REMS: Information for Participants

## What do participants need to know?

Below is a general overview of the REMS for all REMS participants (e.g., patients, pharmacies, and healthcare providers). See the product-specific REMS website or the approved REMS materials for more information.

View application holder(s) REMS Website

Go to application holder's REMS website

+ Healthcare Providers who prescribe isotretinoin products must
+ Patients who are prescribed isotretinoin products
+ Pharmacies that dispense isotretinoin products must

View requirements for each participant

# REMS: Information for HCPs

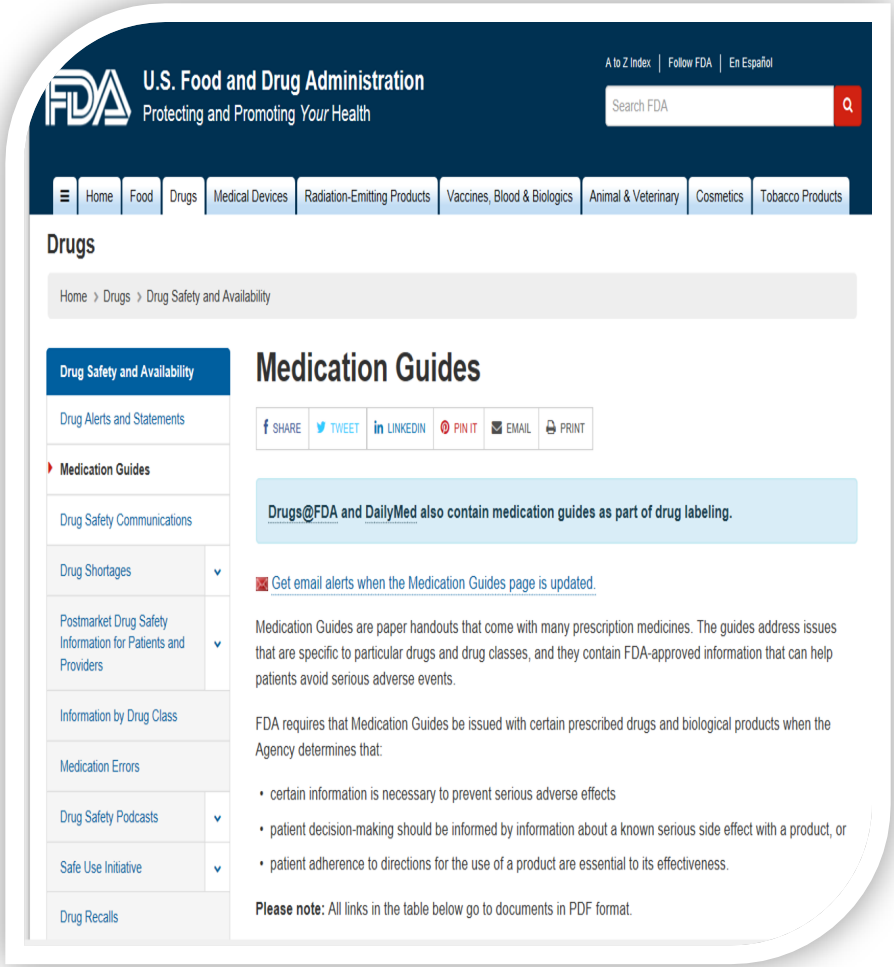
+ Healthcare Providers who prescribe isotretinoin products must
+ Patients who are prescribed isotretinoin products

Find out what you have to do, and when

− Pharmacies that dispense isotretinoin products must

| | |
|---|---|
| **To be able to dispense** | • Designate an authorized representative to carry out the certification process on behalf of the pharmacy.<br>• Have the authorized representative enroll in the REMS by completing the Pharmacy Enrollment Form and submitting it to the REMS Program. |
| **Before dispensing** | • Provide the patient with the Medication Guide.<br>• Obtain authorization to dispense by contacting the iPLEDGE Program via web or voice-based system.Document the Risk Management Authorization (RMA) number on the prescription.<br>• Dispense prior to the "do not dispense to a patient after" date provided by the iPLEDGE Program.<br>• Dispense no more than a 30 days' supply.<br>• Do not dispense refills. |
| **Every year** | • Re-enroll in the iPLEDGE Program. |
| **At all times** | • Return unused product to the manufacturer.<br>• Do not distribute, transfer, loan, or sell product. |

# Medication Guides




- Prevent serious adverse effects
- Assist with informed patient decision making
- Information for patient adherence to directions for use of a product

# Drug Safety Labeling Changes (SLC)

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Sign up for SLC Alerts | Quick Reference

The Drug Safety Labeling Changes (SLC) database provides approved safety labeling changes from January 2016 forward. Data prior to January 2016 will continue to be available on the **MedWatch website**.

Additional information and resources for drug safety labeling.

**There are two ways to search: a Drug Name Search and a Date Search.**

## Drug Name Search

**Drug Name or Active Ingredient:** Enter at least 3 characters

Search | Reset

OR

## Date Search

For Safety Labeling Changes before January 1, 2016 see the **MedWatch Safety Labeling Page**

**Date Range:** 01/01/2016 — 09/02/2016

**Labeling Section:**

- ☑ Boxed Warning
- ☑ Adverse Reactions
- ☑ Drug Interactions
- ☑ Contraindications
- ☑ Warnings and Precautions
- ☑ Use in Specific Populations
- ☑ PCI/PI/MG (Patient Counseling Information/Patient Information/Medication Guide)

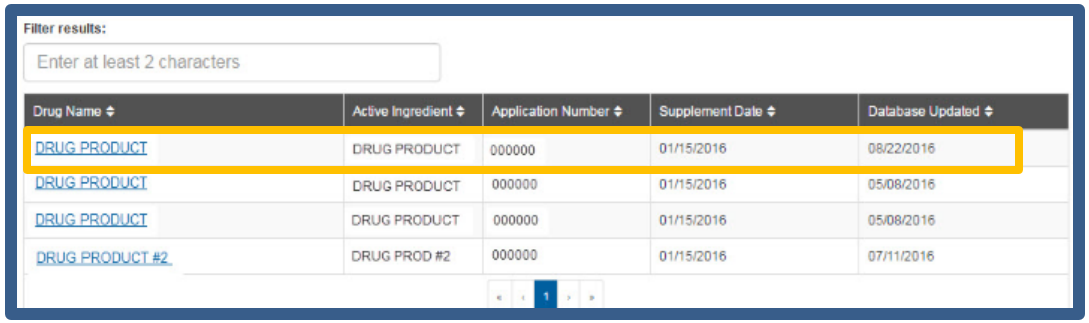
Search | Reset

- Provides approved safety labeling changes from January 2016 forward
- Data prior to January 2016 will continue to be available on the MedWatch website

# SLC Database Search

**How to Search Within Results / Choose Result**

Search within multiple results, filter results, sort by column, or select drug name.




**How to Download Data Files**

Search results can be downloaded and saved in CSV format.

# Stay Informed

- Facebook
- Twitter
- LinkedIn
- Podcasts
- Webinars
- Mobile Apps
- YouTube
- iTunes

**Social Media**

**FDA.gov**

- Drug Safety Communications
- FDA Listserves
- MedWatch Alerts
- Safety Labeling Changes (SLCs)

- Mass Media
- Stakeholder Briefings
- Consumer, Trade, Professional Groups
- Medical Journals

**External Outreach**


*"Webinars"*








PRESS


Listserve

*"MedGuides"*

# Stay Informed


- **Links to social media, webinars, and much more!**

www.fda.gov/AboutDDI

- **Sign up for email updates:** www.fda.gov/aboutfda/contactfda/stayinformed/getemailupdates/default.htm
- **Pharmacy Student Experiential Program:** www.fda.gov/PharmStudentProgram
- **Regulatory Pharmacist Fellowship Program:** www.fda.gov/RegPharmFellowship
- **Global Alliance of Drug Information Specialists (GADIS)** www.fda.gov/GADIS

# Thank you

# QUESTIONS?

**Contact DDI:**

Phone: 855-543-3784 or 301-796-3400

Email: druginfo@fda.hhs.gov