FDALabel Database Amazon Cloud Version 2.3 Quick Start Manual

https://www.fda.gov/scienceresearch/bioinformaticstools/ucm289739.htm

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

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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?

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

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

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

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

FDALabel Interface Overview

1-7 Default search panels

8 Add more criteria

9 Start search

Additional Search Panels

5

User Case 1: Full Text Search

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

Search »

Labeling Types

HUMAN PRESCRIPTION DRUG ×

Step 1: Select "**Human Rx**"

🗑 clear

Clear or remove panels

Choose one or more: Animal Rx   Animal OTC   Human Rx   Human OTC   Medical Device

or choose one or more from the list:

&

Application Types or Marketing Categories

NDA ×

Step 2: Select "**NDA**"

Add "NDA" to exclude some labeling duplications

"And" search

Choose one or more: ANDA   BLA   NDA   OTC Monograph Final   OTC Monograph Not Final

or choose one or more from the list:

&

Labeling Full Text Search

acute liver failure and hepatitis

Step 3: Type "**acute liver failure**" and "**hepatitis**"

Query syntax: use 'and' or 'or' between words if they are not required to occur contiguously

Step 4: **Search**

Add New Group of Criteria   Restore Last Query   Clear All   Search »

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

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Results Overview

66 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

66 labeling results

Basic View | Expanded View

Download Full Results

View Query (permanent link)

Links	Labeling Type	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;]	HUMAN PRESCRIPTION DRUG LABEL	TABLET, FILM COATED	ORAL	Triumeq	ABACAVIR SULFATE, DOLUTEGRAVIR SODIUM, LAMIVUDINE	2017/11/28

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 < 2000 results

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

*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

Search terms are highlighted in SPL

5.3 Hepatotoxicity

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.

Click on a term to remove highlights

5.3 Hepatotoxicity

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.

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

[**☑ 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

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)

acute liver failure | within | BOXED WARNING (12920 labeling) |

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

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**

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

Product Name(s)

Trade or generic | contains | AMOXICILLIN

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

Type 3 letters for AutoComplete list

contains
matches (may use * for wildcard functions)

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

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

Pharmacologic Class(es)

🗑 clear

beta-Adrenergic Blocker [EPC] ✕

Type 3 letters for AutoComplete list
Can include additional classes

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

of type   Established Pharmacologic Class [EPC] ⌄

bet

Must click on class to make selection

Recombinant Human Interferon beta

beta Lactamase Inhibitor [EPC] (22...)

beta-Adrenergic Agonist [EPC] (653 labeling)

beta-Adrenergic Blocker [EPC] (887 labeling)

beta2-Adrenergic Agonist [EPC] (163 labeling)

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

Can select class type to narrow search

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

User Case 5: MedDRA Terms Search

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

Click selected MedDRA term to add or view other associated terms

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

🗑 clear terms

MedDRA Terms

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

Insert Low Level Terms
Show Low Level Terms

Kic — 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

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/5786

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

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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. Abstract