Quick Logic Guide for FDALabel

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

Updated January 2021

There are two types text searches, Full Text and Auto Complete.

Full Text Search: The Full Text search function will query the entire drug labeling document, as well as labeling sections/subsections. There are two types of full text searches: Simple search and Advanced search.

Simple Search: Search for exact text using complete words/phrases (ignores non-alphanumeric characters. (See Guide 1- Simple Search for more detailed information)

All words must appear together: When multiple words are entered, they must appear in a row. For example, a search for "acute liver failure" requires all three words to appear together in that order. Text is searched exactly as entered: Boolean Operators (and/or/not) are treated as exact words. For example, searching for "hypotension or hypertension" requires those three words occur in that exact order, not "hypotension" or "hypertension".

Search characters: Searches are case insensitive and ignore non-alphanumeric characters (-/*/!/>). Characters are treated as a space.

Advanced Search: Conduct a Boolean and/or partial word search. (See <u>Guide 2- Advanced Search</u> for more detailed information)

All words must appear but can be separate: The "and" search requires all words to be found. For example, searching for "bleeding and vomiting" requires both the words "bleeding" and "vomiting" to occur separately anywhere in the document.

At least one word must appear: The "or" search requires only one of the words to be found. For example, searching for "bleeding or vomiting" requires only either "bleeding" or "vomiting" to be present.

Word elimination: The "not" search requires the absence of words. For example, "cirrhosis not glomerulonephritis" requires "cirrhosis" occur but "glomerulonephritis" must be absent.

Combinations: Operators can be used in conjunction - for example, "(bleeding and vomiting) or acute liver failure" will return all labels that have either both "bleeding" and "vomiting" or have the phrase "acute liver failure".

Stemming: The dollar sign "\$" operator can be used for stemming. For example, searching for "\$bleed" will also find "bleeding".

Partial words: The percent "%" symbol can substitute for multiple characters in a word. For example, searching for "dermatop%" will retrieve words beginning with "dermatop" (e.g., "dermatopathy"). Searching for "% steroid" will retrieve words ending with "steroid" (e.g., "corticosteroid"). The underscore "_" symbol can substitute for a single character in the search text. For example, searching for "Ig_" will retrieve "IgA".

Auto Complete Search:

Product Name(s), Pharmacologic Class(es), and MedDRA Terms functions allow for autocomplete searches. When at least three letters of the search text are entered, a drop-down menu appears that shows all available terms containing those letters in contiguous order anywhere in the term. Select one term at a time. There is no limit to the number of terms that can be added; repeat to add multiple terms.

Additional Information: (See Quick Start Guide for more information)

Combinations:

Search box combinations: Search with an unlimited number of search box combinations using the "and/or" options.

Add multiple search boxes: Add multiples of the same search box. For example, a search with two MedDRA Terms boxes: (1) "acute hepatic failure [PT] and LLTs liver failure and fulminant hepatic failure", and/or (2) "blood pressure measurement [PT] and LLTs blood pressure and BP", retrieves labeling containing both or at least one term from each of the two boxes (e.g., 'acute hepatic failure' and/or 'blood pressure measurement').

Labeling Statistics:

Labeling Section(s): Select a drug labeling section from the list (leave term field blank) to search for the presence of that specific section and retrieve the current count of labeling documents with that specific section.

FDALabel Support and Contact:

Comments and Suggestions: Hong Fang Hong.Fang@fda.hhs.gov

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

Technical Support: Steve Harris <u>Stephen.Harris@fda.hhs.gov</u> NCTR Support Team: <u>NCTRBioinformaticsSupport@fda.hhs.gov</u>