Quick Start Manual
FDALabel Database

https://www.fda.gov/science-research/bioinformatics-tools/fdalabel-full-text-search-drug-labeling **(home page)**

https://nctr-crs.fda.gov/fdalabel/ui/search **(launch database)**

Dec. 2020

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

What is FDALabel?

- Free web-based database for managing, querying and organizing drug product labeling information

- Database of over 130,000 FDA Structured Product Labelings (SPL)

- Includes human prescription, biological, over-the-counter (OTC), and animal drug product labeling documents

- 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: https://www.fda.gov/science-research/bioinformatics-tools

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

Example Questions Answered Using FDALabel

1 What drug labelings include a Boxed Warning section with keywords "acute liver failure"?   Query   Results

2 What drug products are indicated for type 2 diabetes mellitus?   Query   Results

3 How many drug labelings contain the MedDRA PT term "acute kidney injury" and related LTTs?   Query   Results

4 What drugs share the same pharmacologic drug class (e.g., beta-Adrenergic Blocker)?   Query   Results
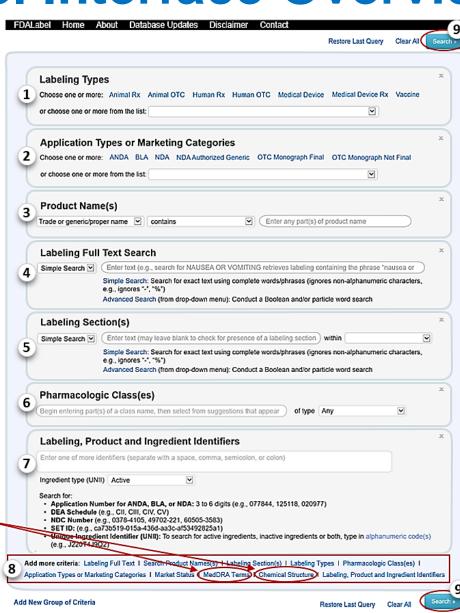
FDALabel Interface Overview
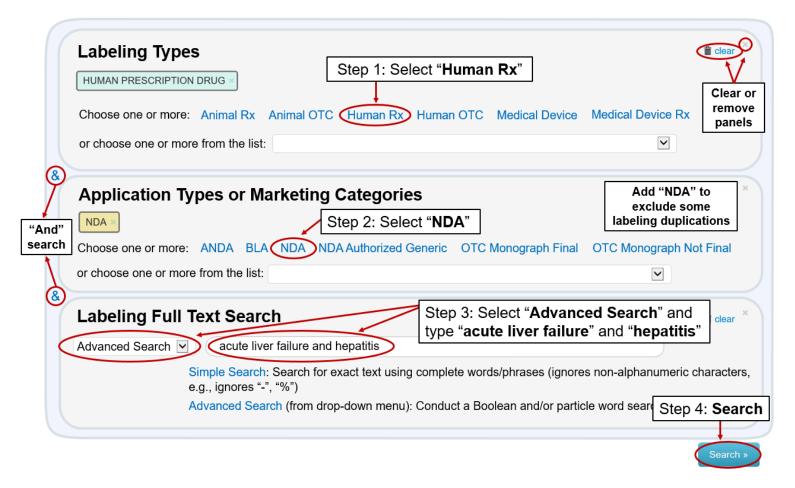

1-7 Default search panels

8 Add more criteria
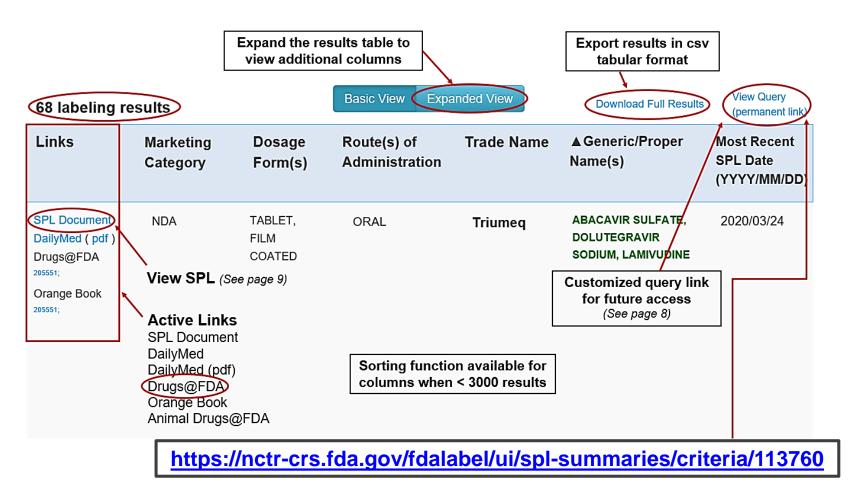
9 Start search

Additional Search Panels

User Case 1: Full Text Search

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

Results Page Overview

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

Expand the results table to view additional columns

Export results in csv tabular format

68 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 (pdf) Drugs@FDA 205551; Orange Book 205551;	NDA	TABLET, FILM COATED	ORAL	Triumeq	ABACAVIR SULFATE, DOLUTEGRAVIR SODIUM, LAMIVUDINE	2020/03/24

View SPL *(See page 9)*

Active Links
SPL Document
DailyMed
DailyMed (pdf)
Drugs@FDA
Orange Book
Animal Drugs@FDA

Customized query link for future access *(See page 8)*

Sorting function available for columns when < 3000 results

https://nctr-crs.fda.gov/fdalabel/ui/spl-summaries/criteria/113760

*SPL counts shown in manual are accurate as of Dec. 2020

SPL Highlighted Terms

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

https://nctr-crs.fda.gov/fdalabel/ui/spl-summaries/criteria/113760

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/113760

Edit Query

(1) Select "**Permanent Query Link**"
(2) Select "**Edit Query**" button

Labeling Types

HUMAN PRESCRIPTION DRUG

&

Application Types or Marketing Categories

NDA

&

Labeling Full Text Search

Advanced Searc ⌄   acute liver failure and hepatitis

User Case 2: Section Search

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

SEARCH:
(1) Select "**Human Rx**"
(2) Select "**NDA**"
(3) Type "**acute liver failure**"
(4) Select within "**BOXED WARNING**"
(5) Select "**Search**"

Labeling Section(s)

Simple Search ▾   acute liver failure   within   BOXED WARNING (14251 labeling) ▾

Simple Search: Search for exact text using complete words/phrases (ignores non-alphanumeric characters, e.g., ignores "-", "%")

Advanced Search (from drop-down menu): Conduct a Boolean and/or particle word search

https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/113818

User Case 3: Product Search

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

SEARCH:
(1) Select "**Human Rx**"
(2) Select "**NDA**"
(3) Type "**Amoxicillin**"

Product Name(s)

Trade or generic/proper name | contains | AMOXICILLIN

Trade or generic/proper name
Trade name
Generic/proper name

Type 3 letter for AutoComplete list

contains
matches (may use * for wildcard functions)

https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/113819

User Case 4: Pharmacologic Class

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

SEARCH:
(1) Select "**Human Rx**"
(2) Select "**NDA**"
(3) Type and <u>select</u> "**beta-Adrenergic Blocker**"

&

Pharmacologic Class(es)

beta-Adrenergic Blocker [EPC] ×

Type 3 letters for AutoComplete list
- Must click to select a class
- Can select multiple classes

Begin entering part(s) of a class name, then select from suggestions that appear

of type   Established Pharmacologic Class [EPC] ▼

Mechanisms of Action [MoA]
Physiologic Effects [PE]
Chemical Ingredient by Structure [CI]
Established Pharmacologic Class [EPC]
Any

Can select class type to narrow search

bet

Adrenergic beta-Agonists [MoA] (655 labeling)
Adrenergic beta-Antagonists [MoA] (809 labeling)
beta-Adrenergic Agonist [EPC] (655 labeling)
beta-Adrenergic Blocker [EPC] (906 labeling)

https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/113822

User Case 5: MedDRA Term Search

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

SEARCH:
(1) Select "**Human Rx**"
(2) Select "**NDA**"
(3) Type "**Acute kidney injury**"
(4) "**Insert Low Level Terms**"

Click selected MedDRA term to add or view other associated terms

MedDRA Terms

Acute kidney injury PT × | Acute kidney failure × | Acute renal failure × | Acute renal insufficiency ×

Insert Low Level Terms
Show Low Level Terms

Renal failure acute ×

Begin entering part(s) of a MedDRA term, then sel | ☐ list preferred terms only

☐ list terms not appearing in any labels

Type 3 letters for AutoComplete list

🗑 clear terms

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 |

https://nctr-crs.fda.gov/fdalabel/ui/search/spl-summaries/criteria/113823

FDALabel Support and Information

FDALabel Public Version (Hosted on Amazon Cloud)
https://nctr-crs.fda.gov/fdalabel/ui/search

FDALabel Public Homepage
https://www.fda.gov/science-research/bioinformatics-tools/fdalabel-full-text-search-drug-labeling

Contact Support

Comments, Suggestions, Questions: Hong Fang Hong.Fang@fda.hhs.gov

Technical Support: Steve Harris Stephen.Harris@fda.hhs.gov

User Support: Taylor Ingle Taylor.Ingle@fda.hhs.gov

NCTR Support Team: NCTRBioinformaticsSupport@fda.hhs.gov

Additional Information

FDALabel Resources

[Simple Search Guide](#)

[Advanced Search Guide](#)

[Query Logic Guide](#)

Publications

Fang, H. et al. FDALabel for drug repurposing studies and beyond. *Nat Biotechnol* 38; 1378-1379 (2020). [Abstract](#)

Mehta, D. et al. Study of pharmacogenomic information in FDA-approved drug labeling to facilitate application of precision medicine. *Drug Discov Today* 25(5):813-820 (2020). [Abstract](#)

Wu, L. et al. Study of serious adverse drug reactions using FDA-approved drug labeling and MedDRA. *BMC Bioinformatics* 14;20(Suppl 2):97 (2019). [Abstract](#)

Fang, H. et al. FDA drug labeling: rich resources to facilitate precision medicine, drug safety, and regulatory science. *Drug Discov Today* 21(10):1566-1570 (2016). [Abstract](#)