

# FDALabel

## Drug Labeling Database Tool

### What Is FDALabel?



FDALabel is an online database tool that allows you to perform customizable searches of drug labeling (e.g., human and animal prescription drugs, human and animal over-the-counter drugs, biological products). The FDALabel database is freely available to the public and contains over 130,000 drug labeling documents that are updated twice a month. The database was developed and is maintained by the FDA's National Center for Toxicological Research (NCTR). It is hosted by Amazon Web Services on the Cloud. Access FDALabel webpage ([www.fda.gov/FDALabelTool](http://www.fda.gov/FDALabelTool)) or tool link ([FDALabel](#)).

### Why Use FDALabel?

With FDALabel you can:



- Conduct full text searches of the entire labeling document or in specific sections/subsections of the labeling (e.g., Indication and Usage, Adverse Reaction, Drug Interactions).
- Perform customized searches with the option to further narrow the search by application type (e.g., NDA, BLA, ANDA).
- Search for information about a pharmacologic drug class (e.g. Serotonin Uptake Inhibitors).
- Search for adverse events across drug labeling documents using MedDRA standard terms.
- Search for active and inactive ingredients by UNII or chemical structures and substructures.
- Export and save results in Microsoft Excel for additional analysis.
- Directly access SPL documents (DailyMed), Drugs@FDA, and Orange Book webpages using links in the search results.
- Use saved query links to repeat searches and to share queries and results with colleagues.



### Questions FDALabel Can Answer:



- What NDA drugs have “acute liver failure” within the Labeling Full Text? [Query](#) | [Results](#)
- What BLA drug products have “lung cancer” in the INDICATIONS AND USAGE Labeling Section? [Query](#) | [Results](#)
- What NDA drug products are classified in the Serotonin Reuptake Inhibitor [EPC] Pharmacologic Class? [Query](#) | [Results](#)

For questions or support, contact:

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