

FDALabel Database Amazon Cloud Version 2.3 Quick Start Manual

https://www.fda.gov/scienceresearch/bioinfor maticstools/ucm289739.htm

> National Center for Toxicological Research (NCTR) U.S. Food and Drug Administration (FDA)

September 2018

What is FDALabel?



- Free web-based database for managing, querying and organizing drug product labeling information
- Database of over 100,000 FDA Structured Product Labelings (SPL)
- Includes human prescription, biological, over-the-counter (OTC), and animal drug product labelings
- User-friendly interface with full-text labeling search, customizable search, and all labeling section search
- Updated monthly from FDA's SPL archive (hosted by DailyMed)
- A secure 3-tier platform web application with Oracle database
- Developed and maintained at NCTR (National Center for Toxicological Research) since 2012
- Most popular NCTR/FDA Bioinformatics tool

FDALabel Database Key Features



- Search using a single field (e.g., full-text search, product or generic name search) or use a combination of fields to create advanced searches including:
 - Document types (e.g., Human Rx, OTC, Animal Rx)
 - Marketing categories (e.g., ANDA, BLA, NDA)
 - Presence of, or text within, specific sections of the prescribing information (e.g., BOXED WARNING, INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, DRUG INTERACTIONS)
 - Pharmacologic class(es)
 - MedDRA terminologies
 - Chemical structure and similarity search
 - SPL identifiers (e.g., Product NDC Codes and SET IDs)
- Summary statistics and total labelings counts by specific sections
- Export and save summary results in spreadsheet format (Excel)
- Create, save, share permanent query links to replicate searches
- User Support Team to answer questions or assist with queries

Examples of What Questions Can Be Answered Using FDALabel?



What drug product labelings have a Boxed Warning section with keywords "acute liver failure"?



What drugs share the same drug class (e.g., beta-Adrenergic Blocker)?



How many drug labelings contain MedDRA term "acute kidney injury"?



What is a drug approval history (integrated to Drugs@FDA)?

FDALabel Interface Overview

	FDALabel Home About Database Updates Disclaimer Contact Restore Last Query Clear All Search
7 Default search panels	Labeling Types
	or choose one or more from the list:
B Add more criteria	Application Types or Marketing Categories 3 2 Choose one or more: ANDA BLA NDA OTC Monograph Not Final OTC Monograph Not Final 3
Start search	or choose one or more from the list:
Start search	Product Name(s)
	3 Trade or generic/proper name contains Enter any part(s) of product name
	Labeling Full Text Search
	Enter full text query Query syntax: use 'and' or 'or' between words if they are not required to occur contiguously
	Labeling Section(s)
	Enter query terms within The query may be empty to check for presence of a section Query syntax: use 'and' or 'or' between words if they are not required to occur contiguously
	Pharmacologic Class(es) Begin entering part(s) of a class name, then select from suggestions that appear of type Established Pharmacologic Class [EPC]
	Labeling, Product and Ingredient Identifiers
dditional Search Panels	Ingredient type (UNII) Active Search for: Application Number (e.g., ANDA077844, BLA125118, NDA020977)
	DEA Schedule (e.g., CII, CIII, CIV, CV) MCC Number (e.g., 0378-4105, 49702-221, 60505-3583) SE HOL (e.g., card) 519-0158-4366-aa3c-af53492825a1) SE HOL (e.g., card) 519-0158-4366-aa3c-af53492825a1) Unique Ingredient Identifier (overly To search for active ingredients, inactive ingredients or both, type in alphanumeric code(s)
	Add more criteria: Labeling Full Text Search Product Name(s) Labeling Section(s) Labeling Types Pharmacologic Class(es) Application Types or Marketing Categories Market Status MedDRA Terms Chemical Structure Labeling, Product and Ingredient Identifiers

User Case 1: Full Text Search

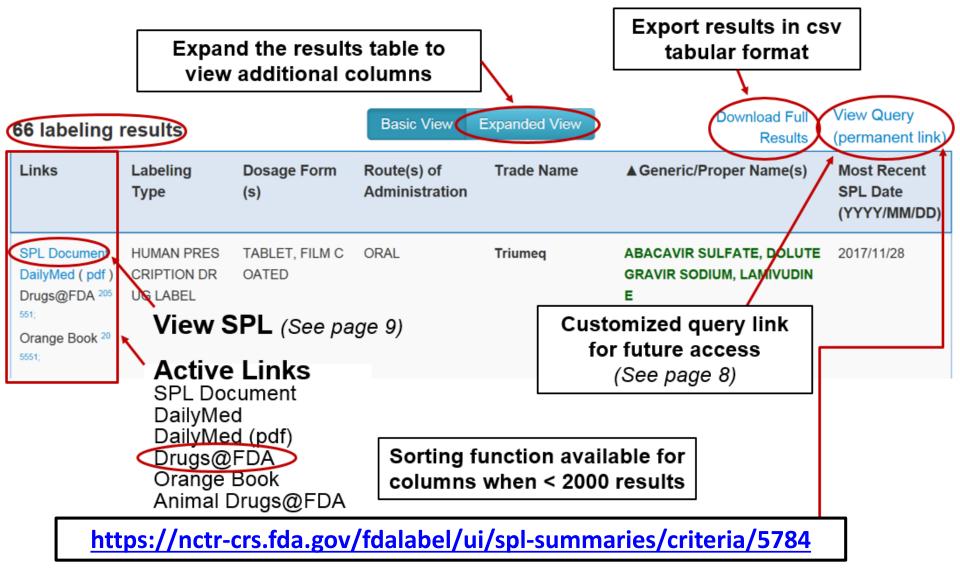
Search for Human Prescription Drug and New Drug Application that have acute liver failure and hepatitis

	Labeling Types	Step 1: Select "Human I	Rx"
	Choose one or more: Animal Rx Animal OT or choose one or more from the list:	TC Human Rx Human OTC	Medical Device Clear or remove panels
(And"	Application Types or Mar	Step 2: Select "NDA"	Add "NDA" to exclude some labeling duplications
search	Choose one or more: ANDA BLA NDA		Ionograph Not Final
8	Labeling Full Text Sear	ch Step 3: Type " acute liver fa	× ilure" and "hepatitis"
	Query syntax: use 'and' or 'or' between words if	f they are not required to occur contigu	Step 4: Search
	New Group of Criteria	Restore Last Query Cle	ar All Search »

Search »

Results Overview

66 Labeling Results for Human Rx and NDA with acute liver failure



*SPL counts shown in manual are accurate as of September 2018

SPL Highlighted Terms

Full Text search for "acute liver failure" AND "hepatitis"

https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/5784

5.3 Hepatotoxicity

Search terms are highlighted in SPL

Click on a term to remove highlights

Hepatic adverse events have been reported in patients receiving a dolutegravir-containing regimen [see Adverse Reactions (6.1)]. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of TRIUMEQ [see Adverse Reactions (6.1)]. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation particularly in the setting where anti-hepatitis therapy was withdrawn. Cases of hepatic toxicity including elevated serum liver biochemistries, hepatitis, and acute liver failure have also been reported in patients receiving a dolutegravir-containing regimen who had no pre-existing hepatic disease or other identifiable risk factors. Drug-induced liver injury leading to liver transplant has been reported with TRIUMEQ. Monitoring for hepatotoxicity is recommended.

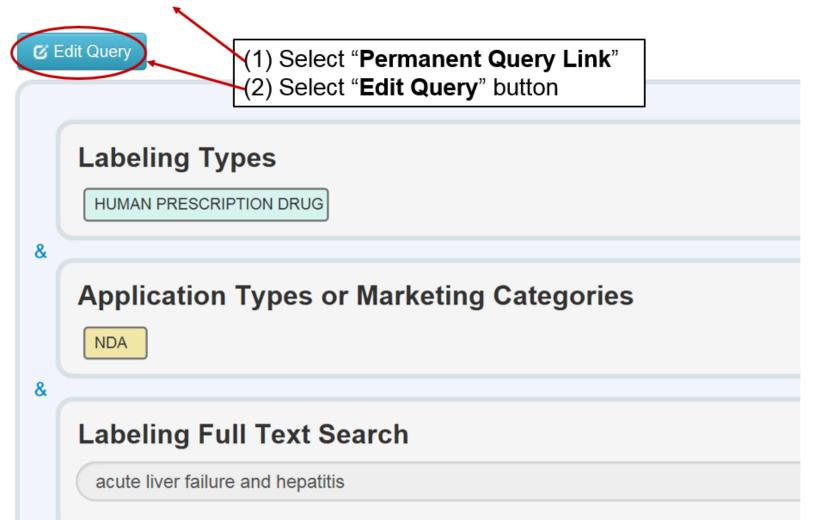
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Permanent Query Link

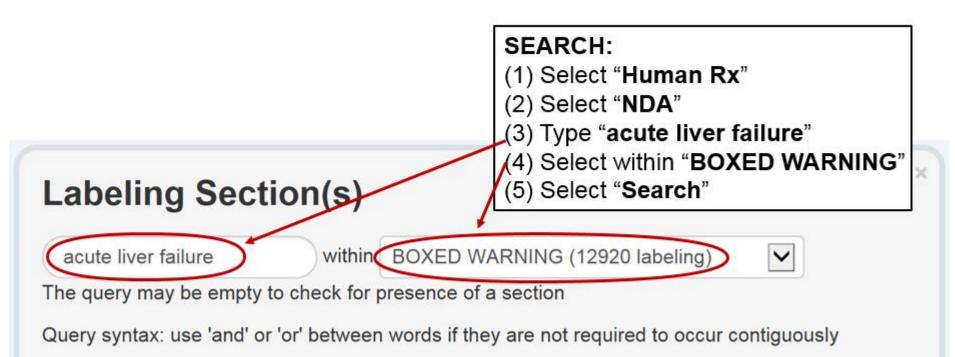
Use Permanent Query Link to save, share, replicate, or modify queries

https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/5784



User Case 2: Section Search

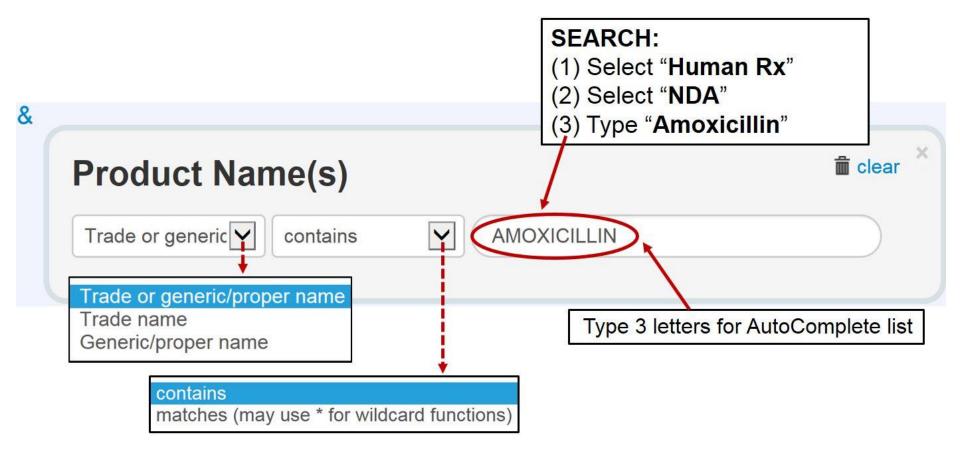
Search for Human Prescription Drug and New Drug Application that have acute liver failure within the BOXED WARNING



https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/5785

User Case 3: Product Title Search

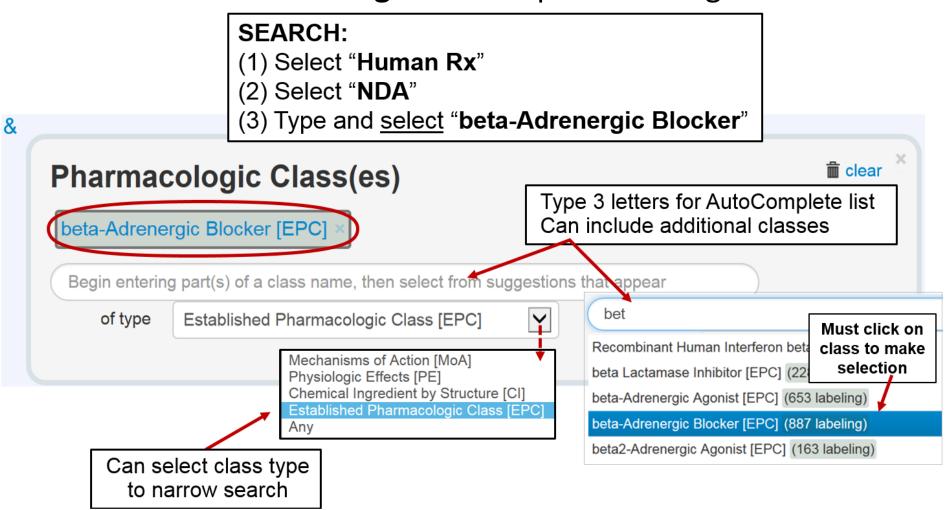
Search for Human Prescription Drug and New Drug Application and drug products with the name Amoxicillin



https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/5788

User Case 4: Pharmacologic Class

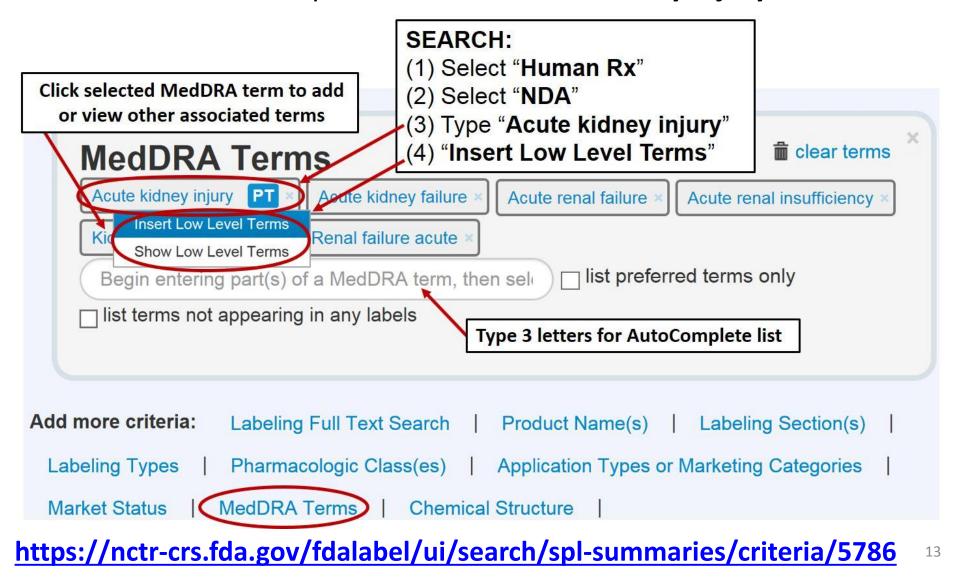
Search for Human Prescription Drug and New Drug Application in the beta-Adrenergic Blocker pharmacologic class



https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/5787 12

User Case 5: MedDRA Terms Search

Search for Human Prescription Drug and New Drug Application and MedDRA preferred term Acute kidney injury



FDALabel Support and Information

FDALabel Amazon Cloud Version

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

FDALabel Amazon Cloud Public Homepage

https://www.fda.gov/ScienceResearch/BioinformaticsTools/ucm289739.htm

Support Contacts

Comments, Suggestions, Questions: Hong Fang <u>Hong.Fang@fda.hhs.gov</u> Technical Support: Steve Harris <u>Stephen.Harris@fda.hhs.gov</u> User Support: Taylor Ingle <u>Taylor.Ingle@fda.hhs.gov</u> NCTR Support Team <u>NCTRBioinformaticsSupport@fda.hhs.gov</u>

Publication

Fang, H. et al. FDA drug labeling: rich resources to facilitate precision medicine, drug safety, and regulatory science. *Drug Discovery Today* (2016) (10):1566-1570. <u>Abstract</u>