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) 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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