U.S. FOOD & DRUG ADMINISTRATION

FDA Drug Topics: Navigating FDA's Drug Information Resources

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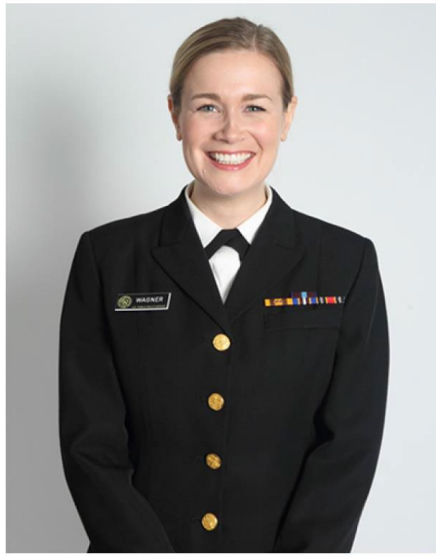
Division of Drug Information | Office of Communications



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. Select the appropriate FDA drug information resource to answer questions from patients.
2. Demonstrate how to use FDA's drug information resources.
3. Identify tools to stay informed with direct updates from FDA.

Division of Drug Information

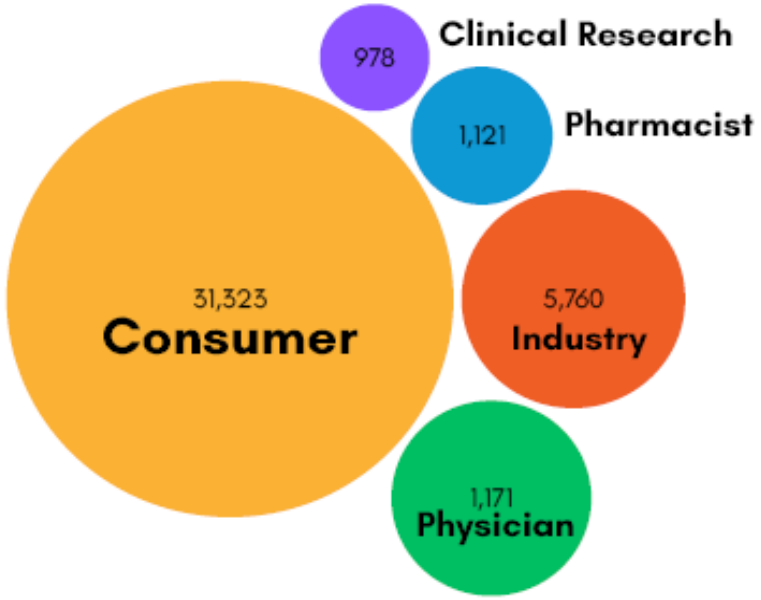
The **mission** of DDI is to optimize the Center for Drug Evaluation and Research (CDER)'s educational and communication efforts to our global community.

DDI is CDER's focal point for public inquiries regarding human drug products.

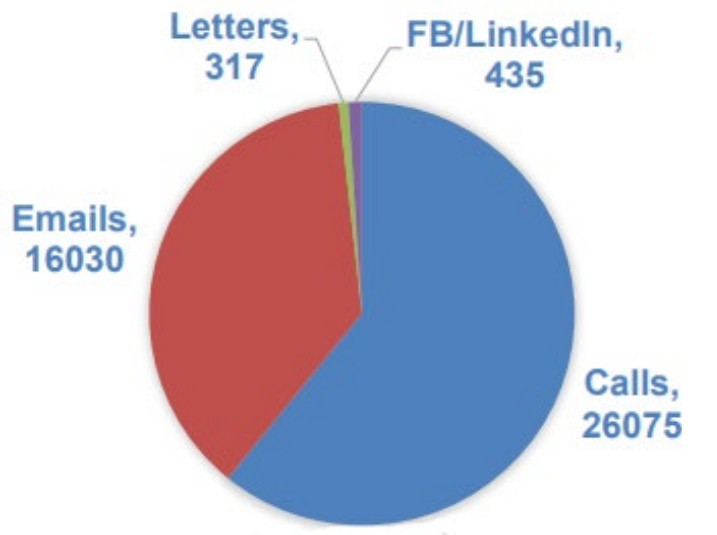
DDI supports the Food and Drug Administration's mission to promote and protect public health with a focus on human drugs and activities related to CDER.

DDI Engagement

Audience



2023 Points of Contact



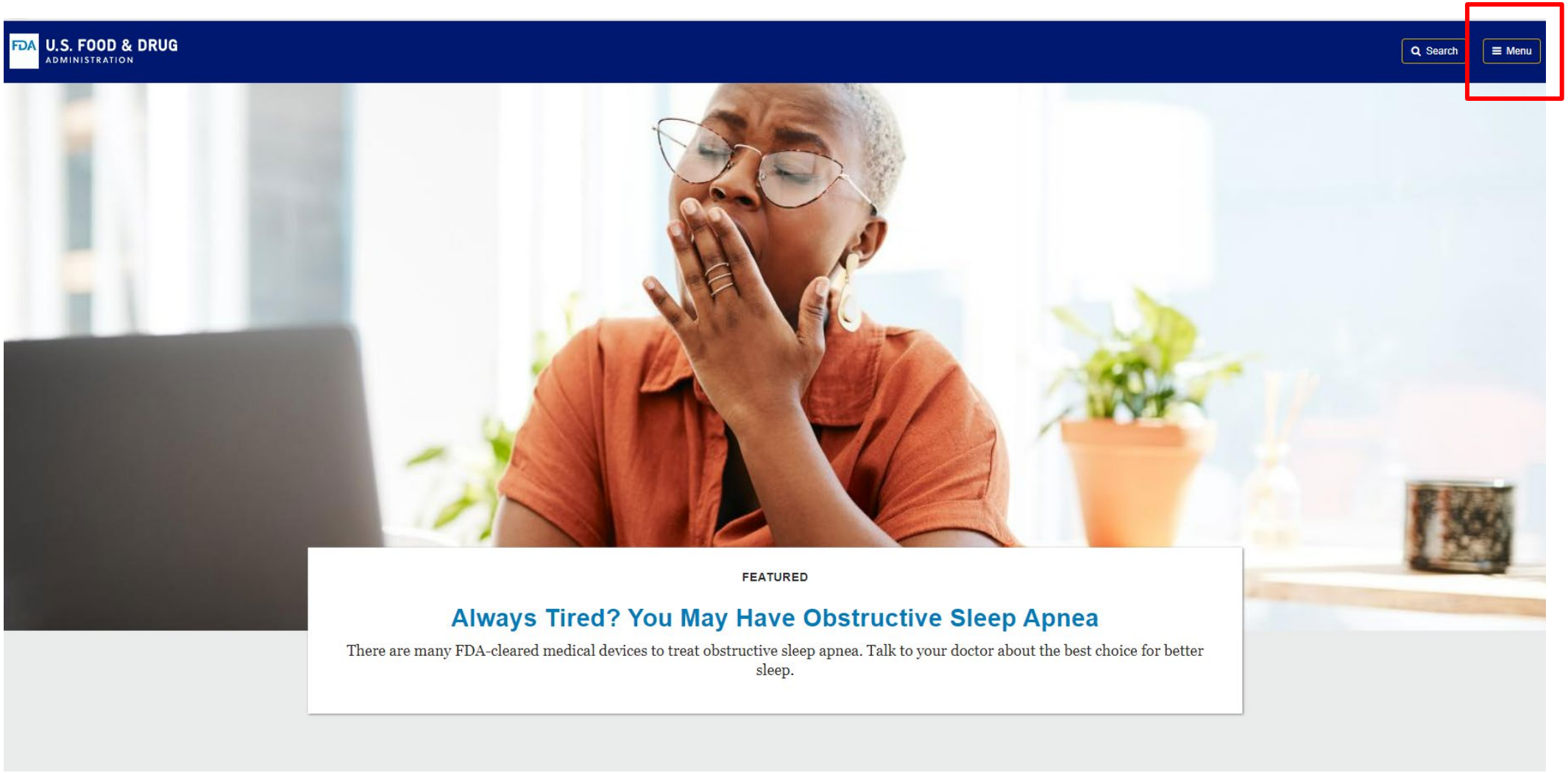
2023 Top 10 Topics

1. Drug Recalls
2. Personal Import
3. Clinical Trials & INDs
4. Opioids
5. Drug Shortages
6. Coronavirus
7. Expanded Access
8. GLP-1 Agonists
9. Registration & Listing
10. ADHD Stimulants

FDA Drug Information Databases & Resources

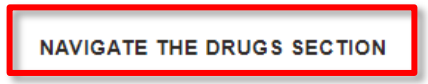
- NDC Directory
- Drugs@FDA
- Labels.fda.gov
- FDALabel
- Orange Book
- Purple Book
- Drug Shortages
- Drug Recalls
- DSC
- SrLC
- Compounding
- Social & More

FDA Home Page: Where to Find Resources



FDA Home Page: Where to Find Resources

FDA Home Page: Where to Find Resources



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

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

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

Share | Post | Linkedin | Email | Print

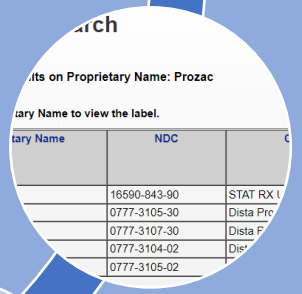
Popular Topics

- Drug Approvals and Databases
- Drugs@FDA
- FDA Updates and Press Announcements on NDMA in Metformin
- Frequently Asked Questions about Labeling for Prescription Medicines
- National Drug Code Directory
- News & Events for Human Drugs
- Orange Book

Drug Labeling & Information

National Drug Code (NDC) Directory

Drugs@FDA



Labels.fda.gov

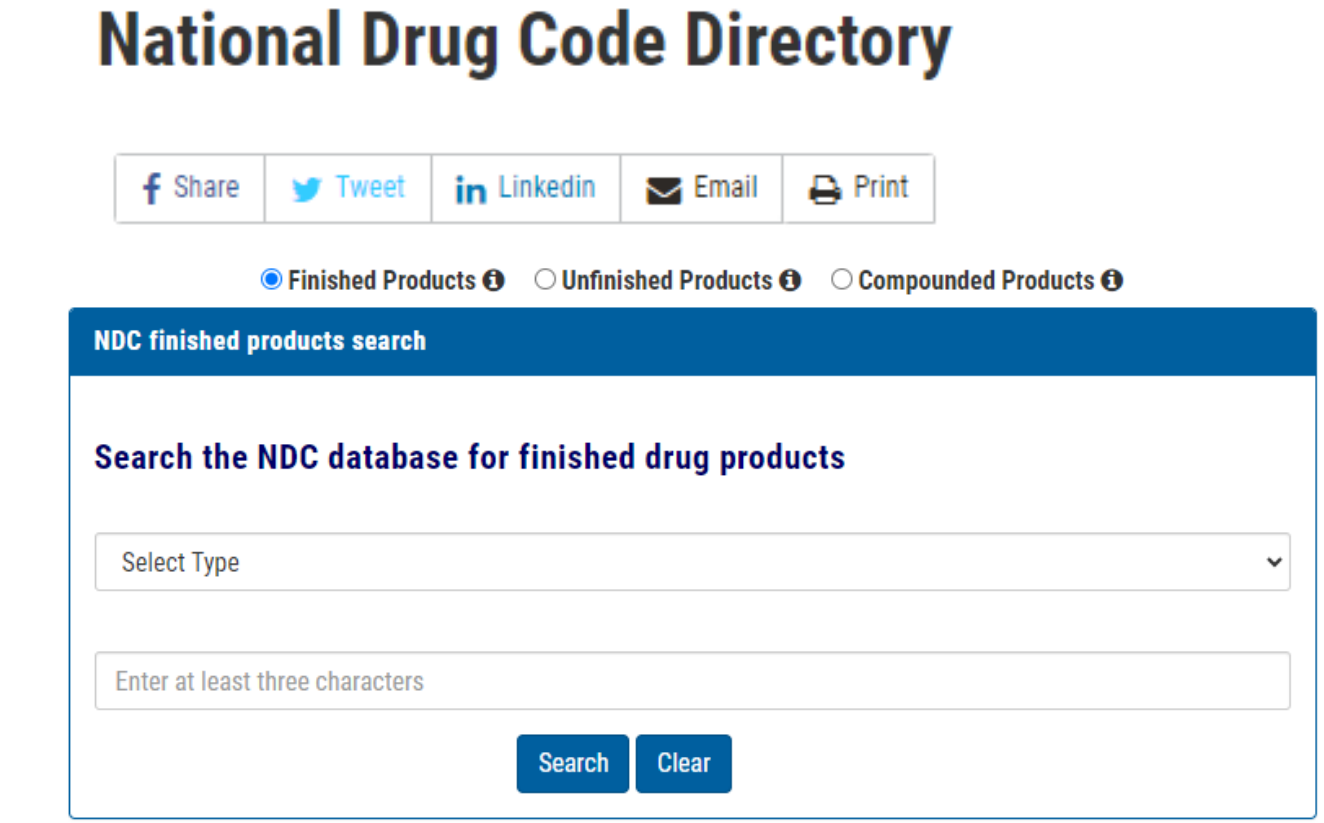
FDA Label

FDA

Can you tell me if an NDC number is correct? My patient's insurance rejected a claim because of the NDC number.

Is sodium sulfacetamide 10% and sulfur 5% cleanser FDA approved? Insurance won't pay for it, claiming it's unapproved.

National Drug Code (NDC) Directory

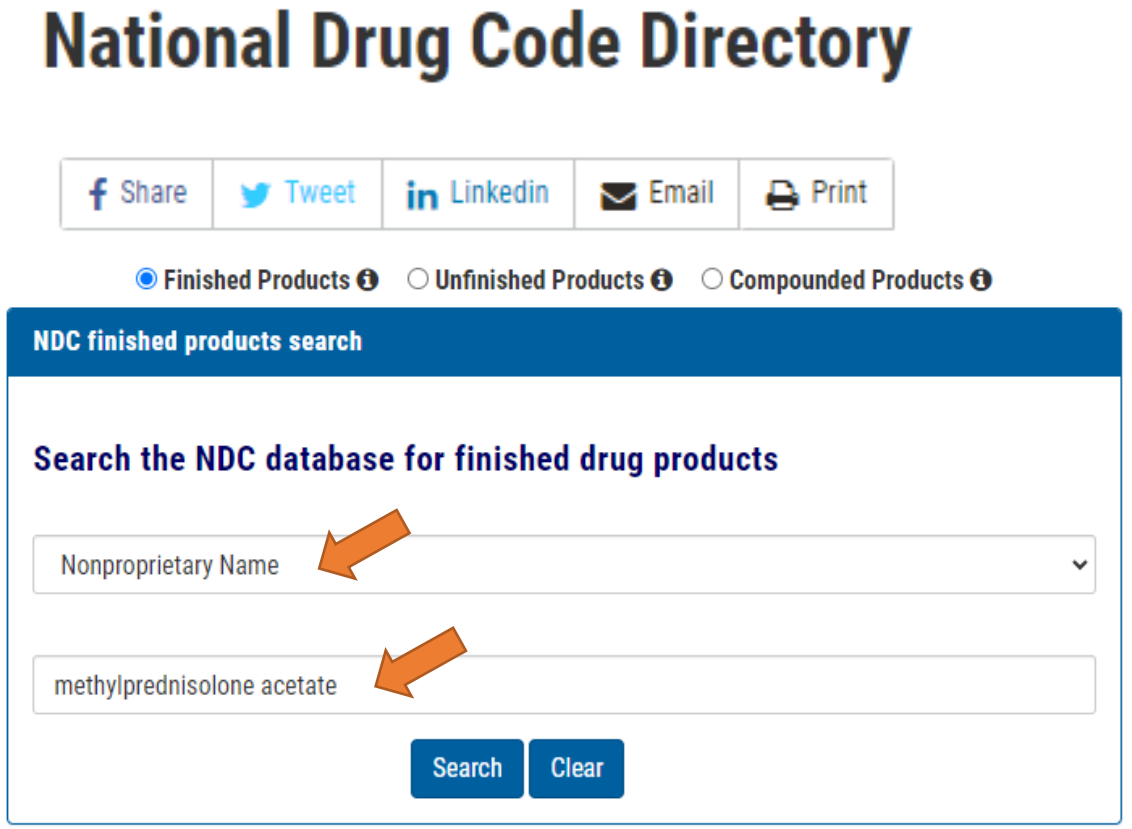


Can you tell me if an NDC number is correct? My patient's insurance rejected a claim because of the NDC number.

www.accessdata.fda.gov/scripts/cder/ndc/index.cfm

National Drug Code (NDC) Directory

Medication Properties	
Given NDC	70121-1552-05
Nonproprietary Name	Methylprednisolone acetate
Strength/Dosage form	80 mg/mL injection
Labeler Name	Amneal Pharmaceuticals LLC



Can you tell me 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

National Drug Code (NDC) Directory

Example NDC: 70121-1552-05

Display 50 records per page

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

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
Methylprednisolone acetate	70121-1552-5	80 mg/mL	INJECTION, SUSPENSION	INTRA-ARTICULAR; INTRALESIONAL; INTRAMUSCULAR; SOFT TISSUE	ANDA210043	Amneal Pharmaceuticals LLC	70121-1552	Methylprednisolone acetate	METHYLPREDNISOLONE ACETATE	HUMAN PRESCRIPTION DRUG	11/01/2021	N/A	ANDA
Methylprednisolone acetate	60219-1574-1	80 mg/mL	INJECTION, SUSPENSION	INTRA-ARTICULAR; INTRALESIONAL; INTRAMUSCULAR; SOFT TISSUE	ANDA210043	Amneal Pharmaceuticals NY LLC	60219-1574	Methylprednisolone acetate	METHYLPREDNISOLONE ACETATE	HUMAN PRESCRIPTION DRUG	04/10/2022	N/A	ANDA
Methylprednisolone acetate	60219-1574-5	80 mg/mL	INJECTION, SUSPENSION	INTRA-ARTICULAR; INTRALESIONAL; INTRAMUSCULAR; SOFT TISSUE	ANDA210043	Amneal Pharmaceuticals NY LLC	60219-1574	Methylprednisolone acetate	METHYLPREDNISOLONE ACETATE	HUMAN PRESCRIPTION DRUG	04/10/2022	N/A	ANDA

Can you tell me 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

Drugs@FDA

Download on the App Store

GET IT ON Google Play

Is sodium sulfacetamide 10% and sulfur 5% cleanser FDA approved? Insurance won't pay for it, claiming it's unapproved.

www.fda.gov/drugsatfda

Drugs@FDA

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.

- Drugs@FDA does ***not*** include the drug you searched for because the drug:
  - Does not require FDA approval to be sold in the United States (Drugs@FDA only includes approved drugs). For example:
  - Over-the-counter (OTC) drugs marketed under the monograph system (See OTC Drug Monograph Process for more information.)
  - Dietary supplements (See Dietary Supplements for more information.)
  - Is approved by FDA's Center for Biologics Evaluation and Research. These FDA-approved drugs are not included in Drugs@FDA. These drugs include vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products, plasma volume expanders, and platelet additive solutions. (See CBER's approved drugs.)
  - Is not marketed in the United States (for example, investigational drugs).
  - Is not for human use (for example, animal prescription and animal OTC drugs). (Drugs@FDA does not include animal drugs; for animal drugs see Animal Drugs@FDA.)

- Your Application Number search did ***not*** include the appropriate number of digits for the application.

Is sodium sulfacetamide 10% and sulfur 5% cleanser FDA approved? Insurance won't pay for it, claiming it's unapproved.

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

Is sodium sulfacetamide 10% and sulfur 5% cleanser FDA approved? Insurance won't pay for it, claiming it's unapproved.

https://labels.fda.gov

Labels.fda.gov

FDA Label Search

FDA Home

NDC Search Results on Proprietary Name: sodium sulfacetamide and sulfur

Click on Proprietary Name to view the label.

Proprietary Name	NDC	Company Name	Application Number or Regulatory Citation	Product Type	Marketing Category
Sodium Sulfacetamide and Sulfur	58657-472-07	Method Pharmaceuticals, LLC		HUMAN PRESCRIPTION DRUG	unapproved drug other
Sodium Sulfacetamide and Sulfur	13925-161-12	Seton Pharmaceuticals		HUMAN PRESCRIPTION DRUG	unapproved drug other
SODIUM SULFACETAMIDE AND SULFUR	44523-602-01	BioComp Pharma, Inc.		HUMAN PRESCRIPTION DRUG	unapproved drug other
SODIUM SULFACETAMIDE AND SULFUR	72162-2188-2	Bryant Ranch Prepack		HUMAN PRESCRIPTION DRUG	unapproved drug other

SODIUM SULFACETAMIDE AND SULFUR- sulfacetamide sodium, sulfur liquid
Method Pharmaceuticals, LLC

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.

Sodium Sulfacetamide 10% - Sulfur 5% Cleanser

Rx Only

Is sodium sulfacetamide 10% and sulfur 5% cleanser FDA approved? Insurance won't pay for it, claiming it's unapproved.

https://labels.fda.gov

FDALabel

To use FDALabel, select the link below or copy URL into browser:
https://nctr-crs.fda.gov/fdalabel/ui/search

Overview of FDALabel Database

The FDALabel Database is a web-based application used to perform customizable searches of over 147,000 human prescription, biological, over-the-counter (OTC), and animal drug labeling documents. The source of FDALabel's data is the FDA's *Structured Product Labeling (SPL)* archive,[1-3] which stores labeling documents submitted by manufacturers. FDALabel is implemented as a secure three-tier application with an Oracle database.

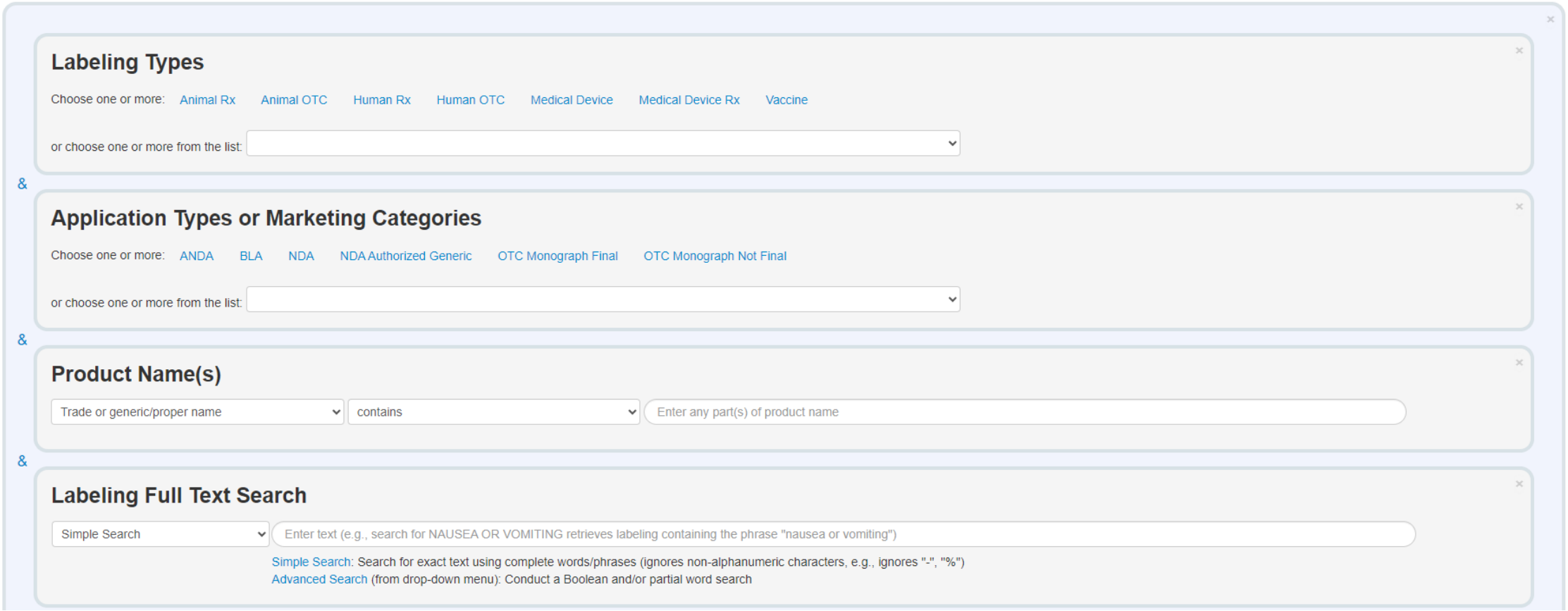
The following table lists the count of several common labeling types in FDALabel.

Labeling Types	Number of Labeling as of February 2, 2024
Human OTC Drugs*	91,330
Human Prescription Drugs and Biological Products**	56,501
Animal Prescription and Animal OTC Products	3,438

What drugs in the Biguanide, Glinide or Sulfonylurea Pharmacologic Classes have BOXED WARNINGS?

https://nctr-crs.fda.gov/fdalabel/ui/search

FDALabel



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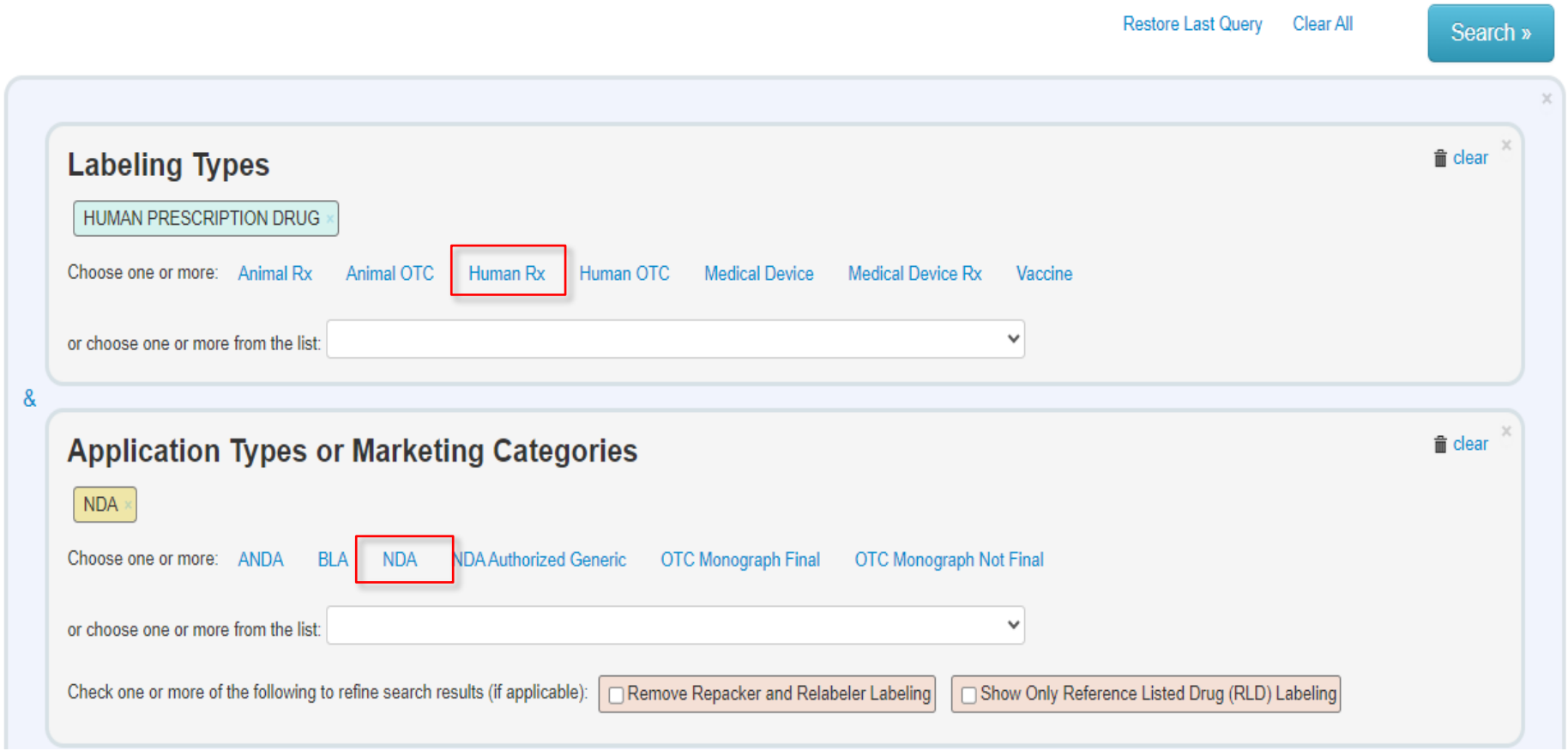
FDALabel



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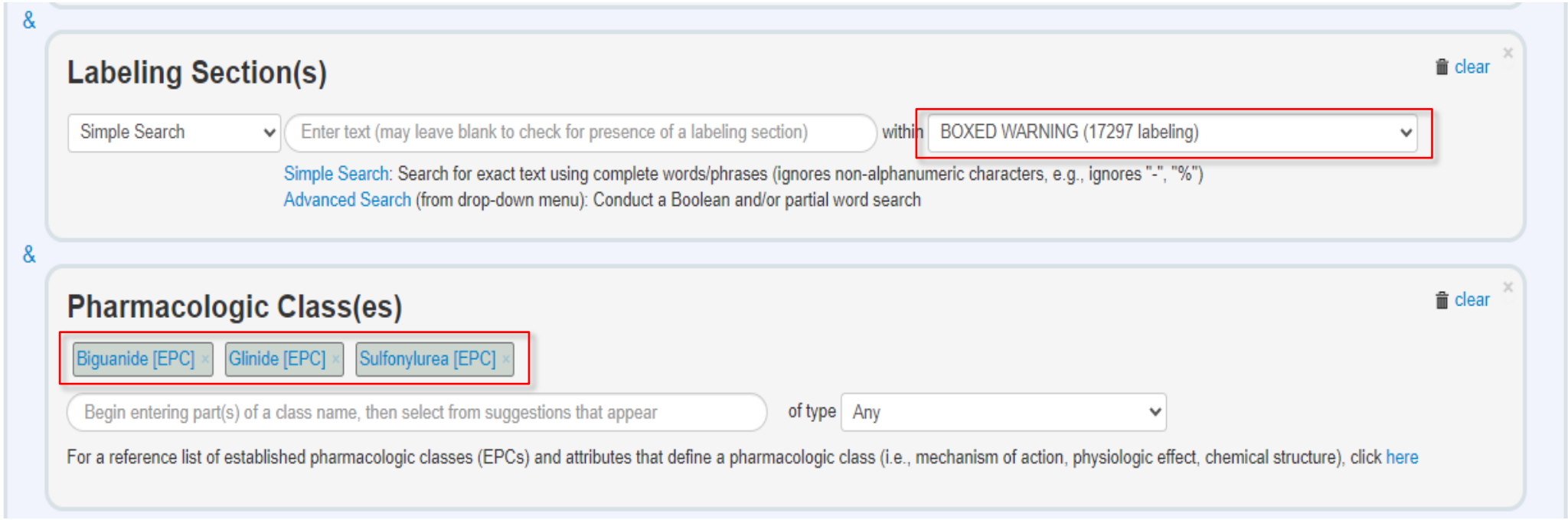
FDALabel



What drugs in the Biguanide, Glinide or Sulfonylurea Pharmacologic Classes have BOXED WARNINGS?

https://nctr-crs.fda.gov/fdalabel/ui/search

FDALabel

32 labeling results

Basic View | Expanded View

Download Full Results View Query (permanent link)

Links	Marketing Category	Dosage Form(s)	Route(s) of Administration	Trade Name	▲Generic/Proper Name(s)	Most Recent SPL Date (YYYY/MM/DD)
SPL Document DailyMed (SPL | PDF) Drugs@FDA 203414; Orange Book 203414;	NDA	TABLET, FILM COATED	ORAL	KAZANO	ALOGLIPTIN AND METFORMIN HYDROCHLORIDE	2023/08/07
SPL Document DailyMed (SPL | PDF) Drugs@FDA 204353; 205879; Orange Book 204353; 205879;	NDA	TABLET, FILM COATED; TABLET, FILM COATED, EXTENDED RELEASE	ORAL	INVOKAMET; INVOKAMET XR	CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE	2024/01/30
SPL Document DailyMed (SPL | PDF) Drugs@FDA 205649; Orange Book 205649;	NDA	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	XIGDUO XR	DAPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE	2023/09/12

What drugs in the Biguanide, Glinide or Sulfonylurea Pharmacologic Classes have BOXED WARNINGS?

https://nctr-crs.fda.gov/fdalabel/ui/search

Searchable online "Books"

Orange Book

Purple Book

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

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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

Orange Book

Display 50 records per page

Showing 1 to 9 of 9 entries (filtered from 124 total records)

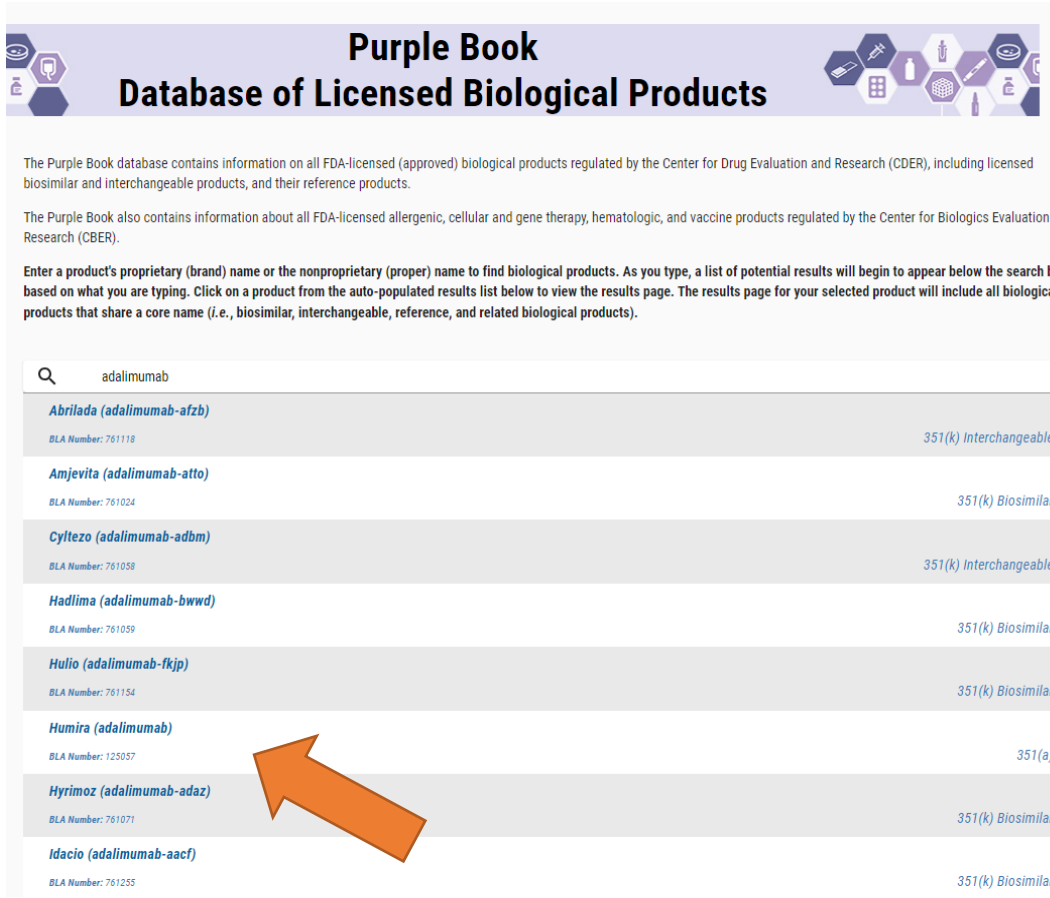
AEROSOL

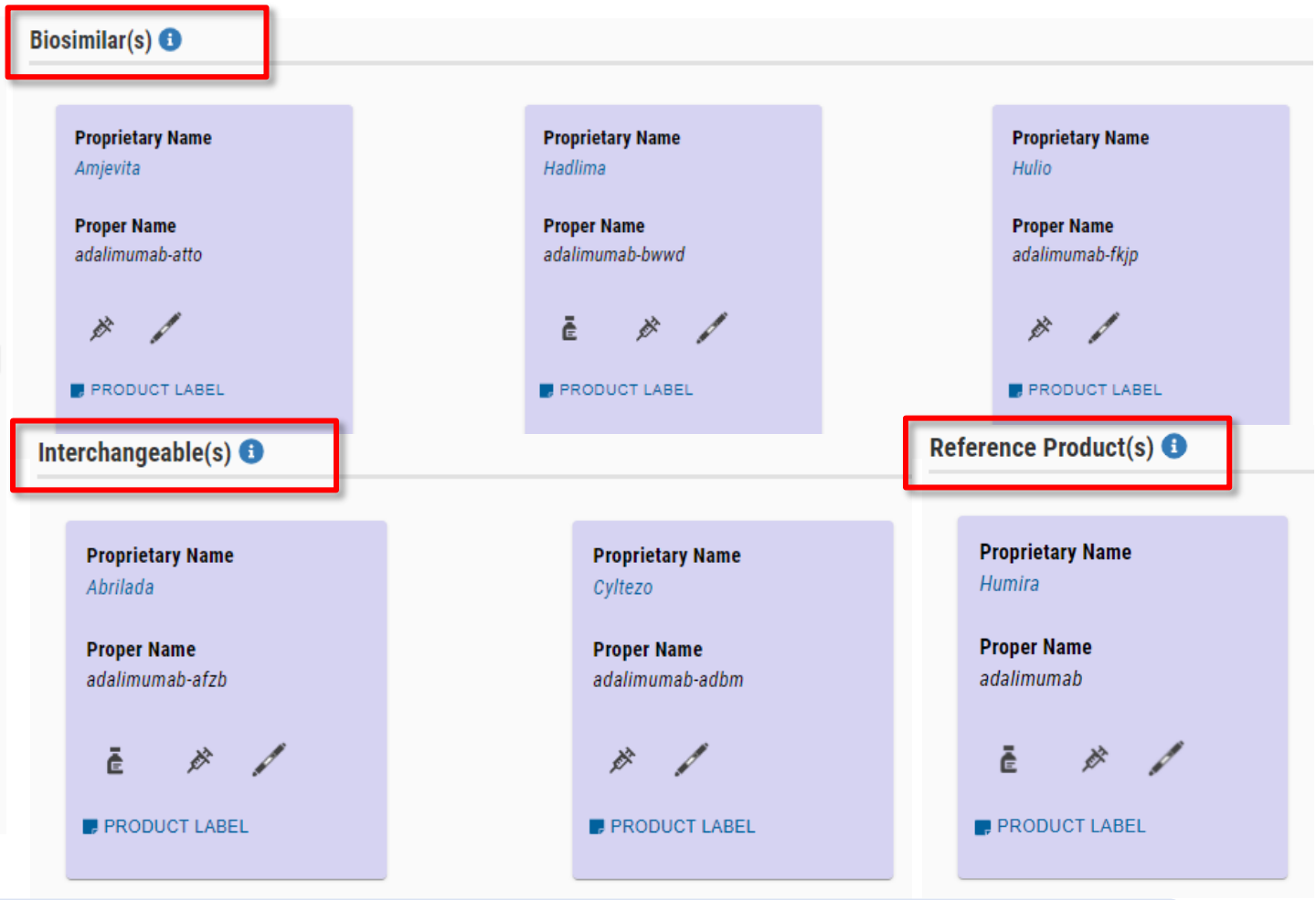
Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ALBUTEROL SULFATE	ALBUTEROL SULFATE	A209959	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB1			CIPLA LTD
RX	ALBUTEROL SULFATE	ALBUTEROL SULFATE	A207085	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB1			SANDOZ INC
RX	ALBUTEROL SULFATE	ALBUTEROL SULFATE	A209954	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB2			LUPIN INC
RX	ALBUTEROL SULFATE	PROAIR HFA	N021457	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB2	RLD	RS	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC
RX	ALBUTEROL SULFATE	PROVENTIL-HFA	N020503	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	AB1	RLD	RS	KINDEVA DRUG DELIVERY LP
RX	ALBUTEROL SULFATE	VENTOLIN HFA	N020983	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH	BX	RLD	RS	GLAXOSMITHKLINE INTELLECTUAL PROPERTY LTD ENGLAND
RX	ALBUTEROL SULFATE; BUDESONIDE	AIRSUPRA	N214070	AEROSOL, METERED	INHALATION	EQ 0.09MG BASE/INH; 0.08MG/INH		RLD	RS	ASTRAZENECA PHARMACEUTICALS LP

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

www.fda.gov/orangebook

Purple Book





https://purplebooksearch.fda.gov

Searching for Drug Shortages & Recalls

Drug Shortages

Drug Recalls

I'm having issues ordering methylphenidate, when will I be able to get that medication?

I heard that some eye drops were recently recalled. How can I check online to see if a certain product is part of the recall?

Drug Shortages

I'm having issues ordering methylphenidate, when will I be able to get that medication?

www.fda.gov/drug-shortages

Drug Shortages

Results for: methylphenidate

- Methylphenidate Hydrochloride Tablet, Extended Release (*Currently in Shortage*)

Methylphenidate Hydrochloride Tablet, Extended Release
Status: Currently in Shortage
»**Date first posted:** 07/26/2023
»**Therapeutic Categories:** Psychiatry

Dr. Reddy's Laboratories, Inc. (*Revised 02/06/2024*)

Company Contact Information:
866-732-3952

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
Tablet, Extended Release, 18 mg (NDC 43598-438-01)	Unavailable	Unavailable, Currently unavailable. Estimated limited supplies from July 2024	Other
Tablet, Extended Release, 27 mg (NDC 43598-439-01)	Unavailable	Unavailable, Currently unavailable. Estimated limited supplies from July 2024	Other
Tablet, Extended Release, 36 mg (NDC 43598-440-01)	Unavailable	Unavailable, Currently unavailable. Estimated limited supplies from July 2024	Other
Tablet, Extended Release, 54 mg (NDC 43598-441-01)	Unavailable	Unavailable, Currently unavailable. Estimated limited supplies from July 2024	Other

Janssen Pharmaceuticals (*Reverified 02/06/2024*)

Company Contact Information:
800-JANSSEN (1-800-526-7736) Monday through Friday from 9:00 AM to 8:00 PM ET

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
Concerta, Tablet, Extended Release, 18 mg (NDC 50458-585-01)	Available		
Concerta, Tablet, Extended Release, 27 mg (NDC 50458-588-01)	Available		
Concerta, Tablet, Extended Release, 36 mg (NDC 50458-586-01)	Available		

Lannett Company, Inc. (*Revised 02/06/2024*)

Company Contact Information:
844-834-0530

Presentation	Availability and Estimated Shortage Duration	Related Information	Shortage Reason (per FDASIA)
Tablet, Extended Release, 18 mg (NDC 62175-310-37)	Allocating limited inventory		Demand increase for the drug
Tablet, Extended Release, 27 mg (NDC 62175-311-37)	Available		
Tablet, Extended Release, 36 mg (NDC 62175-312-37)	Available		Demand increase for the drug
Tablet, Extended Release, 54 mg (NDC 62175-313-37)	Allocating limited inventory		Shortage of an active ingredient

I'm having issues ordering methylphenidate, when will I be able to get that medication?

www.fda.gov/drug-shortages

Drug Recalls

Drug Recalls

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Search

eye drops

Filter by

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

Showing 1 to 10 of 10 entries

Export Excel | Show 10 entries

Date	Brand Name(s)	Product Description	Recall Reason Description	Company Name	Terminated Recall	Excerpt
01/22/2024	Multiple brands	Lubricant Eye Drops & Multi-Symptom Eye Drops	Device & Drug Safety Potential Safety Concerns	Kilitch Healthcare India Limited		… November 13, 2023 issued for nationwide recall of various **eye drops**. There are corrections in product NDC No for the below … LUBRICANT GEL **DROPS** 15 ML Carboxymethylcellulose Sodium **Eye Drops** 1.0% W/V 11822-9706-5 11822-4540-5 Rite Aid …
11/15/2023	Multiple brands	Lubricant Eye Drops & Multi-Symptom Eye Drops	Device & Drug Safety Potential Safety Concerns	Kilitch Healthcare India Limited		… Healthcare India Limited is voluntarily recalling the **eye drops** products listed in the table below to the consumer … who use these products, there is a potential risk of **eye** infections or related harm. These products are intended …

I heard that some eye drops were recently recalled. How can I check online to see if a certain product is part of the recall?

www.fda.gov/drug-recalls

Drug Recalls

COMPANY ANNOUNCEMENT

Kilitch Healthcare India Limited Issues Voluntary Nationwide Recall of Various Eye Drops for Potential Safety Reasons

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

Share | Post | Linkedin | Email | Print

Product	Product Information	NDC NO	Retailer / Label
LUBRICATING TEARS EYE DROPS 15 ML	Dextran 70- 0.1% w/v, Glycerin 0.2% w/v, Hypromellose 0.3% w/v	0536-1282-94	Rugby
Polyvinyl Alcohol 1.4% Lubricating Eye Drops 15 ml	Polyvinyl alcohol Eye Drops 1.4% w/v	0536-1325-94	Rugby
High Performance Lubricant Eye Drops 15 ml (Single Pack)	Polyethylene glycol 400 0.4%, Propylene glycol 0.3% Eye Drops	11673-522-15	Target
High Performance Lubricant Eye Drops 15 ml (Twin Pack)	Polyethylene glycol 400 0.4%, Propylene glycol 0.3% Eye Drops	11673-522-30	Target
MULTI-ACTION RELIEF DROPS 15ML	Polyvinyl alcohol 0.5% w/v, Povidone 0.6%w/v, Tetrahydrozoline 0.05% Eye Drops	11822-2254-3	Rite Aid
LUBRICATING GEL DROPS 10ML	Polyethylene glycol 400 0.4%, Propylene glycol 0.3% Eye Drops	11822-4540-3	Rite Aid
LUBRICANT EYE DROPS 10ML (TWIN PACK)	Propylene glycol Eye Drops 0.6% w/v	11822-4811-3	Rite Aid
LUBRICANT GEL DROPS 15 ML	Carboxymethylcellulose Sodium Eye Drops 1.0% W/V	11822-9706-5	Rite Aid
LUBRICANT EYE DROPS 15ML (TWIN PACK)	Carboxymethylcellulose Sodium Eye Drops 0.5% W/V	11822-9707-5	Rite Aid
Eye Irritation Relief 15 ml	Polyvinyl alcohol 0.5% w/v, Povidone 0.6%w/v, Tetrahydrozoline 0.05% Eye Drops	70000-0087-1	Leader
Dry Eye Relief 10 ml	Polyethylene glycol 400 0.4%, Propylene glycol	70000	Leader

I heard that some eye drops were recently recalled. How can I check online to see if a certain product is part of the recall?

www.fda.gov/drug-recalls

Drug Recalls

Enforcement Reports

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View Weekly Enforcement Reports

Search Enforcement Reports

- What is the Enforcement Report?
- **UPDATED!!!** How do I subscribe to the Enforcement Report mailing list?
- 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?
- Where do I find Additional Resources about Enforcement Reports?
- What if I have additional questions about Enforcement Reports?

U.S. Food and Drug Administration Recall Information Search

Weekly Enforcement Report | Quick Search | Advanced Search

Product Description: eye drops

Code Information:

Product Type: Drugs

Recall Class: Select options

Recalling Firm:

Status: Select options

Recall Number:

Reason for Recall:

Classified From Date: mm/dd/yyyy

Classified To Date: mm/dd/yyyy

Event ID:

Oldest Date Available is 06/08/2012

Product Type	Recently Updated Record**	Product Description	Classification	Code Information	Reason for Recall	Recalling Firm
Drugs + view details	No	Carboxymethylcellulose Sodium 0.5% Ophthalmic Solution, 1 FL OZ (30 mL) bottle, sold under the following labels: (a) CVS	Class I	Lot #: 11440, Exp 09/13, labeled for CVS; 11441, Exp 09/13, labeled for CVS; 12042, Exp 01/14, labeled for CVS and Wal-Mart ; 12103, Exp 02/1	Non-Sterility: Customer complaints of mold in the product after use and handling due	Altaire Pharmaceuticals, Inc. 311 West Lane Aquebogue, NY

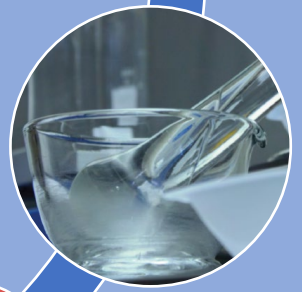
I heard that some eye drops were recently recalled. How can I check online to see if a certain product is part of the recall?

www.fda.gov/drug-recalls

Drug Safety

Drug Safety Communications (DSC)

Drug Safety-related Labeling Changes (SrLC)



Compounding Risk Alerts

MedWatch

FDA

My patient developed a rash while taking a prescription drug, could this be attributed to the medication?

What safety information does FDA have regarding compounded drug products?

Drug Safety Communications (DSCs)

Drug Safety Communications

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Current Drug Safety Communications

- 01-19-2024 FDA adds Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking osteoporosis medicine Prolia (denosumab)
- 01-11-2024 Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity
- 11/28/2023 FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)
- 05/11/2023 FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions
- 04/13/2023 FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use

Previous Drug Safety Communications

2023 | [illegible] | 2021 | 2020 | 2019 | 2018 | 2017 | 2016 | 2015 | 2014 | 2013 | 2012 | 2011 |

My patient developed a rash while taking a prescription drug, could this be attributed to the medication?

2023 Drug Safety Communications

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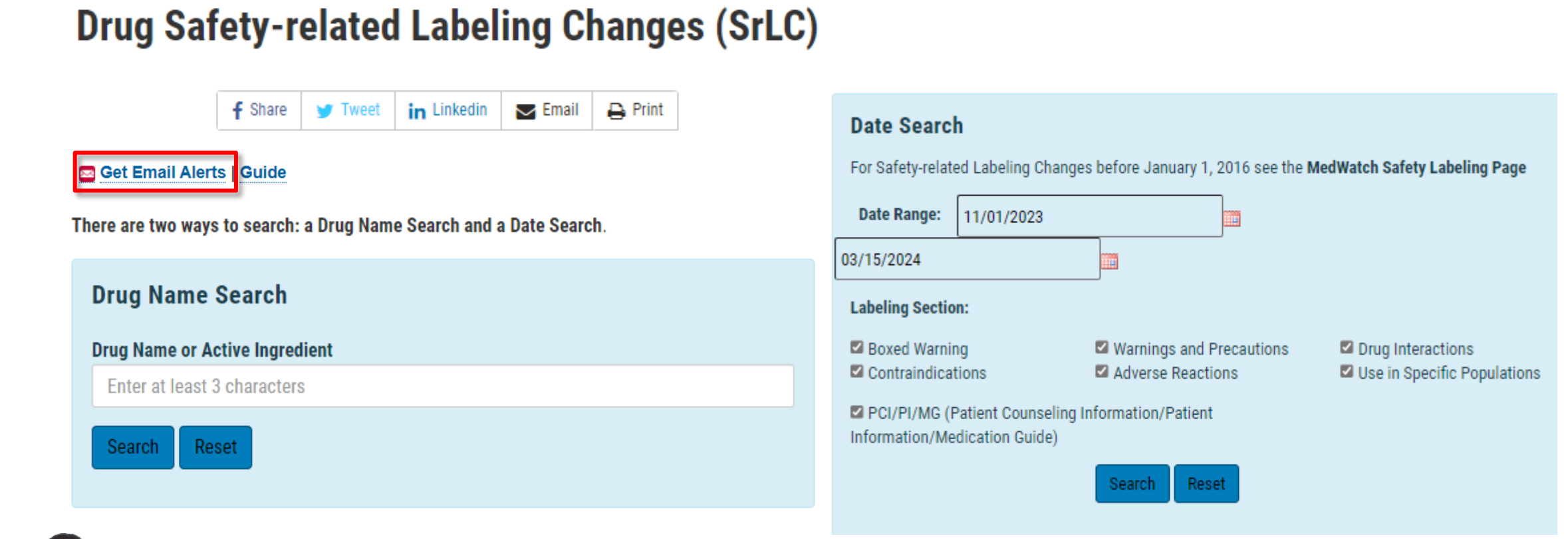
- FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan) 11/28/2023
- FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions 5/11/2023
- FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use 4/13/2023

FDA warns of rare but serious drug reaction to the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan)

Seek immediate medical attention if unexplained rash, fever, or swollen lymph nodes develop

www.fda.gov/drugsafetycommunications

Drug Safety-related Labeling Changes (SrLC)



My patient developed a rash while taking a prescription drug, could this be attributed to the medication?

www.fda.gov/SLC

Drug Safety-related Labeling Changes (SrLC)

Drug Safety-related Labeling Changes (SrLC)

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Get Email Alerts | Guide

Filter results: e.g. drug name, active ingredient

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Drug Name	Active Ingredient	Application Number	Application Type	Supplement Date	Database Updated
ELEPSIA XR	LEVETIRACETAM	204417	NDA	03/12/2024	03/14/2024
KEPPRA	LEVETIRACETAM	021872	NDA	03/12/2024	03/14/2024
KEPPRA	LEVETIRACETAM	021035	NDA	03/12/2024	03/14/2024
KEPPRA	LEVETIRACETAM	021505	NDA	03/12/2024	03/14/2024
KEPPRA XR	LEVETIRACETAM	022285	NDA	03/12/2024	03/14/2024
LEVETIRACETAM IN SODIUM CHLORIDE	LEVETIRACETAM	202543	NDA	03/12/2024	03/14/2024
SPRITAM	LEVETIRACETAM	207958	NDA	03/12/2024	03/14/2024

03/12/2024 (SUPPL-35)

Approved Drug Label (PDF)

5 Warnings and Precautions

5.6 Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Multiorgan Hypersensitivity

Newly added subsection:

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including KEPPRA. These events can be fatal or life- threatening, particularly if diagnosis and treatment do not occur as early as possible. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. KEPPRA should be discontinued if an alternative etiology for the signs or symptoms cannot be established *[see Contraindications (4)]*.

My patient developed a rash while taking a prescription drug, could this be attributed to the medication?

www.fda.gov/SLC

Compounding Risk Alerts

Compounding Risk Alerts

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Many serious patient illnesses and deaths linked to poor quality compounded drugs have occurred since the 2012 fungal meningitis outbreak. In response, FDA has established an Incidents Program to identify and prevent outbreaks through surveillance of adverse events and product quality incidents. This effort has led to many actions by FDA including the issuance of 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 if you have any questions regarding the information provided in a compounding risk alert below:

- FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders (October 10, 2023)
- 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)

What safety information does FDA have regarding compounded drug products?

FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders

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October 10, 2023

What Patients and Health Care Providers Should Know

There is increased interest in compounded ketamine products (including oral formulations) for the treatment of psychiatric disorders. When considering use of compounded ketamine products, patients and health care providers should know:

- Ketamine is *not* FDA approved for the treatment of any psychiatric disorder. FDA is aware that compounded ketamine products have been marketed for a wide variety of psychiatric disorders (e.g., depression, anxiety, post-traumatic stress disorder (PTSD), and obsessive-compulsive disorder); however, FDA has not determined that ketamine is safe and effective for such uses.
- Compounded drugs, including compounded ketamine products, are *not* FDA approved, which means FDA has not evaluated their safety, effectiveness, or quality prior to marketing. Therefore, compounded drugs do not have any FDA-approved indications or routes of administration. Although compounded drugs can serve an important medical need for certain patients when an FDA-approved drug is not medically appropriate, they also present a risk to patients and should only be used under the care of a health care provider.
- Use of compounded ketamine products *without* monitoring by a health care provider for sedation (sleepiness), dissociation (disconnection between a person's thoughts, feelings, and sense of space, time, and self), and changes in vital signs (such as blood pressure and heart rate)

www.fda.gov/compounding

Approved drugs with serious safety concerns

Medication Guides

Risk Evaluation and Mitigation Strategies (REMS)

Risk Evaluation and Mitigation Strategies (REMS)

REMS@FDA

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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.

clozapine

Excel | CSV | Print

Name	REMS Approved	Last Updated	MedGuide (MG)*	Comm. Plan (CP)	ETASU	Imp. System (IS)
Clozapine Shared System REMS		09/29/2023			ETASU	IS

I'm dispensing a drug product and understand the REMS was recently updated; how do I view the changes?

www.fda.gov/REMS

Risk Evaluation and Mitigation Strategies (REMS)

Clozapine

Shared System REMS

REMS last update: 09/29/2023

Products | Goals | Summary | REMS Materials | Assessment Plan | 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 clozapine for outpatient use and/or initiate treatment for inpatients must:
+ Patients who are prescribed clozapine:
+ Pharmacies that dispense clozapine for outpatient use must:
+ Pharmacies that dispense clozapine for inpatient use must:
+ Wholesalers-distributors that distribute clozapine must:

I'm dispensing a drug product and understand the REMS was recently updated; how do I view the changes?

www.fda.gov/REMS

Risk Evaluation and Mitigation Strategies (REMS)

Clozapine

Shared System REMS

REMS last update: 09/29/2023

Products | Goals | Summary | REMS Materials | Assessment Plan | Update history

What updates have been made to the REMS?

Date	Summary of change
09/29/2023	Updates to reflect a change in application ownership
11/10/2021	Modified to make changes to the hours of operations for the Clozapine REMS Contact Center.
07/29/2021	Modified to: • make changes to the frequency of the submission of patient monitoring via a new Patient Status Form and make changes to the pharmacy operations to verify safe use conditions for a REMS dispense authorization • revise the third goal to read from "ensuring compliance with the monitoring schedule for absolute neutrophil count (ANC) prior to dispensing clozapine" to "ensuring prescribers submit documentation that periodic monitoring of patients is performed to identify severe neutropenia"

I'm dispensing a drug product and understand the REMS was recently updated; how do I view the changes?

www.fda.gov/REMS

Risk Evaluation and Mitigation Strategies (REMS)

Information on Clozapine

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Postmarket Drug Safety Information for Patients and Providers

Index to Drug-Specific Information

Latest Update

September 21, 2023 - As part of our regular review of all risk evaluation and mitigation strategies (REMS), and in light of the Agency's continued exercise of enforcement discretion with respect to certain aspects of the Clozapine REMS, FDA is conducting a thorough reevaluation of the Clozapine REMS to determine whether the REMS can be modified to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine.

As part of this reevaluation, FDA has funded a study by Brigham and Women's Hospital that includes an analysis of clozapine utilization, adherence to the REMS requirement for monitoring of absolute neutrophil count (ANC), and clinical outcomes. In addition, FDA is conducting a study in collaboration with the Veterans Health Administration to better understand the incidence and severity of neutropenia in patients taking clozapine, and the Agency is conducting a study using the Sentinel System to better understand adherence to the monitoring requirements. All three studies are currently ongoing, and we expect the findings from these studies to be complete within the next year. The Agency intends to take appropriate regulatory action, as needed, based on its reevaluation of the Clozapine REMS.

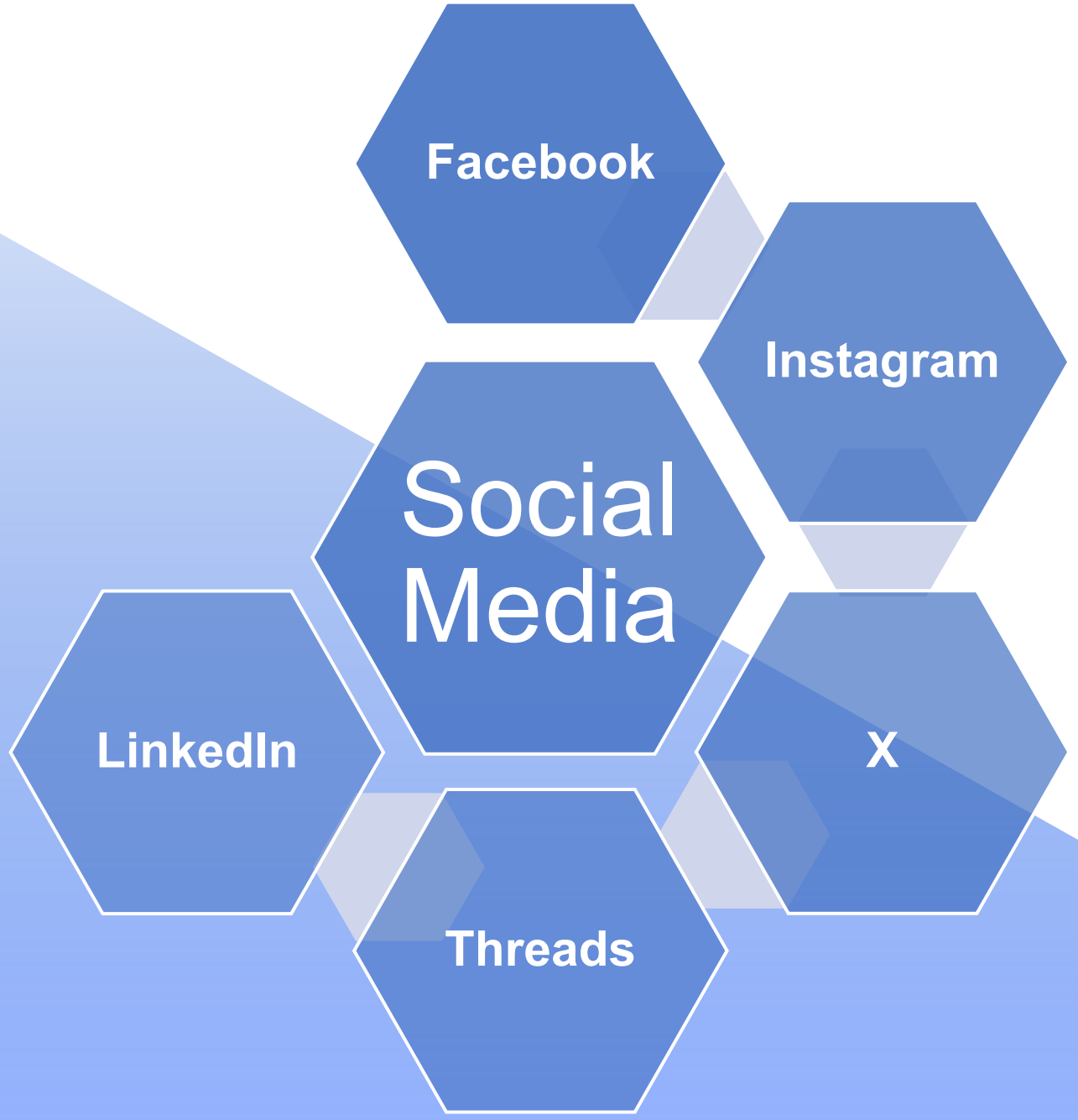
November 2, 2022 - FDA is temporarily exercising additional enforce discretion to prevent interruption of treatment for patients. For more information, please see the updated CDER Statement.

Content current as of:
09/22/2023

Regulated Product(s)
Drugs

I'm dispensing a drug product and understand the REMS was recently updated; how do I view the changes?

www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine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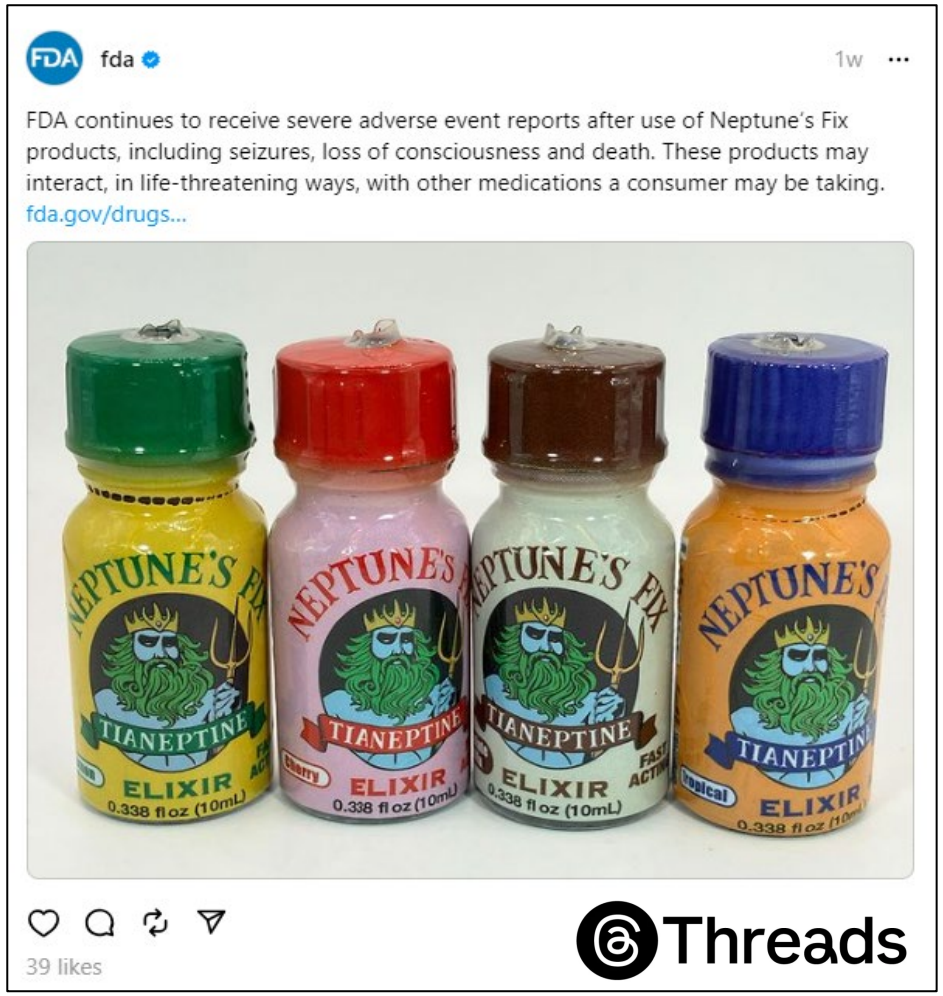

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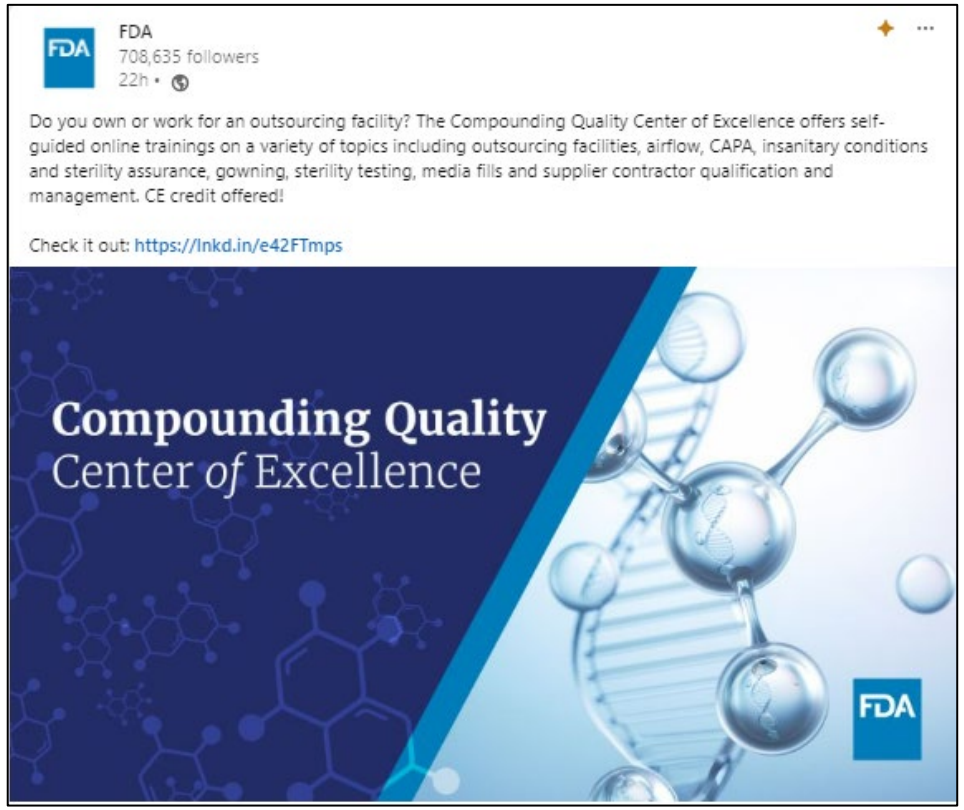

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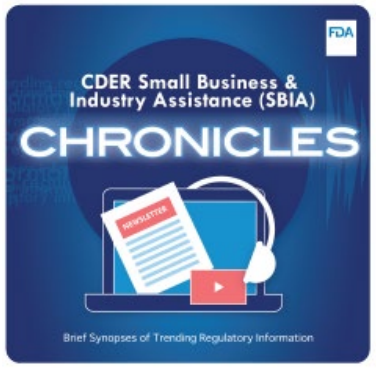

CDER SBIA Chronicles

Highlights on regulatory information

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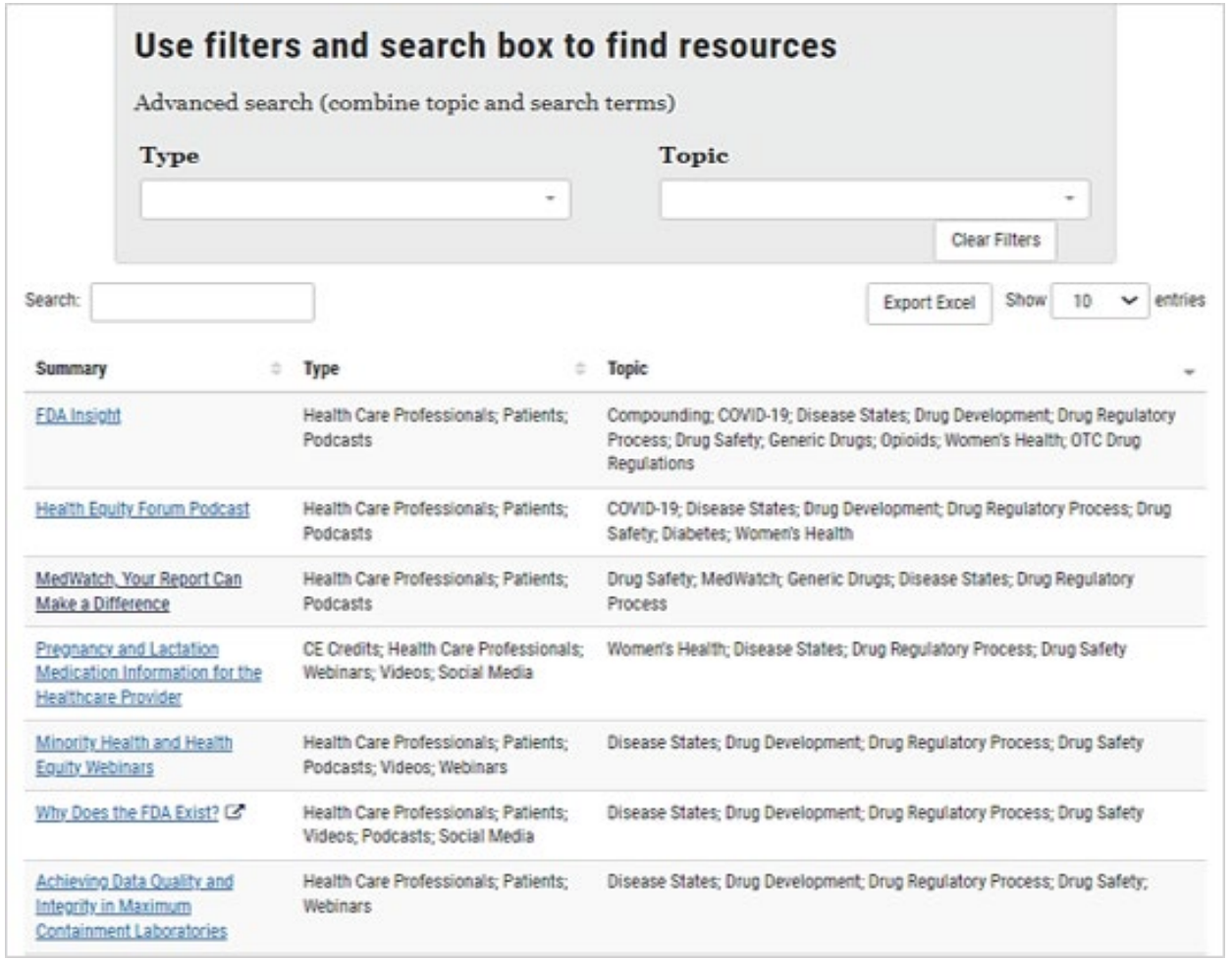

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Advanced search (combine topic and search terms)

Type | **Topic**

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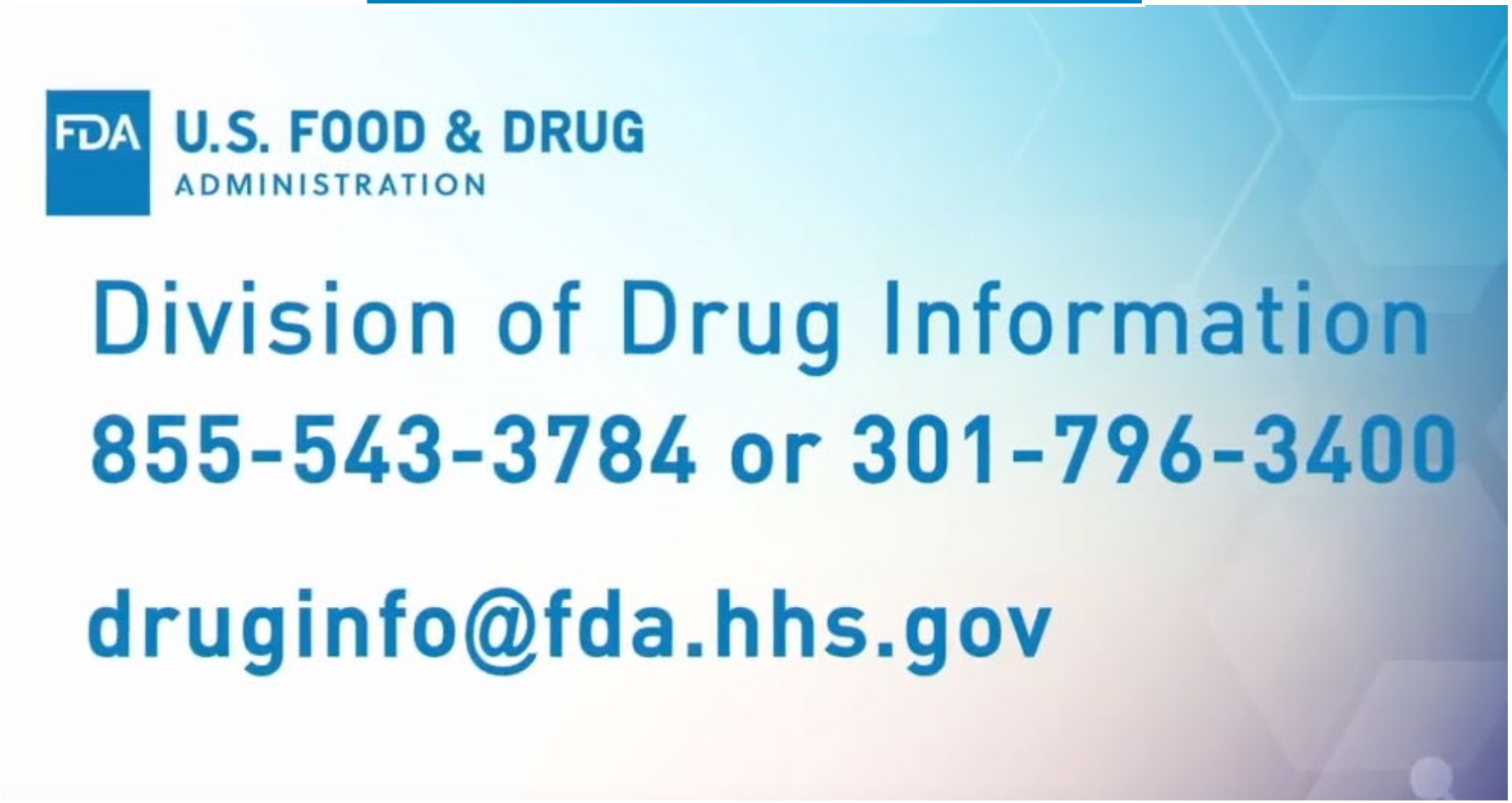
Search: | Export Excel | Show 10 entries

Summary	Type	Topic
FDA Insight	Health Care Professionals; Patients; Podcasts	Compounding; COVID-19; Disease States; Drug Development; Drug Regulatory Process; Drug Safety; Generic Drugs; Opioids; Women's Health; OTC Drug Regulations
Health Equity Forum Podcast	Health Care Professionals; Patients; Podcasts	COVID-19; Disease States; Drug Development; Drug Regulatory Process; Drug Safety; Diabetes; Women's Health
MedWatch, Your Report Can Make a Difference	Health Care Professionals; Patients; Podcasts	Drug Safety; MedWatch; Generic Drugs; Disease States; Drug Regulatory Process
Pregnancy and Lactation Medication Information for the Healthcare Provider	CE Credits; Health Care Professionals; Webinars; Videos; Social Media	Women's Health; Disease States; Drug Regulatory Process; Drug Safety
Minority Health and Health Equity Webinars	Health Care Professionals; Patients; Podcasts; Videos; Webinars	Disease States; Drug Development; Drug Regulatory Process; Drug Safety
Why Does the FDA Exist?	Health Care Professionals; Patients; Videos; Podcasts; Social Media	Disease States; Drug Development; Drug Regulatory Process; Drug Safety
Achieving Data Quality and Integrity in Maximum Containment Laboratories	Health Care Professionals; Patients; Webinars	Disease States; Drug Development; Drug Regulatory Process; Drug Safety;

www.fda.gov/CDERLearn

Thank You!



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