



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

FDALabel Home About Database Updates Disclaimer Contact

Restore Last Query Clear All **9** Search »

1 Labeling Types

Choose one or more: [Animal Rx](#) [Animal OTC](#) [Human Rx](#) [Human OTC](#) [Medical Device](#) [Medical Device Rx](#) [Vaccine](#)
or choose one or more from the list:

2 Application Types or Marketing Categories

Choose one or more: [ANDA](#) [BLA](#) [NDA](#) [NDA Authorized Generic](#) [OTC Monograph Final](#) [OTC Monograph Not Final](#)
or choose one or more from the list:

3 Product Name(s)

Trade or generic/proper name contains Enter any part(s) of product name

4 Labeling Full Text Search

4 Simple Search Enter text (e.g., search for NAUSEA OR VOMITING retrieves labeling containing the phrase "nausea or
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

5 Labeling Section(s)

5 Simple Search Enter text (may leave blank to check for presence of a labeling section) within
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

6 Pharmacologic Class(es)

6 Begin entering part(s) of a class name, then select from suggestions that appear of type [Any](#)

7 Labeling, Product and Ingredient Identifiers

7 Enter one or more identifiers (separate with a space, comma, semicolon, or colon)
Ingredient type (UNII) [Active](#)
Search for:
• Application Number for ANDA, BLA, or NDA: 3 to 6 digits (e.g., 077844, 125118, 020977)
• DEA Schedule (e.g., CII, CIII, CIV, CV)
• NDC Number (e.g., 0378-4105, 49702-221, 60505-3583)
• SET ID: (e.g., ca73b519-015a-436d-aa3c-af53492825a1)
• Unique Ingredient Identifier (UNII): To search for active ingredients, inactive ingredients or both, type in alphanumeric code(s) (e.g., JZ20T4J9CZ)

8 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](#)

Add New Group of Criteria Restore Last Query Clear All **9** Search »

Additional Search Panels

User Case 1: Full Text Search

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

The screenshot shows a search interface with three main sections: Labeling Types, Application Types or Marketing Categories, and Labeling Full Text Search. Annotations include: 'Step 1: Select "Human Rx"' pointing to the 'Human Rx' button; 'Step 2: Select "NDA"' pointing to the 'NDA' button; 'Step 3: Select "Advanced Search" and type "acute liver failure and hepatitis"' pointing to the search type dropdown and the search text; 'Step 4: Search' pointing to the 'Search »' button. Other annotations include 'Clear or remove panels' pointing to a 'clear' button, 'Add "NDA" to exclude some labeling duplications' pointing to a plus icon, and 'And search' pointing to ampersand symbols between sections.

Labeling Types
HUMAN PRESCRIPTION DRUG ✕
Choose one or more: Animal Rx Animal OTC **Human Rx** Human OTC Medical Device Medical Device Rx
or choose one or more from the list:

Application Types or Marketing Categories
NDA ✕
Choose one or more: ANDA BLA **NDA** NDA Authorized Generic OTC Monograph Final OTC Monograph Not Final
or choose one or more from the list:

Labeling Full Text Search
Advanced Search ▾ acute liver failure and hepatitis
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
Search »

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

Basic View Expanded View

Download Full Results View Query (permanent link)

68 labeling results

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 <small>205551;</small> Orange Book <small>205551;</small>	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”

5.3 Hepatotoxicity

Search terms are highlighted in SPL

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/113760>

The screenshot shows a search interface with three main sections, each separated by an ampersand (&):

- Labeling Types**: A button labeled "HUMAN PRESCRIPTION DRUG".
- Application Types or Marketing Categories**: A button labeled "NDA".
- Labeling Full Text Search**: A dropdown menu set to "Advanced Search" and a text input field containing "acute liver failure and hepatitis".

At the top left, there is a blue button with a link icon and the text "Edit Query". A red circle highlights this button. A callout box with a black border contains the following instructions:

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

Two red arrows point from the callout box to the "Edit Query" button and the "Permanent Query Link" text above it.

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)

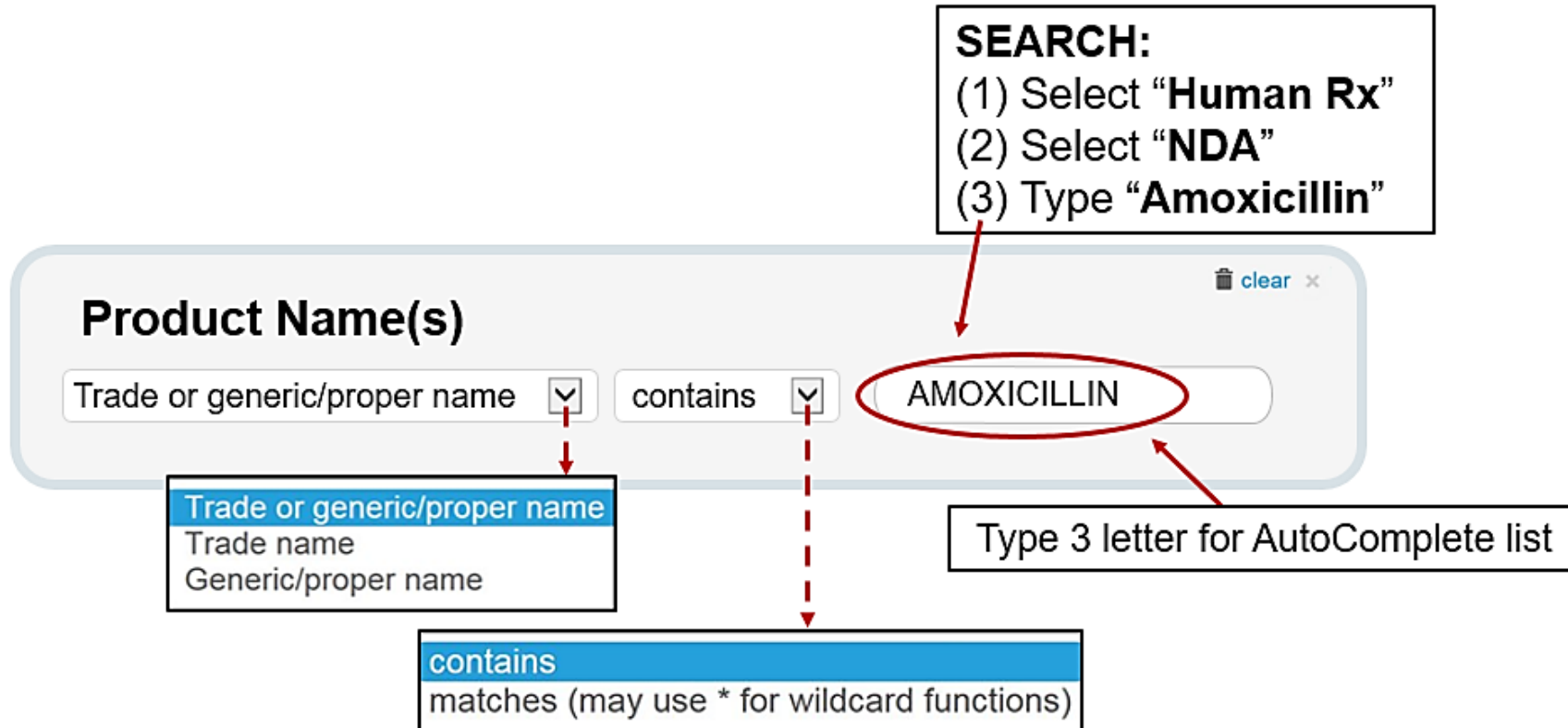
Simple Search: Search for exact text using complete words/phrases (ignores non-alphanumeric characters, e.g., ignores “-”, “%”)

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**



<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 select **"beta-Adrenergic Blocker"**

Pharmacologic Class(es)

beta-Adrenergic Blocker [EPC] x

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] v

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**

The screenshot shows the MedDRA search interface. A search box contains the text "Acute kidney injury" and a "PT" button. Below the search box, there are several buttons: "Insert Low Level Terms", "Show Low Level Terms", "Acute kidney failure", "Acute renal failure", "Acute renal insufficiency", "Kidney failure acute", and "Renal failure acute". A "SEARCH:" box contains the following instructions: (1) Select "Human Rx", (2) Select "NDA", (3) Type "Acute kidney injury", (4) "Insert Low Level Terms". A "clear terms" button is also visible. Below the search box, there are two checkboxes: "list preferred terms only" and "list terms not appearing in any labels". A "Type 3 letters for AutoComplete list" box is also present. At the bottom, there is a "Add more criteria:" section with several options: "Labeling Full Text Search", "Product Name(s)", "Labeling Section(s)", "Labeling Types", "Pharmacologic Class(es)", "Application Types or Marketing Categories", "Market Status", "MedDRA Terms", and "Chemical Structure". The "MedDRA Terms" option is circled in red.

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"

MedDRA Terms

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

Insert Low Level Terms × Show Low Level Terms × Kidney failure acute × Renal failure acute ×

Begin entering part(s) of a MedDRA term, then select 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](#)