



# **FDA Drug Topics: FDA Drug Information Resources and Applicability to Health Care Professionals**

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Center for Drug Evaluation and Research | Food and Drug Administration

# 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 drug information resources for health care professionals to stay informed on FDA actions, decisions, and initiatives.
2. Demonstrate the use and application of these resources for common health-related inquiries.
3. Discuss non-traditional drug information resources – social media, podcasts, and videos.



# Division of Drug Information

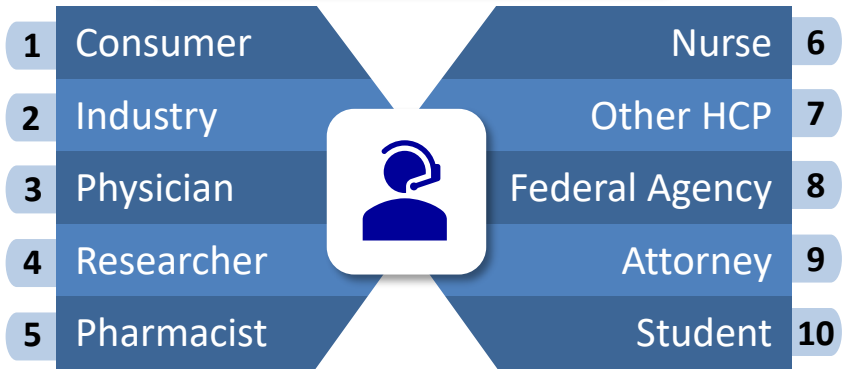
The **mission** of DDI is to optimize the Center for Drug Evaluation and Research's educational and communication efforts to our global community.

DDI is the Center for Drug Evaluation and Research's focal point for public inquiries regarding human drug products.

DDI supports the Food and Drug Administration's mission to promote and protect public health.

# DDI Engagement

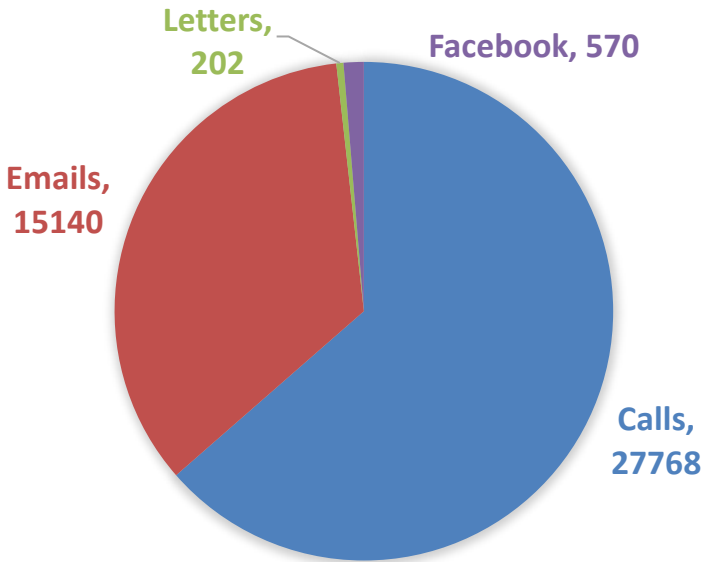
## Audience



## 2021 Top 10 Inquiry Topics

1. COVID-19	6. Expanded Access
2. Isotretinoin REMS	7. Registration
3. Opioids	8. Nitrosamines
4. Investigational New Drug	9. Import/Export
5. Personal Import	10. Clinical trials

## 2021 Points of Contact



# FDA Drug Information Databases/Resources



# FDA Home Page: Where to Find Resources

FDA

**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

Q Search

≡ Menu

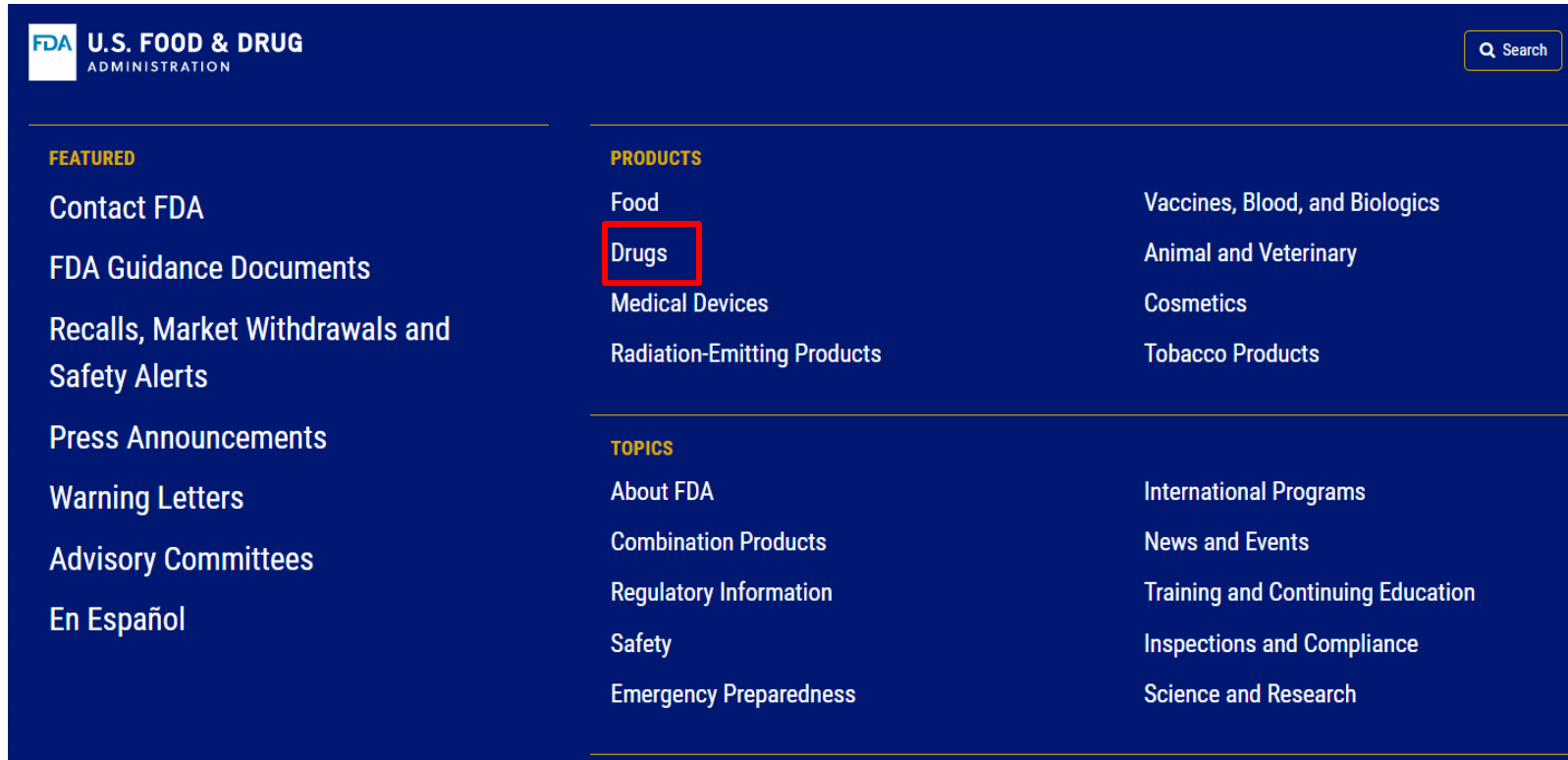


**Don't delay, get your COVID-19 vaccine or booster today!**

Getting vaccinated or receiving a booster if you're already vaccinated is the best thing you can do to help protect yourself, family and friends.

Vaccines.gov

# FDA Home Page: Where to Find Resources



The screenshot shows the FDA Home Page with a dark blue background and white text. The header includes the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION" on the left, and a search bar with a magnifying glass icon and the word "Search" on the right. The main content is organized into three columns. The first column, titled "FEATURED", lists links to "Contact FDA", "FDA Guidance Documents", "Recalls, Market Withdrawals and Safety Alerts", "Press Announcements", "Warning Letters", "Advisory Committees", and "En Español". The second column, titled "PRODUCTS", lists "Food", "Drugs" (which is highlighted with a red rectangular box), "Medical Devices", and "Radiation-Emitting Products". The third column, titled "TOPICS", lists "Vaccines, Blood, and Biologics", "Animal and Veterinary", "Cosmetics", "Tobacco Products", "International Programs", "News and Events", "Training and Continuing Education", "Inspections and Compliance", and "Science and Research".

**U.S. FOOD & DRUG ADMINISTRATION** Search

**FEATURED**

- Contact FDA
- FDA Guidance Documents
- Recalls, Market Withdrawals and Safety Alerts
- Press Announcements
- Warning Letters
- Advisory Committees
- En Español

**PRODUCTS**

- Food
- Drugs**
- Medical Devices
- Radiation-Emitting Products

**TOPICS**

- Vaccines, Blood, and Biologics
- Animal and Veterinary
- Cosmetics
- Tobacco Products
- International Programs
- News and Events
- Training and Continuing Education
- Inspections and Compliance
- Science and Research





# FDA Home Page: Where to Find Resources

## NAVIGATE THE DRUGS SECTION

### [Drug Information, Safety, and Availability](#)

Medication Guides, Drug Safety Communications, Shortages, Recalls

### [Drug Approvals and Databases](#)

Drugs@FDA, Orange Book, National Drug Code, Recent drug approvals

### [Drug Development and Review Process](#)

Drug applications, submissions, manufacturing, and small business help

### [Guidance, Compliance, and Regulatory Information](#)

Guidances, warning letters, drug compounding, international information, registration and listing

### [Regulatory Science and Research](#)

CDER research programs, initiatives, and resources

### [Emergency Preparedness](#)

Prepare and respond to natural disasters, nuclear and chemical attacks

### [Updates, News, Events, and Training](#)

Recent approvals, meetings, workshops, blogs, podcasts, stay connected

### [About the Center for Drug Evaluation and Research \(CDER\)](#)

Our role, mission, organization, history, leadership, job openings

## PRIORITY AREAS & INITIATIVES

### [Coronavirus \(COVID-19\)](#)

Get the latest news and information regarding the global pandemic

### [Opioids](#)

Reducing the impact of opioid misuse and abuse

### [Generics](#)

Ensuring access to safe, affordable, and effective generic drugs

### [Warning Letters](#)

Warning and Notice of Violation Letters to Pharmaceutical Companies

### [Guidances](#)

FDA's current thinking on drug development and review activities

### [Drug Shortages](#)

Search the database, learn about root causes and potential solutions

### [Resources for You](#)

Information for consumers, health professionals, and industry

### [Disposal of Unused Medicines](#)

Learn how to properly get rid of unused or expired medication

# FDA Home Page: Where to Find Resources



## Information for Health Care Professionals | Drugs



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### Information for Health Care Professionals | Drugs

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Know Your Source:  
Protecting Patients from  
Unsafe Drugs

Global Alliance of Drug  
Information Specialists  
(GADIS)

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### Popular Topics

- [Drugs@FDA](#)
- [Orange Book](#)
- [National Drug Code Directory](#)
- [FDA Updates and Press Announcements on NDMA in Metformin](#)
- [Drug Approvals and Databases](#)
- [News & Events for Human Drugs](#)



# Drug Labeling & Information



**National Drug Code (NDC) Directory**



**DRUGS@FDA**

Search results on Proprietary Name: Prozac

Primary Name to view the label.

Primary Name	NDC
16590-843-90	STAT RX <sup>1</sup>
0777-3105-30	Dista Pl <sup>1</sup>
0777-3107-30	Dista Pl <sup>1</sup>
0777-3104-02	Dista Pl <sup>1</sup>
0777-3105-02	Dista Pl <sup>1</sup>

**Labels.fda.gov**



**President's Emergency Plan for AIDS Relief (PEPFAR)**

I need to know if an NDC number is correct? My patient's insurance rejected a claim because of the NDC number.

I went to refill a desiccated thyroid extract and the insurance won't pay because it isn't approved by FDA. Is this true? What changed?



# National Drug Code (NDC) Directory

## National Drug Code Directory



☒ Finished Products ⓘ ☐ Unfinished Products ⓘ

### NDC finished products search

Search the NDC database for finished drug products

Select Type

Enter at least three characters

Search

Clear



I need to know if an NDC number is correct? My patient's insurance rejected a claim because of the NDC number.

[www.accessdata.fda.gov/scripts/cder/ndc/index.cfm](http://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm)

# National Drug Code (NDC) Directory

Medication Properties	
Given NDC	00703-0051-01
Nonproprietary Name	Methylprednisolone acetate
Strength/Dosage form	80 mg/mL injection
Labeler Name	Teva Parenteral Medicines, Inc

## National Drug Code Directory



☒ Finished Products ⓘ 
 ☐ Unfinished Products ⓘ

NDC finished products search

Search the NDC database for finished drug products

Nonproprietary Name

methylprednisolone acetate

Search

Clear

I need to know if an NDC number is correct? My patient's insurance rejected a claim because of the NDC number.




[www.accessdata.fda.gov/scripts/cder/ndc/index.cfm](http://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm)

# National Drug Code (NDC) Directory

Example NDC: 00703-0051-01

Display 50 records per page

Search for text in the table: "80 mg/ml" "Teva"

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name
 Methylprednisolone Acetate	0703-0051-01	80 mg/mL	INJECTION, SUSPENSION	INTRA-ARTICULAR; INTRALESIONAL; INTRAMUSCULAR; SOFT TISSUE	ANDA040557	Teva Parenteral Medicines, Inc.	0703-0051	Methylprednisolone Acetate	METHYLPREDNISOLONE ACETATE
 Methylprednisolone Acetate	0703-0051-04	80 mg/mL	INJECTION, SUSPENSION	INTRA-ARTICULAR; INTRALESIONAL; INTRAMUSCULAR; SOFT TISSUE	ANDA040557	Teva Parenteral Medicines, Inc.	0703-0051	Methylprednisolone Acetate	METHYLPREDNISOLONE ACETATE
 Methylprednisolone Acetate	0703-0063-01	80 mg/mL	INJECTION, SUSPENSION	INTRALESIONAL; INTRAMUSCULAR; INTRASYNOVIAL; SOFT TISSUE	ANDA040620	Teva Parenteral Medicines, Inc.	0703-0063	Methylprednisolone Acetate	METHYLPREDNISOLONE ACETATE

I need to know if an NDC number is correct? My patient's insurance rejected a claim because of the NDC number.

[www.accessdata.fda.gov/scripts/cder/ndc/index.cfm](http://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm)

# Drugs@FDA

## Drugs@FDA: FDA-Approved Drugs

f SHARE t TWEET in LINKEDIN p PIN IT e EMAIL p PRINT

Search by Drug Name, Active Ingredient, or Application Number\*

Armour thyroid

Search

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



I went to refill a desiccated thyroid extract and the insurance won't pay because it isn't approved by FDA. Is this true? What changed?

[www.fda.gov/drugsatfda](http://www.fda.gov/drugsatfda)

# Drugs@FDA

New Drug Application (NDA): 021402  
Company: ABBVIE

## Drugs@FDA: FDA-Approved Drugs

[f SHARE](#)
[TWEET](#)
[in LINKEDIN](#)
[PIN IT](#)
[EMAIL](#)
[PRINT](#)

[Home](#) | [Previous Page](#)  
[Modify Your Search](#)

### Your Drugs@FDA Search Did Not Return Any Results

Your search may not have returned results because of one of these reasons (see [FAQ](#) for more search strategies to find approved drugs in Drugs@FDA):

- Drugs@FDA includes the drug you are looking for, but the drug's name was **not spelled correctly**. For your next search:
  - If you are not sure of the spelling of the drug name, use [Browse by Drug Name](#) on the Drugs@FDA home page to find drug names in alphabetical order.
  - If applicable, ensure that you include special characters or spaces that reside within the drug name in your search. For example, if you are searching for "H.P. ACTHAR GEL" or "X-TROZINE L.A." include the periods and/or the hyphen.
  - If you know part of the spelling of the drug name, include at least three characters from the drug name in the search box.

I went to refill a desiccated thyroid extract and the insurance won't pay because it isn't approved by FDA. Is this true? What changed?

EMAIL

#### Products on NDA 021402

CSV

Excel

Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
SYNTHROID	LEVOTHYROXINE SODIUM	0.025MG **See current Annual Edition, 1.8 Description of Special Situations, Levothyroxine Sodium	TABLET;ORAL	Prescription	AB1,AB2	Yes	No
SYNTHROID	LEVOTHYROXINE SODIUM	0.05MG **See current Annual Edition, 1.8 Description of Special Situations, Levothyroxine Sodium	TABLET;ORAL	Prescription	AB1,AB2	Yes	No
SYNTHROID	LEVOTHYROXINE SODIUM	0.075MG **See current Annual Edition, 1.8 Description of Special Situations, Levothyroxine Sodium	TABLET;ORAL	Prescription	AB1,AB2	Yes	No

#### 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
07/24/2002	ORIG-1	Approval	Type 5 - New Formulation or New Manufacturer	STANDARD	Label (PDF) Letter (PDF) Review	

[www.fda.gov/drugsatfda](http://www.fda.gov/drugsatfda)



# Labels.fda.gov

## FDA Online Label Repository

FDA Home



### IMPORTANT DISCLAIMER

Please be aware of the following when using information from this Web site:

The drug labels and other drug-specific information on this Web site represent the most recent drug listing information companies have submitted to the Food and Drug Administration (FDA). (See 21 CFR part 207.) The drug labeling and other information has been reformatted to make it easier to read but its content has neither been altered nor verified by FDA. The drug labeling on this Web site may not be the labeling on currently distributed products or identical to the labeling that is approved. Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies described in monographs. Drugs marked "OTC monograph final" or "OTC monograph not final" are not checked for conformance to the monograph. Drugs marked "unapproved medical gas", "unapproved homeopathic" or "unapproved drug other" on this Web site have not been evaluated by FDA for safety and efficacy and their labeling has not been approved. In addition, FDA is not aware of scientific evidence to support homeopathy as effective.

The device labeling and other device-specific information on this website have been voluntarily submitted to the FDA by device manufacturers. FDA has not reviewed this information prior to posting on this website. The device labeling has been reformatted to make it easier to read but its content has not been altered nor verified by FDA. The device labeling on this website may not be the labeling on currently distributed products.



Proprietary Name Search   NDC Number Search

Active Ingredient Search   Application Number or Regulatory Citation Search

Company Search   Proprietary Name and Company Search

I went to refill a desiccated thyroid extract and the insurance won't pay because it isn't approved by FDA. Is this true? What changed?

<https://labels.fda.gov/>



# Labels.fda.gov

## FDA Label Search

FDA Home



### NDC Search Results on Proprietary Name: Armour Thyroid

Click on Proprietary Name to view the label.

Proprietary Name	NDC	Company Name	Application Number or Regulatory Citation	Product Type	Marketing Category
<a href="#">Armour Thyroid</a>	71335-1153-3	Bryant Ranch Prepack		HUMAN PRESCRIPTION DRUG	unapproved drug other
<a href="#">Armour Thyroid</a>	54569-4471-0	A-S Medication Solutions LLC		HUMAN PRESCRIPTION DRUG	unapproved drug other
<a href="#">Armour Thyroid</a>	0456-0458-11	Allergan, Inc.		HUMAN PRESCRIPTION DRUG	unapproved drug other
<a href="#">Armour Thyroid</a>	63629-4368-6	Bryant Ranch Prepack		HUMAN PRESCRIPTION DRUG	UNAPPROVED DRUG OTHER
<a href="#">Armour Thyroid</a>	0456-0464-01	Allergan, Inc.		HUMAN PRESCRIPTION DRUG	unapproved drug other

**ARMOUR THYROID-** thyroid, porcine tablet  
Allergan, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. [For further information about unapproved drugs, click here.](#)

I went to refill a desiccated thyroid extract and the insurance won't pay because it isn't approved by FDA. Is this true? What changed?

<https://labels.fda.gov/>

# President's Emergency Plan for AIDS Relief (PEPFAR)

## President's Emergency Plan for AIDS Relief (PEPFAR)

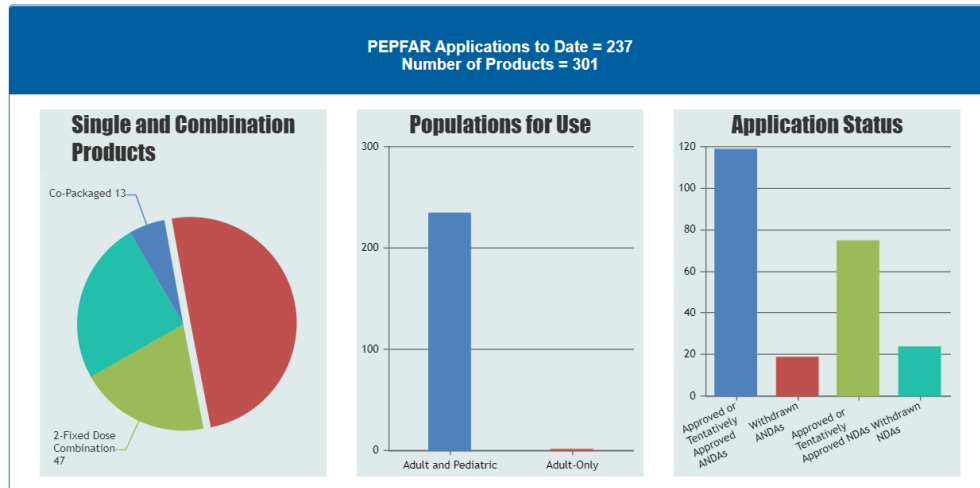
[Share](#)
[Tweet](#)
[LinkedIn](#)
[Email](#)
[Print](#)

### Explore the PEPFAR Interactive Database

Search for information about tentatively approved and approved antiretroviral drugs that are eligible for procurement under the President's Emergency Plan for AIDS Relief (PEPFAR) Program.

[PEPFAR Database](#)

As of January 29, 2020, with support from the U.S. Global AIDS Coordinator and Special Representative for Global Health Diplomacy, Ambassador Deborah L. Birx, FDA launched a new interactive [PEPFAR database](#) that provides information to the public about antiretroviral (ARV) drugs tentatively approved or approved that are eligible for procurement under PEPFAR. The new database is managed by the Center for Drug Evaluation and Research's (CDER's) Office of Communications (OCOMM), Division of Drug Information (DDI) and provides information on a mobile-friendly platform through interactive dashboards and in downloadable and searchable formats.





My patient is requesting a generic version of their inhaler, are there any therapeutically equivalent generics approved?



# Orange Book

## Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

f SHARE t TWEET in LINKEDIN p PIN IT e EMAIL p PRINT

On March 23, 2020, FDA removed from the Orange Book the listings for "biological products" that have been approved in applications under section 505 of the FD&C Act because these products are no longer "listed drugs" (see section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009).

### Find Approved Drugs

▼ Search by Proprietary Name, Active Ingredient or Application Number

ALBUTEROL SULFATE 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



My patient is requesting a generic version of their inhaler, are there any therapeutically equivalent generics approved?



[www.fda.gov/orangebook](https://www.fda.gov/orangebook)

# Orange Book

Display 50 records per page

Showing 1 to 8 of 8 entries (filtered from 123 total records)

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ALBUTEROL SULFATE	ALBUTEROL SULFATE	<a href="#">A209959</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB1			CIPLA LTD
RX	ALBUTEROL SULFATE	ALBUTEROL SULFATE	<a href="#">A207085</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB1			SANDOZ INC
RX	ALBUTEROL SULFATE	ALBUTEROL SULFATE	<a href="#">A209954</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB2			LUPIN INC
RX	ALBUTEROL SULFATE	PROAIR HFA	<a href="#">N021457</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB2	RLD	RS	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC
RX	ALBUTEROL SULFATE	PROVENTIL-HFA	<a href="#">N020503</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB1	RLD	RS	KINDEVA DRUG DELIVERY LP
RX	ALBUTEROL SULFATE	VENTOLIN HFA	<a href="#">N020983</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	BX	RLD	RS	GLAXOSMITHKLINE INTELLECTUAL PROPERTY LTD ENGLAND
DISCN	ALBUTEROL SULFATE	ALBUTEROL SULFATE	<a href="#">A203760</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH				PADAGIS US LLC
DISCN	ALBUTEROL SULFATE; IPRATROPIUM BROMIDE	COMBIVENT	<a href="#">N020291</a>	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH; 0.018MG/INH				BOEHRINGER INGELHEIM PHARMACEUTICALS INC
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	>RLD	RS	Applicant Holder



My patient is requesting a generic version of their inhaler, are there any therapeutically equivalent generics approved?

[www.fda.gov/orangebook](http://www.fda.gov/orangebook)

# Purple Book

## Purple Book Database of Licensed Biological Products

The Purple Book database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products.

The Purple Book also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER).

Enter a product's proprietary (brand) name or the nonproprietary (proper) name to find biological products. As you type, a list of potential results will begin to appear below the search box based on what you are typing. Click on a product from the auto-populated results list below to view the results page. The results page for your selected product will include all biological products that share a core name (i.e., biosimilar, interchangeable, reference, and related biological products).

Q	adalimumab
<i>Abrilada (adalimumab-afzb)</i>	351(k) Biosimilar
<i>Amjevita (adalimumab-atto)</i>	351(k) Biosimilar
<i>Cyltezo (adalimumab-adbm)</i>	351(k) Interchangeable
<i>Hadlima (adalimumab-bwwd)</i>	351(k) Biosimilar
<i>Hulio (adalimumab-fkjp)</i>	351(k) Biosimilar
<i>Humira (adalimumab)</i>	351(a)
<i>Hyrimoz (adalimumab-adaz)</i>	351(k) Biosimilar
<i>Yusimry (adalimumab-aqvh)</i>	351(k) Biosimilar

### Biosimilar(s)


Proprietary Name

*Abrilada*

Proper Name

*adalimumab-afzb*



 PRODUCT LABEL


Proprietary Name

*Amjevita*

Proper Name

*adalimumab-atto*



 PRODUCT LABEL


Proprietary Name

*Hadlima*

Proper Name

*adalimumab-bwwd*



 PRODUCT LABEL

### Interchangeable(s)


Proprietary Name

*Cyltezo*

Proper Name

*adalimumab-adbm*



 PRODUCT LABEL

### Reference Product(s)


Proprietary Name

*Humira*

Proper Name

*adalimumab*



 PRODUCT LABEL

# Purple Book

**FDA Drug Topics: Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources – January 25, 2022**

View the **free**  
**Home Study CE Webinar**  
@ [www.fda.gov/DDIwebinars](http://www.fda.gov/DDIwebinars)

Health care providers can be confident the biosimilar provides the same safety and effectiveness as the reference product.

Videos, Fact Sheets, Infographics, and Stakeholder Toolkit @ [www.fda.gov/drugs/biosimilars/health-care-provider-materials](http://www.fda.gov/drugs/biosimilars/health-care-provider-materials)



## Searching for Drug Shortages & Recalls



**Drug Shortages**



**Drug Recalls**

I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?



# Drug Shortages

## FDA Drug Shortages

[f SHARE](#) [TWEET](#) [in LINKEDIN](#) [PIN IT](#) [EMAIL](#) [PRINT](#)

### Current and Resolved Drug Shortages and Discontinuations Reported to FDA

[Report a Drug Shortage](#) | [Contact Us](#) | [FAQ](#) | [Background Info](#) | [Get Email Alerts](#) | [Download Current Drug Shortages](#)

Search by Generic Name or Active Ingredient:

Current/Resolved Shortages

Discontinuations

Therapeutic Categories

New and Updated

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.

Show  entries

Search:



I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?

[www.fda.gov/drug-shortages](http://www.fda.gov/drug-shortages)

# Drug Shortages

## Results for: epinephrine

- [Bupivacaine Hydrochloride and Epinephrine Injection](#) (Currently in Shortage)
- [Epinephrine Injection, 0.1 mg/mL](#) (Currently in Shortage)
- [Epinephrine Injection, Auto-Injector](#) (Currently in Shortage)
- [Lidocaine Hydrochloride \(Xylocaine\) Injection with Epinephrine](#) (Currently in Shortage)

## Epinephrine Injection, Auto-Injector

**Status:** Currently in Shortage

» **Date first posted:** 05/09/2018

» **Therapeutic Categories:** Pulmonary/Allergy

Adamis Pharmaceuticals Corporation (Reverified 12/17/2019)

Impax Laboratories (Revised 04/28/2021)

### Company Contact Information:

877-99-Impax(46729); option 2

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
0.15 mg/0.15 mL epinephrine injection, USP, pre-filled auto-injector (two pack)(NDC 0115-1695-49)	On allocation to current customers.	<a href="#">Dear Healthcare Provider Letter</a> <a href="#">Patient Inspection Instructions</a>	Manufacturing delays
0.3 mg/0.3 mL epinephrine injection, USP, pre-filled auto-injector (two pack)(NDC 0115-1694-49)	On allocation to current customers.	<a href="#">Important Safety Information for Healthcare Providers</a> <a href="#">Important Safety Information for Consumers</a>	Manufacturing delays

Kaleo (Reverified 01/27/2021)

Mylan Specialty, a Viatris Company (Reverified 03/25/2022)

I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?

[www.fda.gov/drug-shortages](http://www.fda.gov/drug-shortages)

# Drug Shortages

Mylan Specialty, a Viatris Company (Reverified 03/25/2022)

## Company Contact Information:

800-796-9526

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
0.3 mg EpiPen® (NDC 49502-500-02); Authorized Generic (NDC 49502-102-02)	Available	Product is readily available and not currently in shortage. <u>Dear Healthcare Provider Letter: Important Safety Information This letter is to communicate important safety information and is not a recall of the product.</u>	
0.15 mg EpiPen® (NDC 49502-501-02); Authorized Generic (NDC 49502-101-02)	Available	Product is readily available and not currently in shortage. <u>Dear Healthcare Provider Letter: Important Safety Information This letter is to communicate important safety information and is not a recall of the product.</u>	



March 23, 2020

## Important Prescribing Information

**Subject:** Important Safety Information on the EpiPen® and EpiPen Jr® Auto-Injectors and their authorized generic versions:

- Risk of device failure due to spontaneous activation.
- Difficulty removing the device from the carrier tube may also occur.
- Use errors.

These issues could delay or prevent emergency treatment when needed.

Dear Healthcare Provider,

The purpose of this letter is to inform you that the administration of EpiPen® 0.3 mg and EpiPen Jr® 0.15 mg Auto-Injectors and the authorized generic versions (referenced collectively as EpiPen in the remainder of this letter) may be delayed or prevented during an emergency due to:

1. Device failure from spontaneous activation caused by using a sideways force to remove the blue safety release.
2. Device failure from inadvertent or spontaneous activation due to a raised blue safety release
3. Difficulty removing the device from the carrier tube.
4. Certain identified use errors.

I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?

[www.fda.gov/drug-shortages](http://www.fda.gov/drug-shortages)

# Drug Recalls

## Recalls, Market Withdrawals, & Safety Alerts

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### Search

Showing 1 to 5 of 5 entries

[Export Excel](#)
 Show  entries

### Filter by

#### Product Type

Drugs

#### Terminated Recall

- Any -

A Terminated Recall is a recall where the FDA has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard. Recalls that are not indicated as being terminated are either ongoing or completed.

Clear Filters

Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Excerpt
03/22/2022	Adamis Pharmaceuticals Corporation	SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg (0.3 mg/0.3 mL) Pre-Filled Single-Dose Syringes	Drugs	Potential clogging of the needle preventing the dispensing of epinephrine	... ADMP is voluntarily recalling certain lots of SYMJEPI (epinephrine) Injection 0.15 mg (0.15 mg/0.3 mL) and 0.3 mg ... clogging of the needle preventing the dispensing of epinephrine. US WorldMed (USWM) exclusively markets and ... and/or anaphylaxis and is unable to access life-saving epinephrine due to the syringe malfunction, it can lead to ...

I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?

[www.fda.gov/drug-recalls](http://www.fda.gov/drug-recalls)

# Drug Recalls

COMPANY ANNOUNCEMENT

## Adamis Pharmaceuticals Corporation Issues Nationwide Voluntary Recall of SYMJEPI® (Epinephrine) Injection for Potential Manufacturing Defect

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service.  
FDA does not endorse either the product or the company.

Read Announcement

View Product Photos



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I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?

[www.fda.gov/drug-recalls](https://www.fda.gov/drug-recalls)

# Drug Recalls

## Enforcement Reports



View Weekly  
Enforcement Reports

Search  
Enforcement Reports

- [What is the Enforcement Report?](#)
- [What is a pending recall classification?](#)
- [What is the History feature?](#)
- [How are recalls categorized in the Enforcement Reports?](#)
- [How else does FDA provide early notification about recalls?](#)
- **New!!** [How do I subscribe to the Enforcement Report mailing list?](#)
- [What if I have additional questions about Enforcement Reports?](#)
- [Where do I find Additional Resources about Enforcement Reports?](#)

### U.S. Food and Drug Administration Recall Information Search

Weekly Enforcement Report

Quick Search

Advanced Search

Product Description:

epinephrine

Product Type:

Drugs

Recalling Firm:

Recall Number:

Classified From Date:

mm/dd/yyyy

Oldest Date Available is 06/08/2012

Classified To Date:

mm/dd/yyyy

Code Information:

Recall Class:

Select options

Status:

Select options

Reason for Recall:

Event ID:

Product Type	Recently Updated Record**	Product Description	Classification	Code Information	Reason for Recall	Recalling Firm
Drugs	No	Epinephrine Injection, USP, 1:1000 (1 mg/mL), 25 x 1 mL Ampules, For SC and IM Use, For IV and IC Use after Dilution, Rx Only, American Regent, Inc., Shirley, NY 11967 --NDC 0517-1071-25	Class II	Lot #1395 Exp: July 2012	Presence of Particulate Matter	Luitpold Pharmaceuticals, Inc. One Luitpold Drive P.O. Box 9001 Shirley, Drugs NY

I'm reading conflicting reports regarding epinephrine auto-injectors, is there a shortage or a recall?

[www.fda.gov/drug-recalls](http://www.fda.gov/drug-recalls)



My patient experienced an arrhythmia while taking a prescription drug, could this be attributed to the medication?

What safety information does the FDA have regarding compounded drug products?





# Drug Safety Communications



## Drug Safety Communications

Subscribe to Email Updates



### Current Drug Safety Communications

- 2/3/2022 [FDA investigating possible increased risk of death with lymphoma medicine Ukoniq \(umbralisib\)](#)
- 1/12/2022 [FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain](#)
- 11/02/2021 [FDA warns that getting alcohol-based hand sanitizer in the eyes can cause serious injury](#)
- 9/01/2021 [FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions](#)
- 7/20/2021 [FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins](#)

### Previous Drug Safety Communications

- [2022 Drug Safety Communications](#)
- [2021 Drug Safety Communications](#)

My patient experienced an arrhythmia while taking a prescription drug, could this be attributed to the medication?

## 2021 Drug Safety Communications



- [FDA warns that getting alcohol-based hand sanitizer in the eyes can cause serious injury](#)
- [FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions](#) 9/01/21
- [FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins](#) 7/20/2021
- [FDA warns that vapors from alcohol-based hand sanitizers can have side effects](#) 6/16/2021
- [Due to risk of serious liver injury, FDA restricts use of Ocaliva \(obeticholic acid\) in primary biliary cholangitis \(PBC\) patients with advanced cirrhosis](#) 5/26/2021
- [Studies show increased risk of heart rhythm problems with seizure and mental health medicine lamotrigine \(Lamictal\) in patients with heart disease](#) 3/31/2021

[www.fda.gov/drugsafetycommunications](https://www.fda.gov/drugsafetycommunications)

# Drug Safety-related Labeling Changes (SrLC)

## Drug Safety-related Labeling Changes (SrLC)

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[Get Email Alerts](#) [Guide](#)

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

### Date Search

For Safety-related Labeling Changes before January 1, 2016 see the [MedWatch Safety Labeling Page](#)

Date Range:

01/01/2022

03/28/2022

Labeling Section:

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

Search

Reset

My patient experienced an arrhythmia while taking a prescription drug, could this be attributed to the medication?

[www.fda.gov/SLC](https://www.fda.gov/SLC)

# Drug Safety-related Labeling Changes (SrLC)



## Drug Safety-related Labeling Changes (SrLC)

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Search Results for: Active Ingredient: LAMOTRIGINE

Filter results:

PDF

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CSV

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Drug Name	Active Ingredient	Application Number	Application Type	Supplement Date
<a href="#">LAMICTAL</a>	LAMOTRIGINE	020241	NDA	03/31/2021
Database Updated 04/02/2021				
<a href="#">LAMICTAL CD</a>	LAMOTRIGINE	020764	NDA	03/31/2021
<a href="#">LAMICTAL ODT</a>	LAMOTRIGINE	022251	NDA	03/31/2021
<a href="#">LAMICTAL XR</a>	LAMOTRIGINE	022115	NDA	03/31/2021

LAMICTAL (NDA-020241)

(LAMOTRIGINE)

Safety-related Labeling Changes Approved by FDA Center for Drug Evaluation and Research (CDER)

[Download Data](#)

[Expand all](#)

03/31/2021 (SUPPL-64)

[Approved Drug Label \(PDF\)](#)

### 5 Warnings and Precautions

#### 5.4 Cardiac Rhythm and Conduction Abnormalities

*(Additions and/or revisions underlined)*

In vitro testing showed that LAMICTAL exhibits Class IB antiarrhythmic activity at therapeutically relevant concentrations [see *Clinical Pharmacology* (12.2)]. Based on these in vitro findings, LAMICTAL could slow ventricular conduction (widen QRS) and induce proarrhythmia, which can lead to sudden death, in patients with clinically important structural or functional heart disease (i.e., patients with heart failure, valvular heart disease, congenital heart disease, conduction system disease, ventricular arrhythmias, cardiac channelopathies (e.g., Brugada syndrome), clinically important ischemic heart disease, or multiple risk factors for coronary artery disease). Any expected or observed benefit of LAMICTAL in an individual patient with clinically important structural or functional heart disease must be carefully weighed against the risks for serious arrhythmias and/or death for that patient. Concomitant use of other sodium channel blockers may further increase the risk of proarrhythmia.

My patient experienced an arrhythmia while taking a prescription drug, could this be attributed to the medication?

[www.fda.gov/SLC](http://www.fda.gov/SLC)

# Compounding Risk Alerts

## Compounding Risk Alerts



Many serious patient illnesses and deaths linked to poor quality compounded drugs have occurred since the 2012 fungal meningitis outbreak. FDA issues compounding risk alerts to inform health care professionals, compounders and consumers about risks associated with compounded drugs, including information on adverse events, outbreaks or product quality. These are intended to alert stakeholders of the risks so that practitioners can more effectively protect patients from unsafe, ineffective and poor-quality compounded medicines.

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

- [FDA alerts health care professionals of potential risks associated with compounded ketamine nasal spray](#) (February 16, 2022)
- [FDA highlights concerns with compounding of drug products by medical offices and clinics under insanitary conditions](#) (October 25, 2021)
- [FDA alerts health care professionals and compounders of potential risks associated with the compounding of remdesivir drug products](#) (February 4, 2021)
- [FDA alerts health care professionals of risks associated with intraocular use of compounded moxifloxacin](#) (August 12, 2020)
- [FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables](#) (June 7, 2019)



## FDA alerts health care professionals of potential risks associated with compounded ketamine nasal spray



February 16, 2022

### Background

FDA has become aware of safety reports involving compounded intranasal ketamine to treat psychiatric disorders which may be putting patients at risk. Compounded drugs are not FDA-approved, which means FDA has not evaluated their safety, effectiveness, or quality prior to marketing.

Ketamine hydrochloride<sup>[a]</sup> (tradename: Ketalar) is a Schedule III controlled substance that is FDA-approved as an intravenous or intramuscular injection solution for induction and maintenance of general anesthesia. Ketamine is a racemic mixture consisting of two mirror image molecules, R- and S-ketamine. FDA-approved labeling for ketamine contains warnings and precautions on hemodynamic instability, emergence reactions (vivid dreams, hallucinations, or delirium), respiratory depression, and drug-induced liver injury, among others.

What safety information does the FDA have regarding compounded drug products?

[www.fda.gov/compounding](https://www.fda.gov/compounding)

# FDA's MedWatch Program



Reports about problems with medical products come **IN**

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

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MedWatch, the FDA's medical product safety reporting program for health professionals, patients and consumers.

Report a Problem

Safety Information

Stay Informed

### MedWatch Online Voluntary Reporting Form

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### Welcome

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA. Voluntary reporting can help FDA identify unknown risk for approved medical products. Reporting can be done through our online reporting portal or by downloading, completing and then submitting FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient) to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

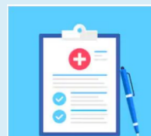
#### Begin Online Report



Health Professional  
(FDA Form 3500)



Consumer/Patient  
(FDA Form 3500B)



Continue an incomplete report

En español para el  
consumidor / paciente  
(formulario 3500B de la FDA)

Click here to continue filling out an incomplete report. You will need Report ID and Report Date. You will have 3 days to complete this report from the start date.

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)

# FDA's MedWatch Program

FDA

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

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*MedWatch*, the FDA's medical product safety reporting program for health professionals, patients and consumers.

🚑 Report a Problem

ℹ Safety Information

✉ Stay Informed

## Subscribe to MedWatch Safety Alerts

*Medical product safety information delivered to you via e-mail, Twitter, or RSS*

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## Stay Informed: Timely Safety Information Delivered To You

FDA MedWatch offers several ways to help you stay informed about the medical products you prescribe, administer, or dispense every day: e-mail (MedWatch E-list), Twitter, and RSS. [Learn more about the MedWatch E-list](#)

## Follow MedWatch on Twitter @FDAMedWatch

🐦 Follow MedWatch on Twitter

## MedWatch RSS Feed

Safety alerts delivered to your desktop or web page. To subscribe, copy and paste the address of the MedWatch RSS Feed to your RSS reader software or browser:

📡 MedWatch RSS Feed

[www.fda.gov/medwatch](http://www.fda.gov/medwatch)



Where can I find the most up-to-date Medication Guide for a particular medication?

I'm dispensing a drug product and understand the REMS program was recently updated; how do I view the changes to see if there are new requirements?



# Medication Guides

## Medication Guides

Providing information on proper drug use, safety, and storage

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[Search the Medication Guides Database](#)

Search:

### What are Medication Guides?

Medication Guides are paper handouts that come with many prescription medicines. The guides address issues that are specific to particular drugs and drug classes, and they contain FDA-approved information that can help patients avoid serious adverse events.

### Why do some medicines have Medication Guides?

FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that:

- certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or
- patient adherence to directions for the use of a product are essential to its effectiveness.

Drug Name	Active Ingredient	Form;Route
<a href="#">Cipro</a>	Ciprofloxacin	INJECTABLE;INJECTION
<a href="#">Cipro</a>	Ciprofloxacin Hydrochloride	TABLET;ORAL
<b>Appl. No.</b> 019537 <b>Company</b> BAYER HLTHCARE <b>Date</b> 07/26/2017		
<a href="#">Cipro</a>	Ciprofloxacin	FOR SUSPENSION;ORAL
<a href="#">Cipro in Dextrose 5% in Plastic Container</a>	Ciprofloxacin	INJECTABLE;INJECTION

Where can I find the most up-to-date Medication Guide for a particular medication?

[www.fda.gov/drugs/drug-safety-and-availability/medication-guides](http://www.fda.gov/drugs/drug-safety-and-availability/medication-guides)



# Risk Evaluation and Mitigation Strategy (REMS)

## REMS@FDA

[Contact Us](#) | [REMS Resources](#)

[Get REMS Email Alerts](#) | [Reports & Data Files](#) | [REMS Public Dashboard \(NEW\)](#)

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

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 is available in downloadable: [data files](#).

The REMS@FDA webpage is currently undergoing maintenance. As a result, any changes or updates to REMS will not be reflected on this website until after 04/08/2022.

Thank you for your patience.

[Excel](#)
[CSV](#)
[Print](#)

Name ▲	REMS Approved ▲	Last Updated ▲	MedGuide (MG)* ▲	Comm. Plan (CP) ▲	ETASU ▲	Imp. System (IS) ▲
<a href="#">Isotretinoin iPLEDGE</a> Shared System REMS	10/22/2010	10/08/2021			<a href="#">ETASU</a>	IS

I'm dispensing a drug product and understand the REMS program was recently updated; how do I view the changes to see if there are new requirements?

[www.fda.gov/REMS](http://www.fda.gov/REMS)

# Risk Evaluation and Mitigation Strategy (REMS)

## Isotretinoin iPLEDGE

Shared System REMS

REMS last update: 10/08/2021


[Products](#) [Goals](#) [Summary](#) [REMS Materials](#) [Update history](#)

### 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 application holder(s) REMS Website or the approved REMS materials for more information.

[View application holder\(s\) REMS Website](#)

- + Healthcare providers who prescribe isotretinoin must:
- + Patients who can become pregnant who are prescribed isotretinoin:
- + Patients who cannot become pregnant who are prescribed isotretinoin:
- + Pharmacies that dispense isotretinoin must:
- + Wholesaler-distributors that distribute isotretinoin must:



I'm dispensing a drug product and understand the REMS program was recently updated; how do I view the changes to see if there are new requirements?

[www.fda.gov/REMS](http://www.fda.gov/REMS)


# Risk Evaluation and Mitigation Strategy (REMS)

## Isotretinoin iPLEDGE

Shared System REMS

REMS last update: 10/08/2021

Products	Goals	Summary	REMS Materials	Update history
<b>What updates have been made to the REMS?</b>				
Date	Summary of change			
10/08/2021	<p>Modified to:</p> <ul style="list-style-type: none"><li>• Remove the Medication Guide as an element of the Risk Evaluation and Mitigation Strategy (REMS)</li><li>• Make changes to the REMS document and appended materials to align with labeling changes related to gender neutral patient risk categories</li><li>• Make changes to the REMS appended materials to reduce redundancy and streamline the content</li><li>• Make changes to the pharmacy operations to verify safe use conditions for the REMS risk management authorization</li><li>• Add an optional quick reference (QR) code for use by patients enrolled in the REMS</li><li>• Convert the REMS Document to the new, standardized format</li></ul>			



I'm dispensing a drug product and understand the REMS program was recently updated; how do I view the changes to see if there are new requirements?

[www.fda.gov/REMS](https://www.fda.gov/REMS)

# Risk Evaluation and Mitigation Strategy (REMS)



## iPLEDGE Risk Evaluation and Mitigation Strategy (REMS)



Postmarket Drug Safety  
Information for Patients and  
Providers

[Index to Drug-Specific  
Information](#)

### iPLEDGE REMS Program for Isotretinoin Products


The iPLEDGE Program was originally implemented in early 2005 and approved as the iPLEDGE REMS in 2010. The goals of the iPLEDGE REMS are to prevent fetal exposure to [isotretinoin](#) and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. It is a "shared system" REMS, meaning that it includes all FDA-approved isotretinoin products. It provides a centralized system for prescribers, pharmacies, and patients to manage patient risk, regardless of which isotretinoin product is being used.

In an effort to provide timely isotretinoin information to prescribers, pharmacies, patients, and distributors, the FDA will post any related updates on isotretinoin and the iPLEDGE REMS on this page.

Please see the [iPLEDGE REMS website](#) , for up-to-date and detailed information about the program.

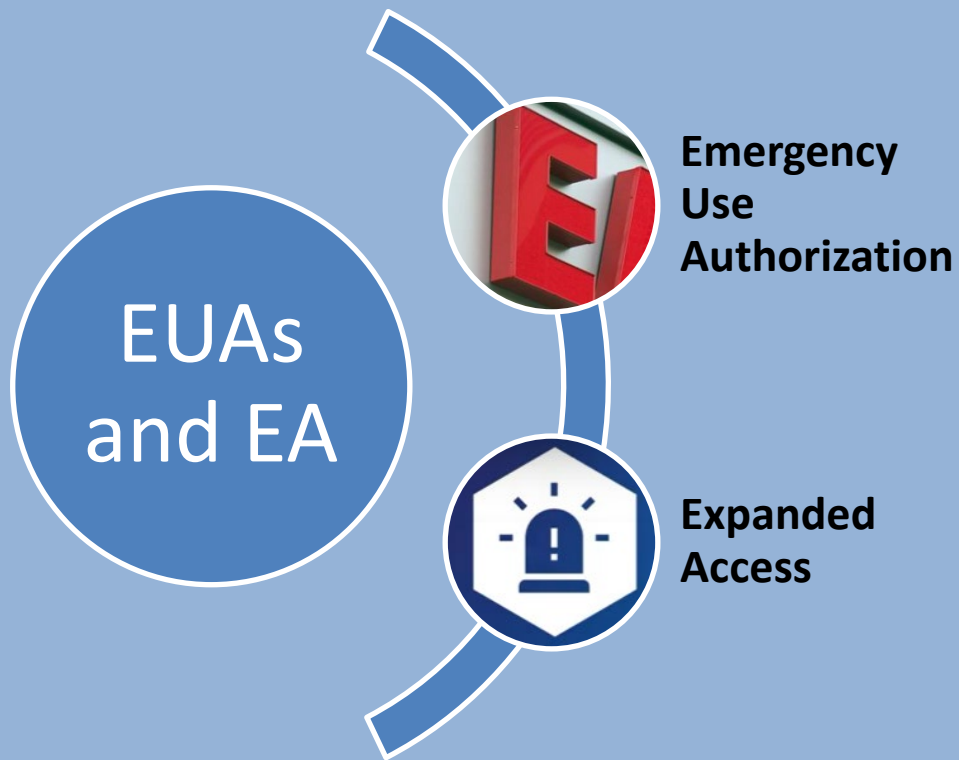
Content current as of:  
01/14/2022

Regulated Product(s)  
Drugs



I'm dispensing a drug product and understand the REMS program was recently updated; how do I view the changes to see if there are new requirements?

[www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/pledge-risk-evaluation-and-mitigation-strategy-rems](https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/pledge-risk-evaluation-and-mitigation-strategy-rems)



I heard that some of the monoclonal antibodies authorized to treat COVID-19 have limited use currently. Where can I find additional information?



# Emergency Use Authorization

## Emergency Use Authorization



### On this page:

- [About Emergency Use Authorizations \(EUAs\)](#)
- [PREP Act](#)
- [EUA Guidance](#)
- [COVID-19 EUAs](#)
  - [Vaccines](#)
  - [Drugs and Non-Vaccine Biological Products](#)
  - [Information About COVID-19 EUAs for Medical Devices](#)
- [Other Current EUAs](#)
- [Related Links](#)

### Drugs and Non-Vaccine Biological Products

The HHS Secretary declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, effective March 27, 2020. The EUAs subsequently issued by FDA are listed in the table below this blue box.

- [Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564\(b\) of the FD&C Act](#) (February 4, 2020)
- [Emergency Use Authorization Declaration](#) (March 27, 2020)

Related information: [FDA Combating COVID-19 With Therapeutics](#) (PDF, 610 KB)

#### COVID-19 EUA FAERS Public Dashboard

The dashboard provides weekly updates of adverse event reports submitted to FAERS for drugs and therapeutic biological products used under EUA during the COVID-19 public health emergency. After launching the [FAERS Public Dashboard](#), click on the COVID-19 EUA link at the top of the home page to open the COVID-19 EUA FAERS Public Dashboard.

#### Federal Register notices:

[Office of the Assistant Secretary for Preparedness and Response \(ASPR\) Important Updates: COVID-19 Therapeutics](#)

[www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)

I heard that some of the monoclonal antibodies authorized to treat COVID-19 have limited use currently. Where can I find additional information?

# Emergency Use Authorization

05/26/2021

[Sotrovimab](#) (375KB) (reissued October 8, 2021, December 16, 2021 and February 23, 2022)

[Letter Granting EUA Amendment](#) (December 22, 2021) (161KB)

**[Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant](#)**

Important updates about [sotrovimab](#) (ASPR)

For the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

**Due to the high frequency of the Omicron BA.2 sub-variant, sotrovimab is not currently authorized in any U.S. region. Therefore, sotrovimab may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.**

[Healthcare Providers](#) (1.38MB) (updated March 25, 2022)

- [Spanish](#) (770KB, November 3, 2021)

[Patients, Parents, and Caregivers](#) (352KB) (updated February 23, 2022)

- [Spanish](#) (122KB, November 3, 2021)

[Frequently Asked Questions on the Emergency Use Authorization of Sotrovimab](#) (257KB) (updated March 25, 2022)

[CDER Scientific Review Documents Supporting EUA](#)

I heard that some of the monoclonal antibodies authorized to treat COVID-19 have limited use currently. Where can I find additional information?

[www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)

# Emergency Use Authorization

## CDER Scientific Review Documents Supporting Emergency Use Authorizations for Drug and Biological Therapeutic Products | COVID-19


### Sotrovimab

EUA Action	Action Date	CDER Review Document
Original authorization	5/26/2021	<a href="#">CDER Review (2 MB)</a>

Emergency Use Authorization (EUA) for Sotrovimab 500 mg  
Center for Drug Evaluation and Research (CDER) Review

**Identifying Information**

Application Type (EUA or Pre-EUA) If EUA, designate whether pre-event or intra-event EUA request.	EUA
EUA Application Number(s)	EUA 000100
Sponsor (entity requesting EUA or pre-EUA consideration), point of contact, address, phone number, fax number, email address	<p><u>EUA Sponsor</u> GlaxoSmithKline Research &amp; Development Limited 980 Great West Road Brentford Middlesex, TW8 9GS UK</p> <p><u>GSK US Point of Contact</u> Debra H. Lake, M.S. Sr. Director Global Regulatory Affairs GlaxoSmithKline 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709-3398 Email: [REDACTED] Phone: [REDACTED]</p>
Manufacturer, if different from Sponsor	GlaxoSmithKline, Parma.
Submission Date(s)	Part 1: March 24, 2021 Part 2: March 29, 2021
Receipt Date(s)	Part 1: March 24, 2021 Part 2: March 29, 2021
OND Division / Office	Division of Antivirals /Office of Infectious Disease



I heard that some of the monoclonal antibodies authorized to treat COVID-19 have limited use currently. Where can I find additional information?

[www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological](https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)



# Expanded Access

## Expanded Access



Sometimes called “compassionate use”, expanded access is a potential pathway for a patient with an [immediately life-threatening condition or serious disease or condition](#) to gain access to an [investigational medical product](#) (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product’s development or marketing approval for the treatment indication.



## Information for Patients, Physicians and Industry

### Patients

Learn about expanded access, including information about the expanded access process, what FDA considers, and what costs may be involved.

### Physicians

Learn about expanded access, including information about the different types of expanded access, how to submit expanded access requests, and reporting requirements.

### Industry

Learn about expanded access, including information about posting your expanded access policy, how to submit expanded access requests, and reporting requirements.

### Forms

Learn about how to complete and submit forms needed for each type of expanded access request.

[www.fda.gov/expanded-access](https://www.fda.gov/expanded-access)

# Expanded Access



## Expanded Access | Information for Physicians



What are the roles and responsibilities? ▼

What are the different types of expanded access? ▼

What is the licensed physician's role in the expanded access process? ▼

What are the reporting requirements for Sponsor-Investigators of expanded access? ▼

How do Sponsor-Investigators submit expanded access requests and reports to FDA? ▼

### Additional resources

[21 CFR 312 Subpart I](#)

Learn more about FDA's current expanded access regulations for investigational drugs (including biologics).

[21 CFR 812.35](#) - [21 CFR 812.36](#)

Learn more about FDA's regulations supporting investigational device expanded access.

### Clinical Trial Information

- Search for possible clinical trials you may qualify for by using our [clinical trials search tool](#) or visiting [www.clinicalTrials.gov](http://www.clinicalTrials.gov).

### Expanded Access Search Tools

- [Reagan-Udall Foundation's Expanded Access Navigator](#)

### Form and Letter Resources

- [How to submit an expanded access request \(form\)](#) provides step-by-step instructions for expanded access submissions for investigational drugs and biologics

[www.fda.gov/expanded-access](http://www.fda.gov/expanded-access)

# Expanded Access

## For Physicians and Healthcare Providers

The EA Navigator helps you explore options for accessing investigational treatments. First, you must identify investigational treatments appropriate for your patient and search for related clinical trials. If you've already done this and ruled out clinical trials as an option, you may want to go directly to sections of the EA Navigator that explain expanded access and the single-patient expanded access request process.

### Guide for Physicians and Other Healthcare Providers

- Identifying Treatment
- Exploring Clinical Trials
- Considering EA Programs
- Considering Single-Patient EA
- Requesting EA
- Submitting to the FDA
- Seeking IRB Approval
- Treating and Reporting



Investigational treatments may be appropriate if your patient has no available treatment, has exhausted all FDA-approved options or has no available treatment, as is the case for 95% of the 7,000 known rare diseases. There are several ways to research investigational treatments and this tool allows you to skip ahead to different stages of the process if you do not need to scroll through all the pages.

<https://navigator.reaganudall.org/physicians-and-healthcare-providers>

# Expanded Access



## FDA Drug Info Rounds Expanded Access Video Series

Welcome to the FDA Drug Info Rounds Expanded Access (EA) Video series. Expanded access is a program regulated by FDA through which manufacturers can provide investigational medical products to patients for treatment use. Expanded access can provide seriously ill patients with access to investigational treatments when they have no other options and they are willing to accept greater risk.

This series of videos provides an introduction to EA, instructions on submitting a single patient investigational new drug application, and tutorials on completing Form FDA 3926 for initial and follow-up submissions.

### Videos

- **[Expanded Access Part 1: Introduction](#)**  
An introduction to Expanded Access for investigational medical products
- **[Expanded Access Part 2: How to Submit a Single Patient IND](#)**  
An overview on the submission process for emergency and non-emergency expanded access applications.
- **[Expanded Access Part 3: How to Complete Form FDA 3926 for Initial Submissions](#)**  
Provides instructions on completing Form FDA 3926, a one-page form, front and back for initial submissions.
- **[Expanded Access Part 4: How to Complete Form FDA 3926 for Follow-up Submissions](#)**  
Provides instructions on completing Form FDA 3926 for follow-up submissions.

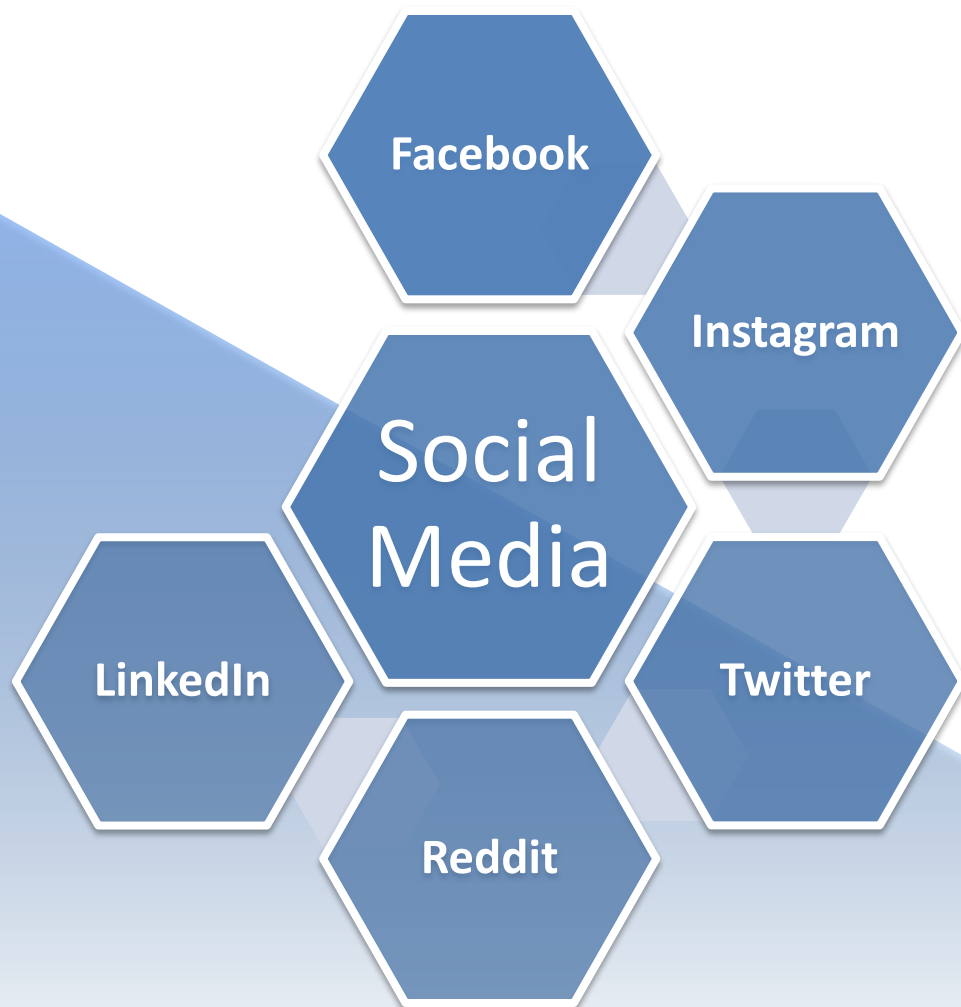
## Expanded Access Part 1: Introduction (May 2019)

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)



What is Expanded Access? FDA Chief Project Manager Monica Hughes discusses a potential pathway for a seriously ill patient to gain access to an investigational medical product when they have no other options and are willing to accept greater risk.

[www.fda.gov/drugs/information-health-care-professionals-drugs/fda-drug-info-rounds-expanded-access-video-series](https://www.fda.gov/drugs/information-health-care-professionals-drugs/fda-drug-info-rounds-expanded-access-video-series)



# Facebook | Instagram



U.S. Food and Drug Administration

April 1 at 9:00 AM · 🌐

This [#AprilFools](#) and every other day, don't be fooled by health fraud during the pandemic. We're still monitoring for any firm marketing products with fraudulent [#COVID19](#) prevention and treatment claims. <https://bit.ly/3DkRLGU>



[www.facebook.com/FDA](https://www.facebook.com/FDA)



Whether at your local pharmacy or the FDA, pharmacists are a bridge between you and your prescriber by helping to ensure you achieve the best possible outcome when taking medications.

Take time to thank a pharmacist today!

[#NationalPharmacistDay](#)

[www.instagram.com/FDA](https://www.instagram.com/FDA)

# Twitter | Reddit

## @FDA\_Drug\_Info | @FDA\_CDOR



**Twitter Direct Message**

AAPA, PCMA, ACP, ACCP, AMA, Mental...

Shared. Thank you

1

AOA · 10:19 AM

Done! Thanks.

1

NCPA · 10:29 AM

Shared, thanks!

1

ASHP · 11:18 AM

Shared! Thanks for passing along.

1

National Association of Boards of Pharmacy · 11:57 AM

APHA HQ Retweeted

**FDA Drug Information** @FDA\_Drug\_Info · Sep 16

REMINDER: Prescribers and Pharmacies must re-certify in the Clozapine REMS by Nov 15, 2021 to continue to prescribe or dispense clozapine.

To re-certify, see the Important Program Update at [clozapinerems.com](https://www.clozapinerems.com)

NCPA Retweeted

**FDA Drug Information** @FDA\_Drug\_Info · Sep 16

REMINDER: Prescribers and Pharmacies must re-certify in the Clozapine REMS by Nov 15, 2021 to continue to prescribe or dispense clozapine.

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National Association of Boards of Pharmacy Retweeted

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ASHP Retweeted

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To re-certify, see the Important Program Update at [clozapinerems.com](https://www.clozapinerems.com)

**/r/pharmacy Reddit**

r/pharmacy · Posted by u/FDA

42

**Do you dispense clozapine?**

FDA approved a modification to the Clozapine REMS that will go into effect on Nov 15, 2021. Pharmacies must re-certify in the Clozapine REMS by then to continue to dispense the medication.

To re-certify, see the Important Program Update at [www.clozapinerems.com](https://www.clozapinerems.com).

6 Comments Share Save Hide Report 100% Upvoted

**FDA\_CDOR** · 11d

Starting Nov 15, 2021, you can no longer use the switch system to obtain a dispense authorization for clozapine. You can obtain it via <https://www.clozapineREMS.com> or by calling the Clozapine REMS Call Center at 888-586-0758.

7 Reply Share Report Save

[www.twitter.com/fda\\_drug\\_info](https://www.twitter.com/fda_drug_info)

[www.reddit.com/r/pharmacy/](https://www.reddit.com/r/pharmacy/)



# Twitter

## @FDACDERDirector



CENTER FOR DRUG EVALUATION AND RESEARCH



**Dr. Patrizia Cavazzoni** ✓  
@FDACDERDirector

Official Twitter account for the Director of FDA's Center for Drug Evaluation and Research (CDER). Privacy Policy - [fda.gov/privacy](https://www.fda.gov/privacy)

📍 Silver Spring, MD 🔗 [fda.gov/drugs](https://www.fda.gov/drugs) 📅 Joined October 2020

55 Following 2,990 Followers

Tweets Tweets & replies Media Likes

Follow

**Dr. Patrizia Cavazzoni** ✓  
@FDACDERDirector

I want to thank the members of the Peripheral and Central Nervous System Drugs Advisory Committee for their participation in today's meeting to discuss an investigational therapy for Amyotrophic Lateral Sclerosis, or [#ALS](#).

5:05 PM · Mar 30, 2022 · Twitter Web App

10 Retweets 3 Quote Tweets 37 Likes

🗨️ ↺️ ❤️ ↗️

**Dr. Patrizia Cavazzoni** ✓ @FDACDERDirector · Mar 30  
Replying to @FDACDERDirector  
This is a devastating disease and the agency recognizes the desire of patients and their families for safe and effective therapies that provide clear clinical benefit.

🗨️ 3 ↺️ 2 ❤️ 4 ↗️

**Dr. Patrizia Cavazzoni** ✓ @FDACDERDirector · Mar 30  
The FDA will now consider the feedback from the committee members and insights provided by the broader patient and research communities, as we continue our review of this application.

[www.twitter.com/FDACDERDirector](https://www.twitter.com/FDACDERDirector)



# LinkedIn

## Global Alliance of Drug Information Specialists

Happy New Year, Drug Information Specialists! Test your knowledge of FDA's Drug Information Resources by answering the poll question below by 1/17/2022. We look forward to your participation and sharing the results with you.

**In emergency cases, a physician can begin Expanded Access treatment with an investigational drug before FDA authorization.**

The author can see how you vote. [Learn more](#)

True

37%

False ☒

63%

30 votes • Poll closed • [Remove vote](#)

Pharmacist at FDA

Thank you for participating in our new monthly poll! The correct answer to our January's polling question was "False".

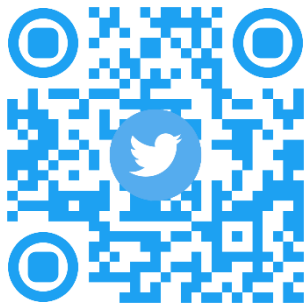
Even in an emergency, FDA must give authorization to use the product for treatment before it begins. There is a process to request and authorize treatment quickly – by telephone or other rapid means of communication.

To learn more about Expanded Access, visit <https://go.usa.gov/xt8mK> and listen to the recording on "FDA Drug Topics: Overview of Expanded Access (EA) Program and EA eRequest Site" at <https://go.usa.gov/xen8H>.

Mark your calendars to attend our upcoming 1-hr free virtual Live CE webinar titled "FDA Drug Topics: Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources" on January 25, 2022 at 1pm ET. For more details and to register, please visit: <https://go.usa.gov/xt8c4>.

[www.linkedin.com/groups/8421517/](https://www.linkedin.com/groups/8421517/)

# Tools To Keep You Informed



@FDA\_Drug\_Info



@FDA



Email Updates



GADIS LinkedIn Group



**SCAN ME**

Hold phone camera  
to the image



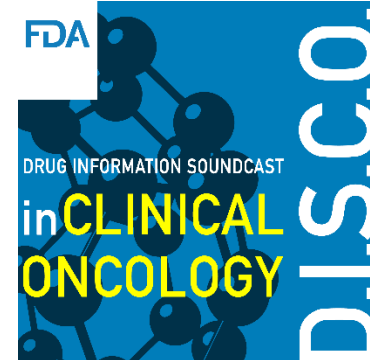
# Podcasts



**Drug Safety  
Communications**



**Industry  
Education**



**Topics in Cancer  
Drug  
Development**



# Videos

## FDA Drug Info Rounds Video

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Drug Info Rounds is a series of educational videos for health care professionals brought to you by the FDA's Center for Drug Evaluation and Research (CDER), Office of Communications (OCOMM), Division of Drug Information (DDI). DDI answers hundreds of questions daily about drug products and FDA actions. Our goal is to provide important and timely drug information to health care professionals on pertinent health topics so they can help patients make better medication decisions.



### Videos

- Medication Guides: Distribution Requirements for Health Care Professionals (March 2020)**

Provides health care professionals with an overview of when Medication Guides may be required to distribute to a patient or caregiver.

- Expanded Access Part 4: How to Complete Form FDA 3926 for Follow-up Submissions (September 2019)**

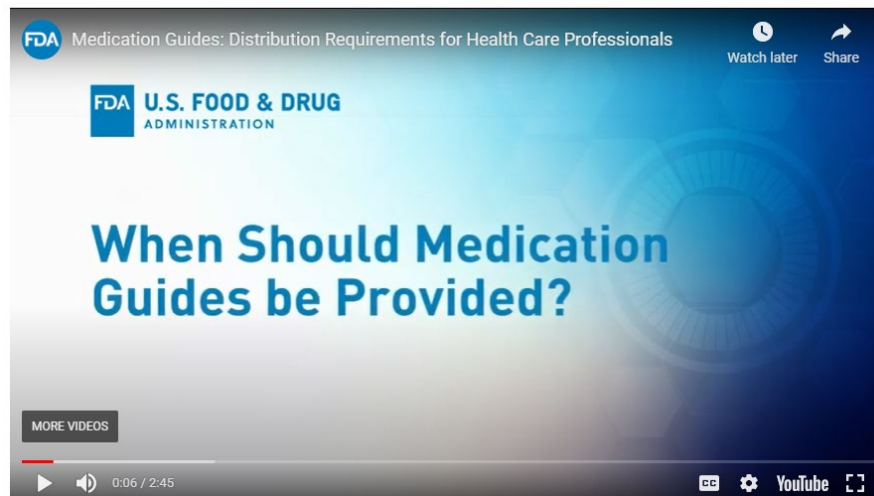
Provides instructions on completing Form FDA 3926 for follow-up submissions.

- Expanded Access Part 3: How to Complete Form FDA 3926 for Initial Submissions (September 2019)**

Provides instructions on completing Form FDA 3926, a one-page form, front and back for initial submissions.

## Medication Guides: Distribution Requirements for Health Care Professionals (March 2020)

Share
 Tweet
 LinkedIn
 Email
 Print



[www.fda.gov/drugs/information-health-care-professionals-drugs/fda-drug-info-rounds-video](https://www.fda.gov/drugs/information-health-care-professionals-drugs/fda-drug-info-rounds-video)

# Webinars



## DIVISION OF DRUG INFORMATION WEBINARS for Health Care Professionals

### Educational Webinars for Health Care Professionals and Students

FDA's Division of Drug Information in the Center for Drug Evaluation and Research (CDER) sponsors a series of educational webinars targeting the needs of health care professionals and students. The webinars cover a broad range of FDA drug regulation and medication safety topics. These focused webinars support FDA's mission of promoting and protecting public health through interaction and education to strengthen current and future partnerships and relationships with clinicians and researchers.

### Continuing Education (CE) Credit

CE credit is available for our live and home study webinars. If you are a physician, physician assistant, nurse, pharmacist, or pharmacy technician, refer to the individual webinar listing for complete CME/AAPA/CNE/CPE/CPT/CPH information.

### For more information

- Visit the Division of Drug Information web site at:  
<http://www.fda.gov/AboutDDI>
- Call us at: 1-855-543-3784 or 301-796-3400
- Email us at: [DDIWebinars@fda.hhs.gov](mailto:DDIWebinars@fda.hhs.gov)

## NEW! Home Study CE Webinars

- [FDA's Office of Orphan Products Development \(OOPD\) – An Overview and Update](#)
- [The Ins and Outs of Prescription Drug Labeling](#)
- [Enhanced Drug Distribution Security: 2023 and Beyond](#)
- [Safety Labeling Changes for Leukotriene Receptor Antagonists and Decisions Behind a Boxed Warning](#)
- [Fraudulent Products – Hidden Ingredients and Unproven Claims in Products Marketed as Dietary Supplements](#)
- [Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources](#)
- [How FDA and ISMP Utilize Medication Error Reports to Improve Drug Safety](#)
- [FDA's Role in Postmarketing Drug Safety Surveillance](#)
- [Overview of Expanded Access \(EA\) Program and EA eRequest Site](#)
- [Overview of Risk Evaluation and Mitigation Strategies \(REMS\) for Health Care Providers](#)
- [Project Facilitate: Oncology Expanded Access Program Update](#)

[www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars)

# Challenge Question #1

**What is the best resource for finding information about a drug product authorized for emergency use?**

- A. Drugs@FDA
- B. Orange Book
- C. EUA webpage
- D. Expanded Access webpage

## Challenge Question #2

**True or False: The SrLC database provides information on elements to assure safe use.**

- A. True
- B. False



## Challenge Question #3

**What social media group brings together pharmacists interested in drug information?**

- A. Global Alliance of Drug Information Specialists on LinkedIn
- B. @FDA\_Drug\_Info on Twitter
- C. @FDACDERDirector on Twitter
- D. U.S. Food and Drug Administration Facebook Page

# Thank You!



**U.S. FOOD & DRUG**  
ADMINISTRATION

**Division of Drug Information**  
**855-543-3784 or 301-796-3400**  
**[druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)**

**[www.fda.gov/aboutDDI](http://www.fda.gov/aboutDDI)**



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