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TC 1600 Examiner training using FDA and NIH databases to search drugs, formulations and their methods of treatment/use

November 2023

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Goals

1. Understand that a complete and thorough search is required by the Examiner performance and appraisal plan (i.e. PAP) and MPEP 904.
2. Recognize various FDA and NIH resources for searching drug information.
3. Understand the differences between various FDA and NIH resources.
4. Given key claim terms and/or a drug name, retrieve the relevant information using the appropriate resource.
5. Given the relevant information retrieved from the appropriate resource, locate the relevant information having the earliest publication.

Agenda

- Background & Overview
- Introductions to:
  - FDALabel
  - Drugs@FDA
  - DailyMed
  - Google search of FDA.gov
- Conclusion
- Live Demo

Searching is KEY!

- Searching is an important part of the Patent Examiner’s job.
- Examiners search to learn technology, keep abreast of state of the art, and determine patentability among other things.
- Further, search is used to evaluate an examiner's performance under the quality element of the PAP.

MPEP 904 how to search:

The examiner, after having obtained a thorough understanding of the invention disclosed and claimed in the nonprovisional application, then searches the prior art as disclosed in patents and **other published documents, i.e., nonpatent literature (NPL)**.

904.02 General Search Guidelines [R-07.2022]

In the examination of an application for patent, an examiner must conduct a thorough and complete search of the prior art. A search is considered thorough when all areas with the highest probability of finding prior art relevant to the invention as it is claimed and described in the specification are identified for search. Planning a thorough search of the prior art requires three distinct steps by the examiner: (A) identifying the field of search; (B) selecting the proper tool(s) to perform the search; and (C) determining the appropriate search strategy for each search tool selected. A search is considered complete when each of the identified areas are fully considered.

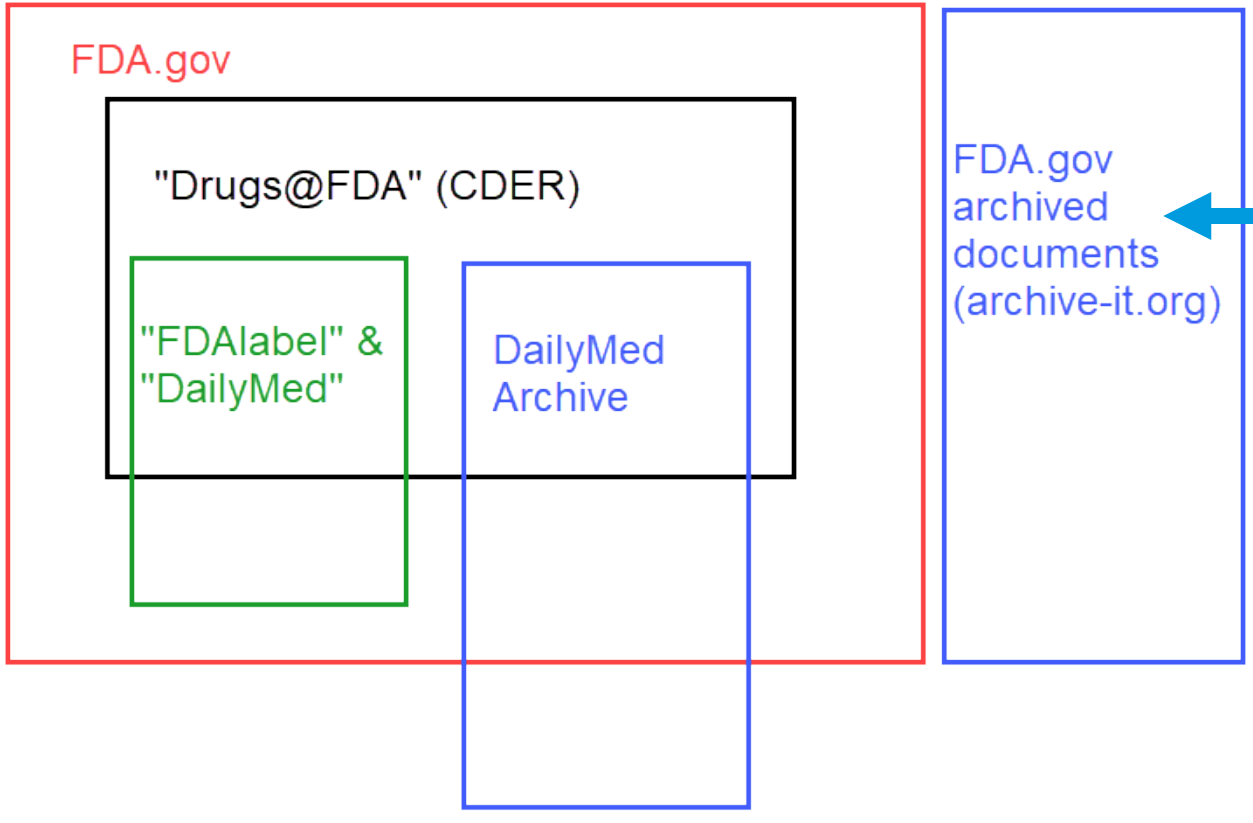
Overview

- This training will provide important ways to search for available FDA documents with the various tools already available to examiners.
- This search is a ‘how to’ on searching several FDA resources and is intended to ensure a complete and thorough understanding of them.

Database content

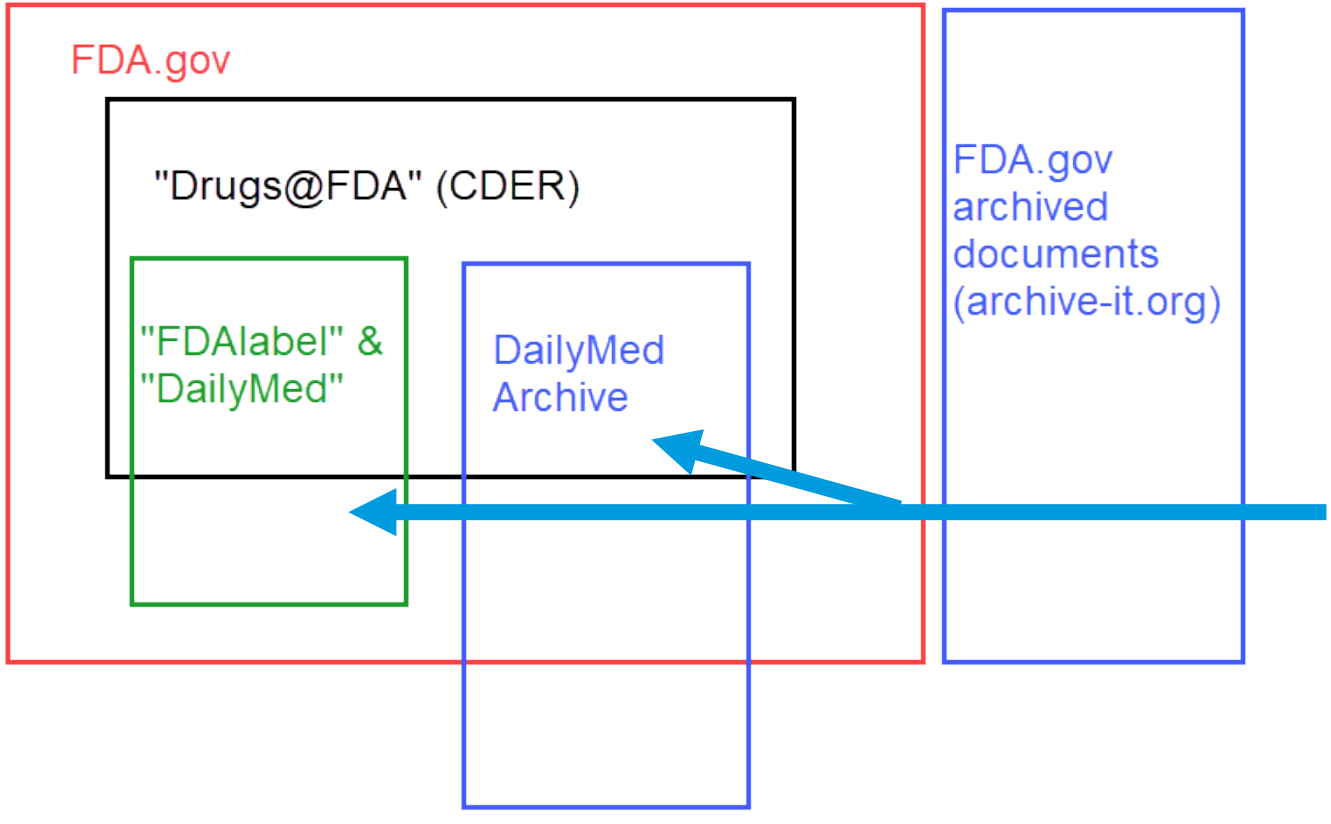
- The search resources that will be presented simultaneously have a significant amount of overlapping content and do contain different strengths.
- Choosing which database(s) to search will depend upon field availability, preference, and case specifics.
- Consider the strategy as a finite number of relevant search choices, of which, more than one can be chosen:
  - FDALabel
  - Drugs@FDA
  - DailyMed & DailyMed Archive (NIH)
  - Google search of FDA.gov domain(s)

Venn diagram of document location



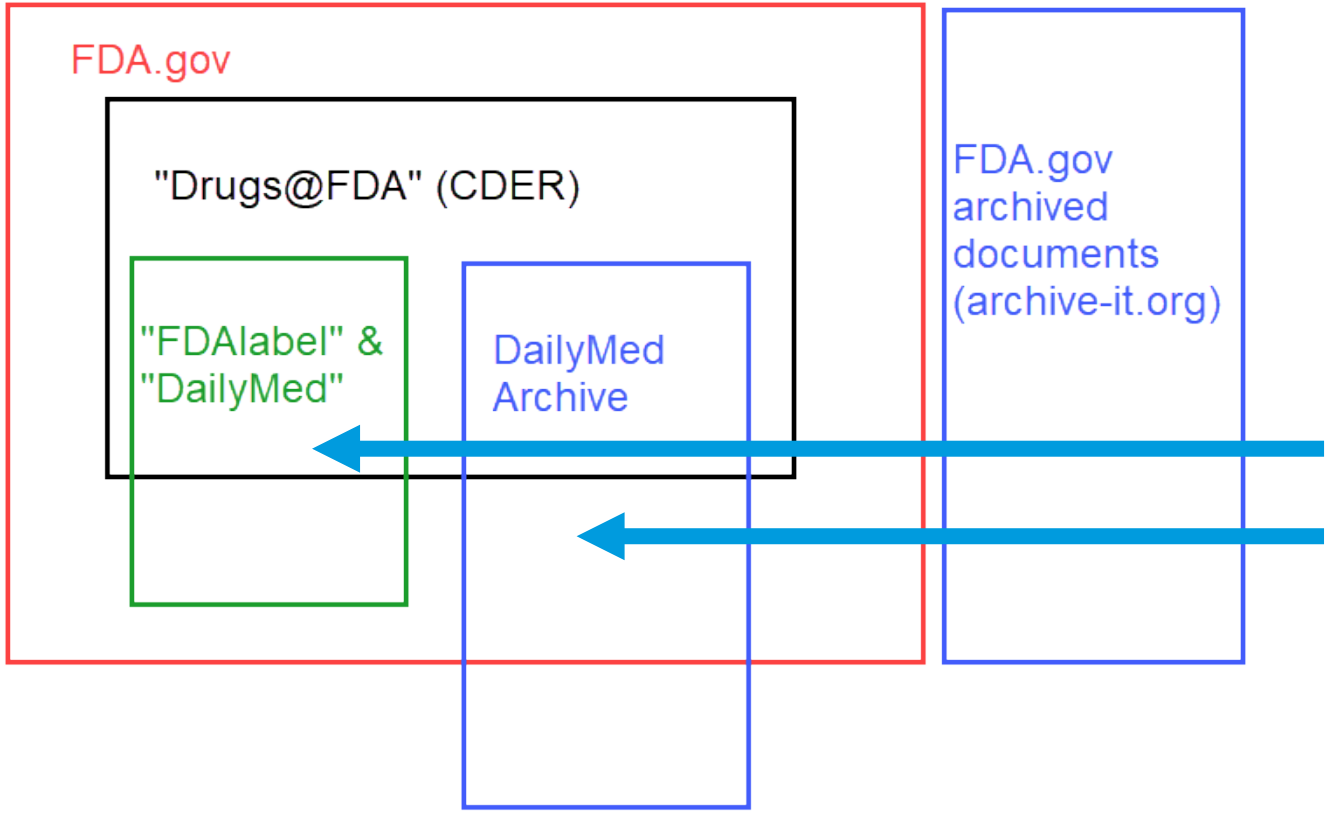
Old FDA documents are archived at *archive-it.org/organizations/1137*

Venn diagram of document location



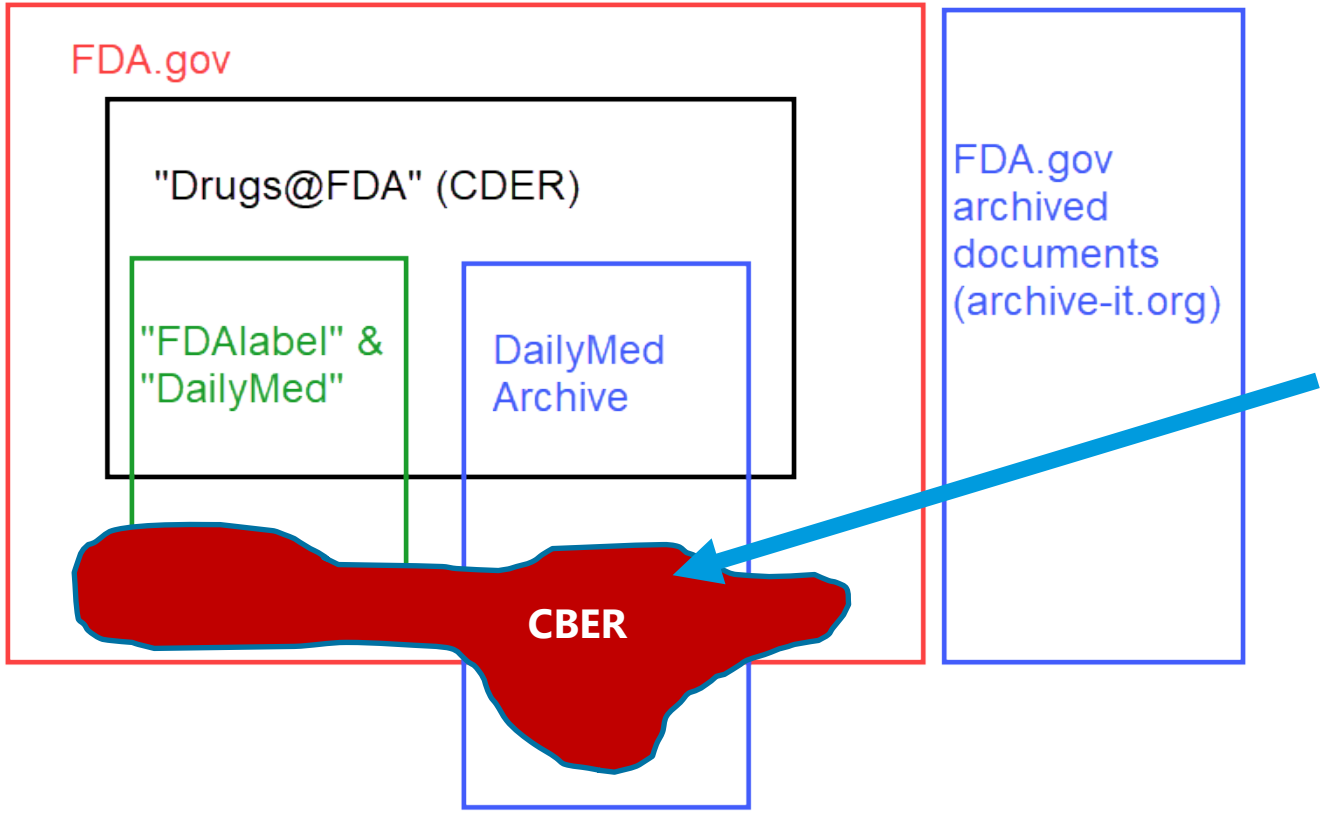
FDALabel, DailyMed, and the DailyMed Archive contain drug labels/inserts only.

Venn diagram of document location



- FDALabel and DailyMed contain current drug labels.
- The DailyMed Archive contains retired drug labels.
- The DailyMed Archive is best used to obtain a label with a good priority date after perusing current labels.

Venn diagram of document location



Although there is overlap, many biologics and vaccines fall under CBER (rather than CDER) guidance and therefore are not in Drugs@FDA.

FDALabel search

Database content and capabilities

	Search multiple terms	Current drug labels	Retired drug labels	Generic drug labels	Non-label content	Structure search	"Publicly available" date	Document location clarity
FDALabel	Y	Y		Y		Y		
Drugs@ FDA (CDER)		Y	Y		Y			Y
DailyMed	Y	Y		Y			Y	Y
DailyMed Archive			Y	Y			Y	Y
Google search of FDA.gov	Y	Y	Y	Y	Y			

What information is contained in the FDALabel Database?

Over 140,000 human prescription, biological, over-the-counter and animal drug label documents, including:

Labeling Types	Number of Labeling as of February 21, 2023
Human OTC Drugs*	90,518
Human Prescription Drugs and Biological Products**	53,188
Animal Prescription and Animal OTC Products	3,390

* Includes Human OTC drugs approved for marketing through a New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or the OTC monograph system.

** Includes drug products, therapeutic biologics, vaccines, plasma derivatives, allergenics (standardized and non-standardized), cellular therapy, and licensed minimally manipulated cells.

Source: www.fda.gov/science-research/bioinformatics-tools/fdalabel-full-text-search-drug-product-labeling#Overview

What is FDALabel?

- A web-based database maintained by FDA, allowing for full-text and structure searching of FDA-approved drug product labeling.
- Accessible via https://nctrcrs.fda.gov/fdalabel/ui/search
- Updated on a weekly basis

  – Note: This database is **different** from the FDA Online Label Repository (labels.fda.gov), which has a minimalistic search interface.

What information is contained in the FDALabel Database? (cont.)

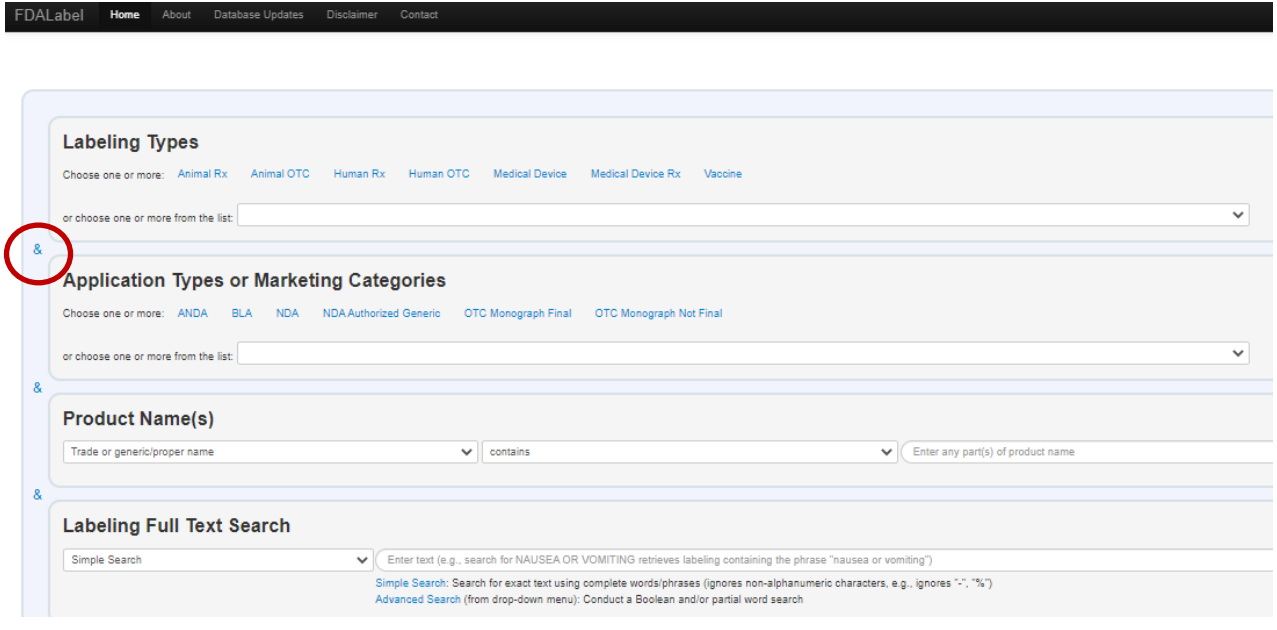
- Prescribing information, patient labeling, and carton/container labeling for the drugs and biologics, as well as label documents for homeopathic remedies, medical devices, dietary supplements, cosmetics, and medical foods.
- May be used to find information on indications, dosage and administration, contraindications (including warnings, adverse reactions, drug interactions, or information about use in particular populations of patients)

Search capabilities within FDALabel Database

- Full text searches of entire label, or within particular sections of labeling information
- Complex query builder, allowing you to "and/or" together searches within the following areas:
  - Document types
  - Marketing categories
  - Presence of (or text within) specific sections of prescribing information
  - SPL identifiers (e.g., NDC codes, UNIIs, SETIDs)
  - Market start/end date
  - Pharmacologic classes
  - Chemical structure

Navigating the search platform

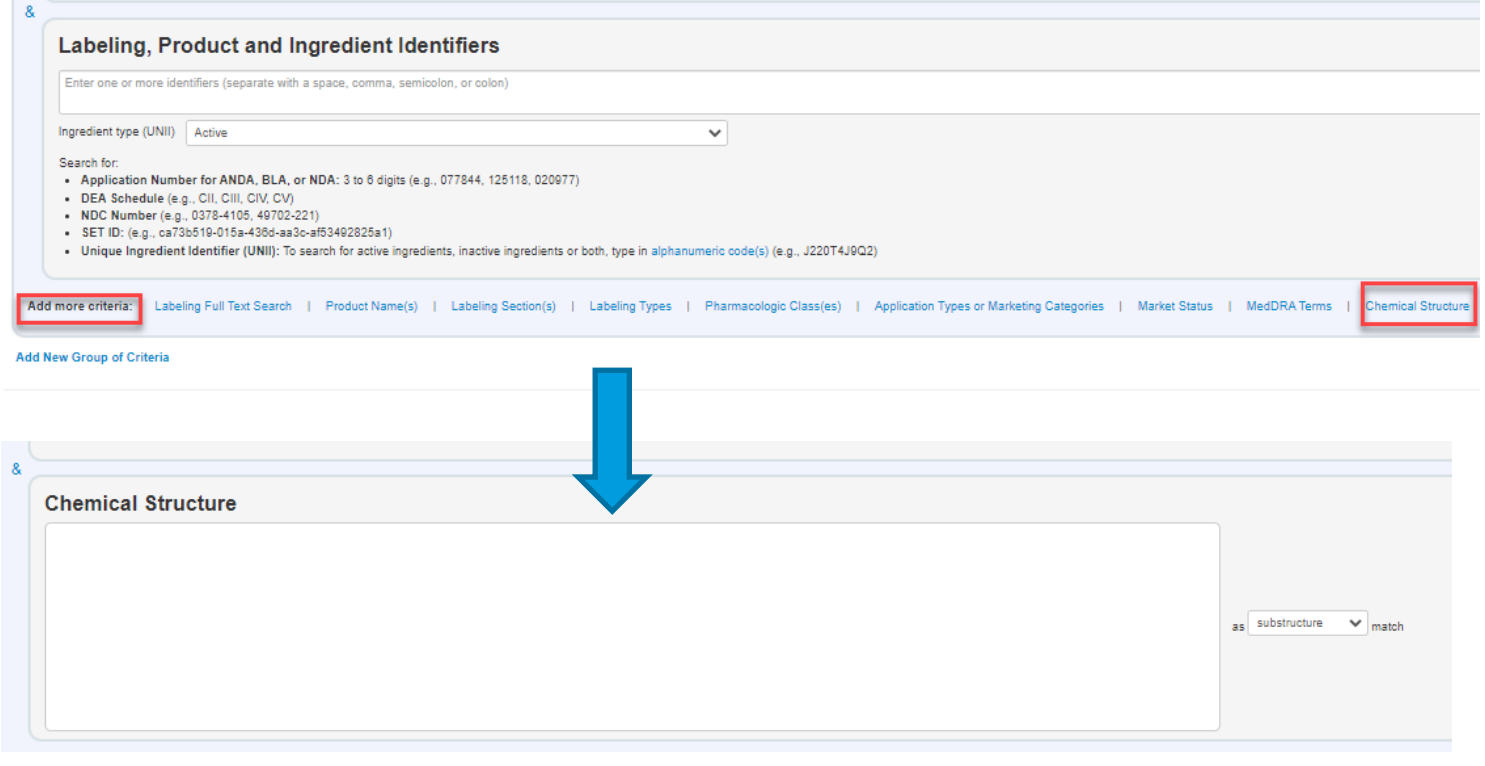
The home page is pre-populated with criteria you can fill in to begin building a search string:



Note the "&" between each box indicates these criteria will be "AND-ed" together

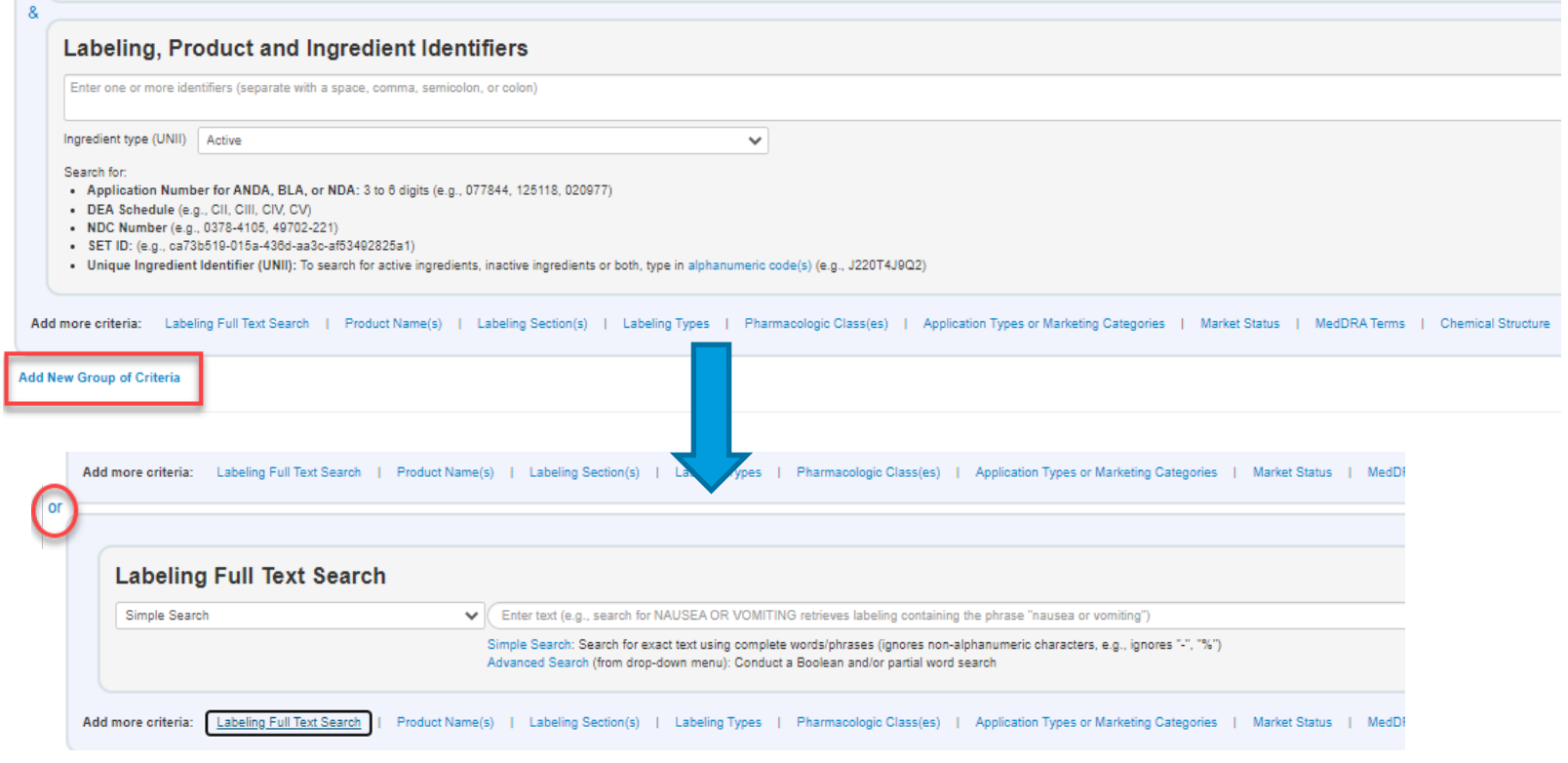
Navigating the search platform (cont.)

More criteria can be added at the bottom of the page:



Navigating the search platform (cont.)

A new group of criteria may be added to include alternatives in your search



Navigating the search results

Basic (Previous slide) vs. Expanded view

Sort ascending or descending by clicking any column heading

180 labeling results

Basic View | Expanded View

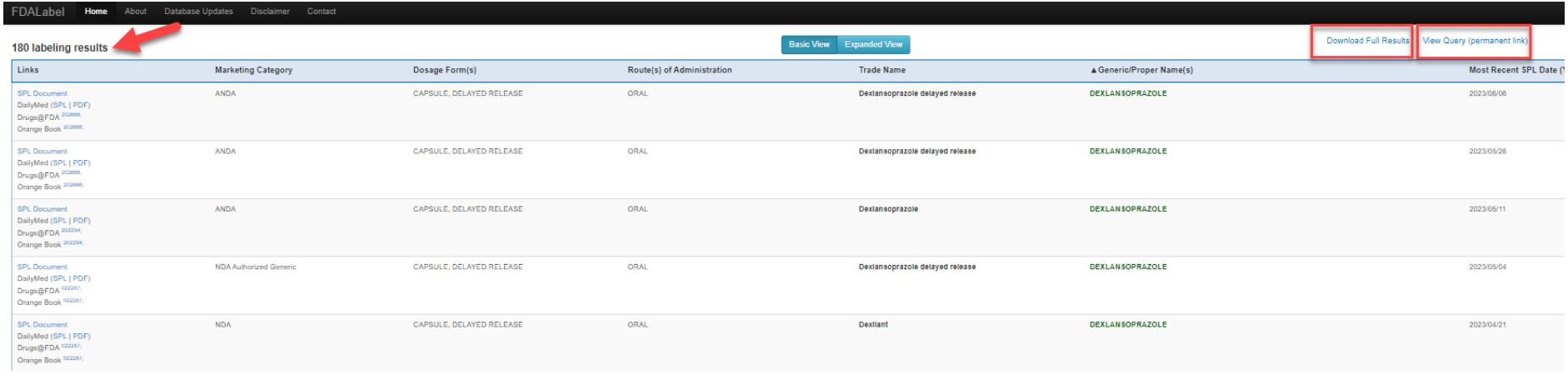
Links	Labeling Type	Dosage Form(s)	Route(s) of Administration	Marketing Category	Application Number(s)	Trade Name	Generic/Proper Name(s)	Most Recent SPL Date (YYYY/MM/DD)	Marketing Date(s) (YYYY/MM/DD)	Established Pharmacologic Class(es)	▼Initial U.S. Approval	Company	NDC(s)	Active Ingredient UNII(s)	MedDRA Report
SPL Document DailyMed (SPL | PDF) Drugs@FDA 202666; Orange Book 202666;	HUMAN PRESCRIPTI... DRUG LABEL	CAPSULE, DELAYED RELEASE	ORAL	ANDA	202666	Dexlansoprazole delayed release	DEXLANSOPRAZOLE	2023/06/06	2022/12/01-		1995	A S MEDICATION SOLUTIONS	50090-6514	UYE4T5I70X	Excel CSV
SPL Document DailyMed (SPL | PDF) Drugs@FDA 202666; Orange Book 202666;	HUMAN PRESCRIPTI... DRUG LABEL	CAPSULE, DELAYED RELEASE	ORAL	ANDA	202666	Dexlansoprazole delayed release	DEXLANSOPRAZOLE	2023/05/26	2022/12/01-	Proton Pump Inhibitor	1995	TWI PHARMACEU... INC	24979-001; 24979-002	UYE4T5I70X	Excel CSV
SPL Document DailyMed (SPL | PDF) Drugs@FDA 202294; Orange Book 202294;	HUMAN PRESCRIPTI... DRUG LABEL	CAPSULE, DELAYED RELEASE	ORAL	ANDA	202294	Dexlansoprazole	DEXLANSOPRAZOLE	2023/05/11	2022/11/22-; 2023/06/10-	Proton Pump Inhibitor	1995	PAR PHARMACEU... INC	49884-147; 49884-148	UYE4T5I70X	Excel CSV

Links available for SPL Document, Daily Med link, Drugs@FDA listing, and Orange Book listing

Note earliest US Approval Date for potential prior art

Navigating the search results

- Example: "lansoprazole" as Product Name, "Oral" as Route(s) of Administration



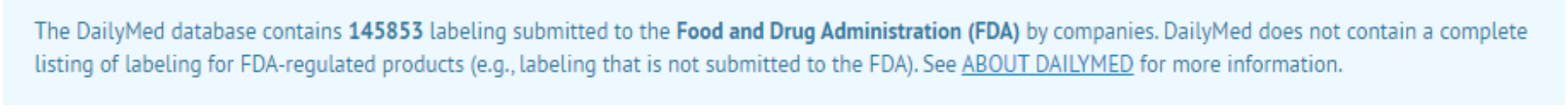
- Results page tells you how many label results you have, allows you to download an Excel file of the full results, and provides a link to a printable query page to print/save details of your search query

DailyMed

What does DailyMed contain?

- The DailyMed database contains labeling, submitted to the Food and Drug Administration (FDA) by companies, for the following products:
- FDA-approved products:
  - Prescription drug and biological products for human use
  - Nonprescription (e.g., over-the-counter) drug and biological products for human use
  - Certain medical devices for human use
  - Medical gases for human and animal use
  - Prescription and nonprescription drugs for animal use
- Additional products regulated, but not approved, by the FDA

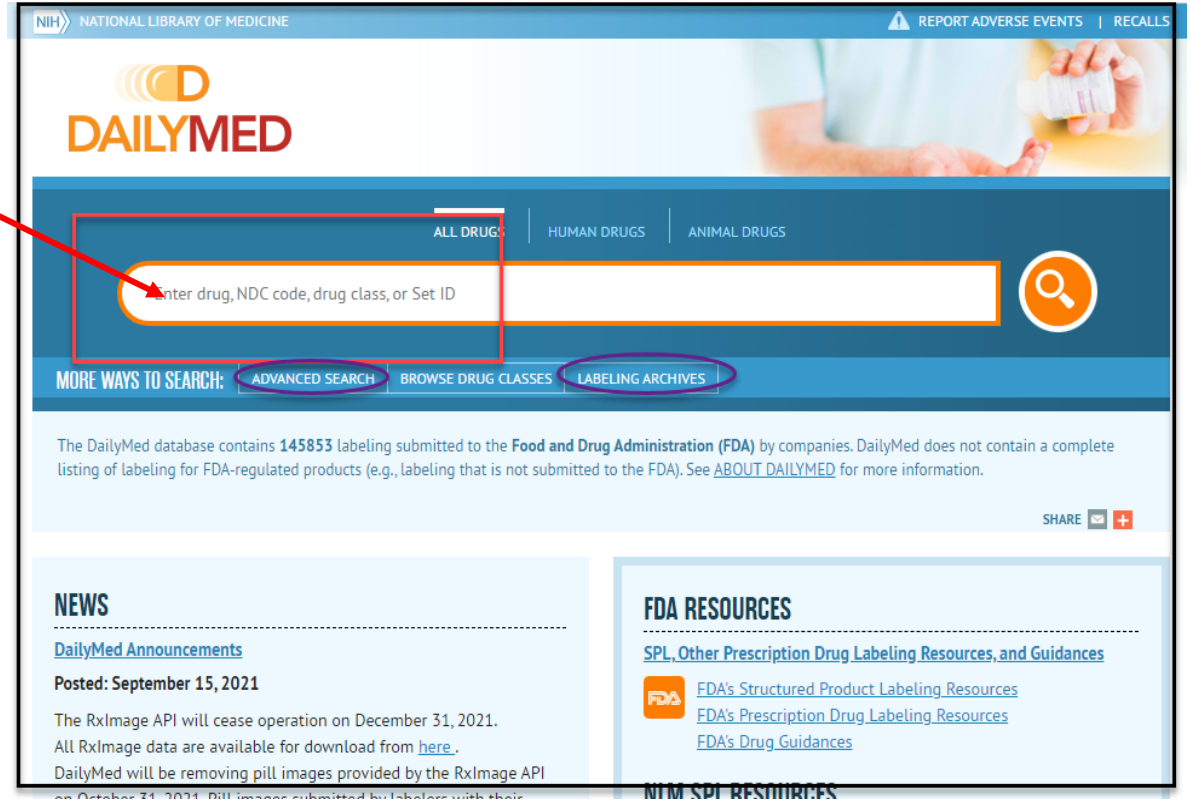
DailyMed provides a large number of product labels (amongst other items)



- Can search via drug name, drug class, NDC code or Set ID.
- No structure search is possible.
- Additionally can limit via advanced Search or also Archived labels search of the same drugs.

What areas can be searched

Insert drug name (or can also do an advanced search or labelling archives as shown) (https://dailymed.nlm.nih.gov/dailymed/)



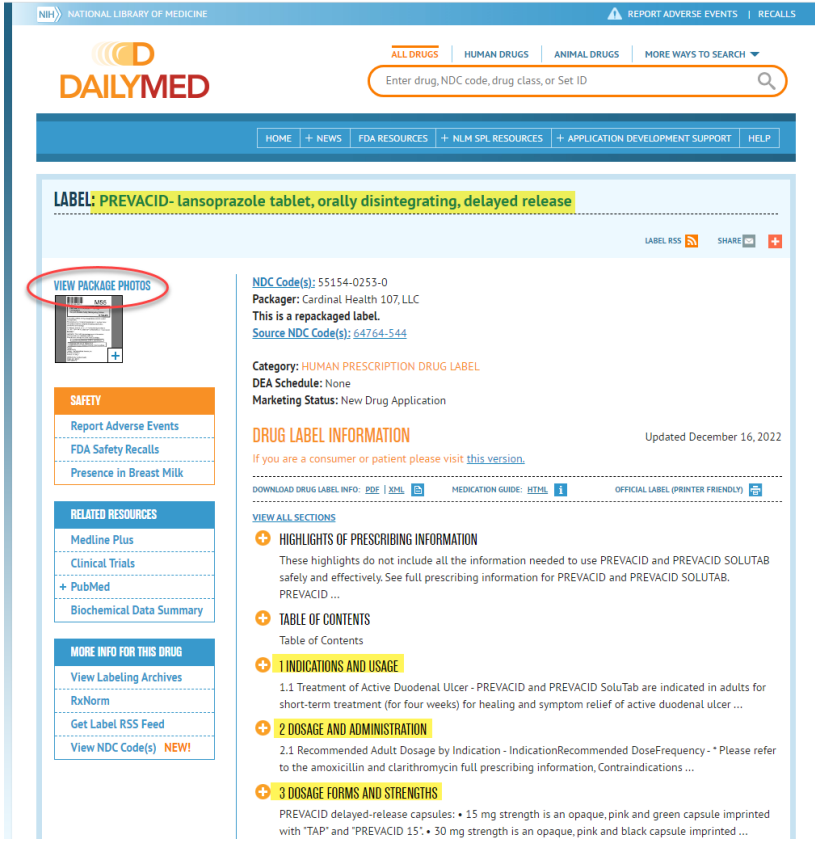
To search Prevacid (lansoprazole tablet)

Results include:

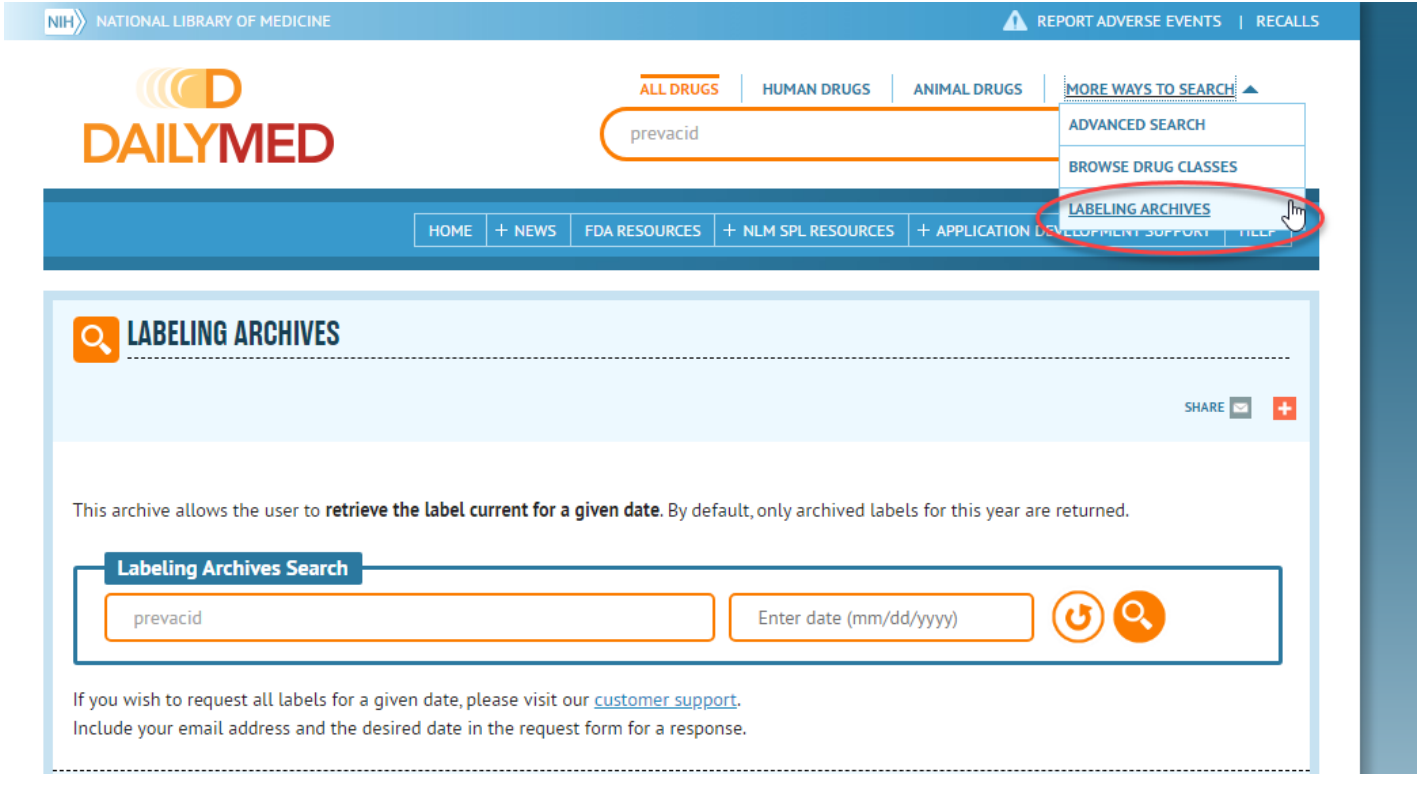
- Usage/indications
- Dosage/administration
- Forms/strengths

Main page results might not be prior art

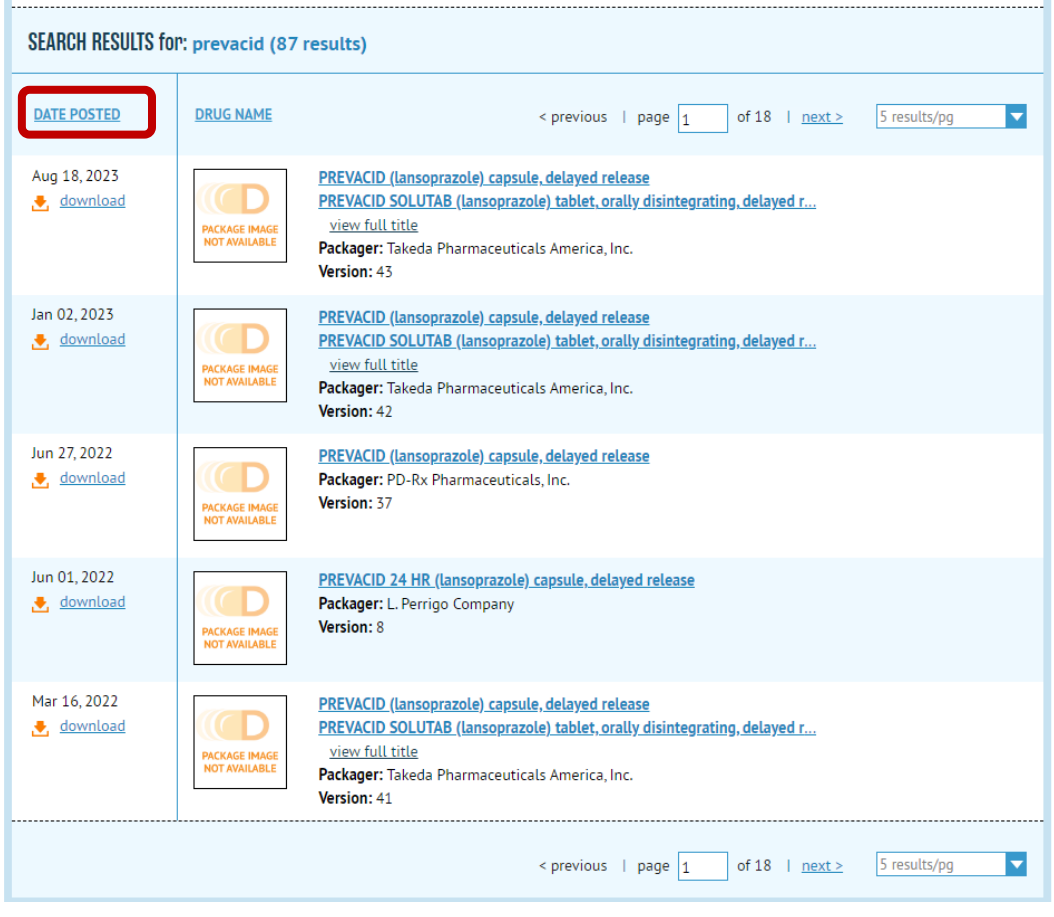
Click on thru to the archives to find a prior art date



Access labeling archive



Results within labeling archive



Archive label search results:
show all labels with earlier dates and can be date limited if need be to overcome a priority date.

Drugs@FDA

Drugs@FDA vs. DailyMed: labeling differences

	Drugs@FDA	DailyMed
Labeling Type	Last FDA-approved PI[1]	Most recent labeling submitted to FDA (may not be FDA-approved)
Format	PDF	SPL (hyperlinks, allows indexing)
Includes recent PI updates: • Annual reportable changes • Pending CBE-0 supplements	No	Yes
Includes carton/container labeling	Sometimes	Always
Includes previously approved labeling, regulatory history, and FDA reviews	Yes	No
FDA reviews labeling prior to posting	Always	Generally, no

www.fda.gov

PI = Prescribing Information; PDF = Portable Document Format; SPL = Structured Product Labeling; CBE = changes being effected; [1] Drugs@FDA does not always include the last FDA-approved PI

How to search Drugs@FDA?

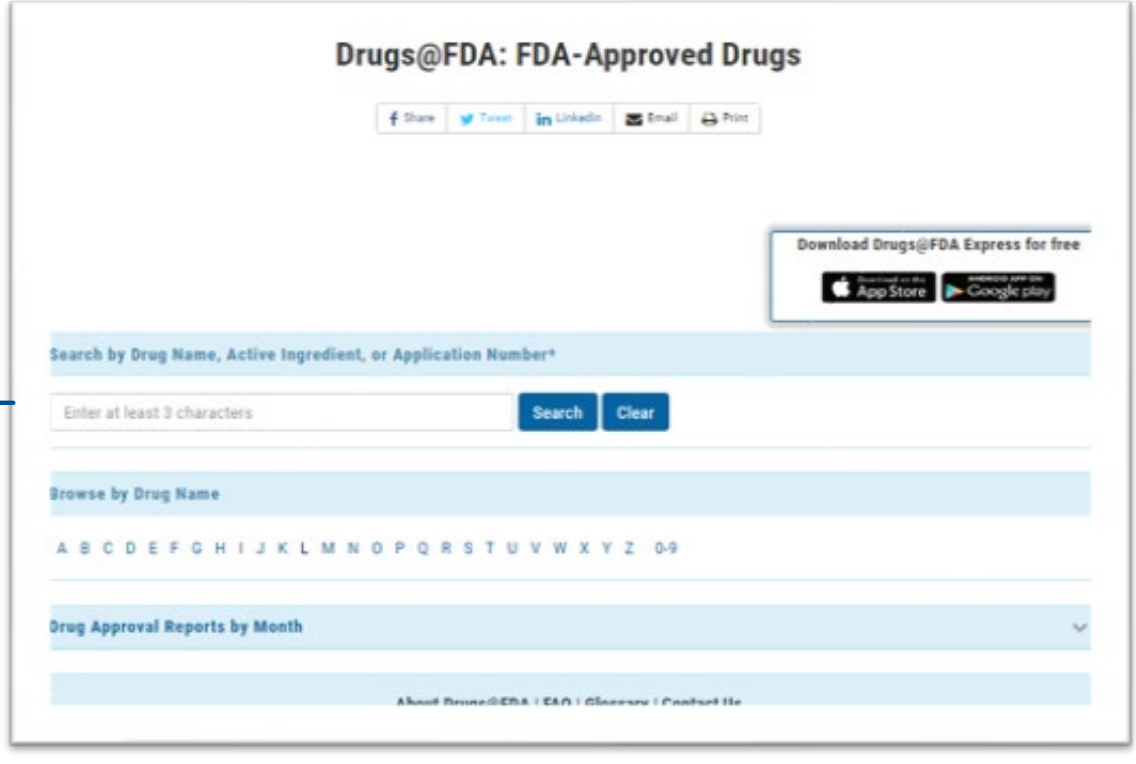
- You can search **Drugs@FDA** in the following ways:
- Use the **search box** on the home page to search by:
  - Drug name(s)
  - Active ingredient(s)
  - Application number (NDA, ANDA, or BLA number)
- **Browse by drug name** (in alphabetical order) using the **A-Z Index**.
- Use the "Drug Approval Reports by Month" menus on the Drugs@FDA home page to find the following information by month:*
  - All approvals and tentative approvals
  - Original NDA and original BLA approvals
  - Original ANDA approvals
  - Supplemental approvals to NDAs and BLAs
  - Tentative ANDA approvals

Drugs@FDA (www.fda.gov/drugsatfda)

- Contains information about the following FDA-approved products for human use:
  - Prescription brand-name drug products, generic drug products,
  - Therapeutic biological products, and
  - Over-the-counter brand-name and generic drugs.
- The database includes most of the drug products approved since 1939.
- For drug products approved since 1998 the following information is available:
  - The majority of patient information,
  - Labels,
  - Approval letters,
  - Reviews,
  - Other information.
- Update frequency: Daily

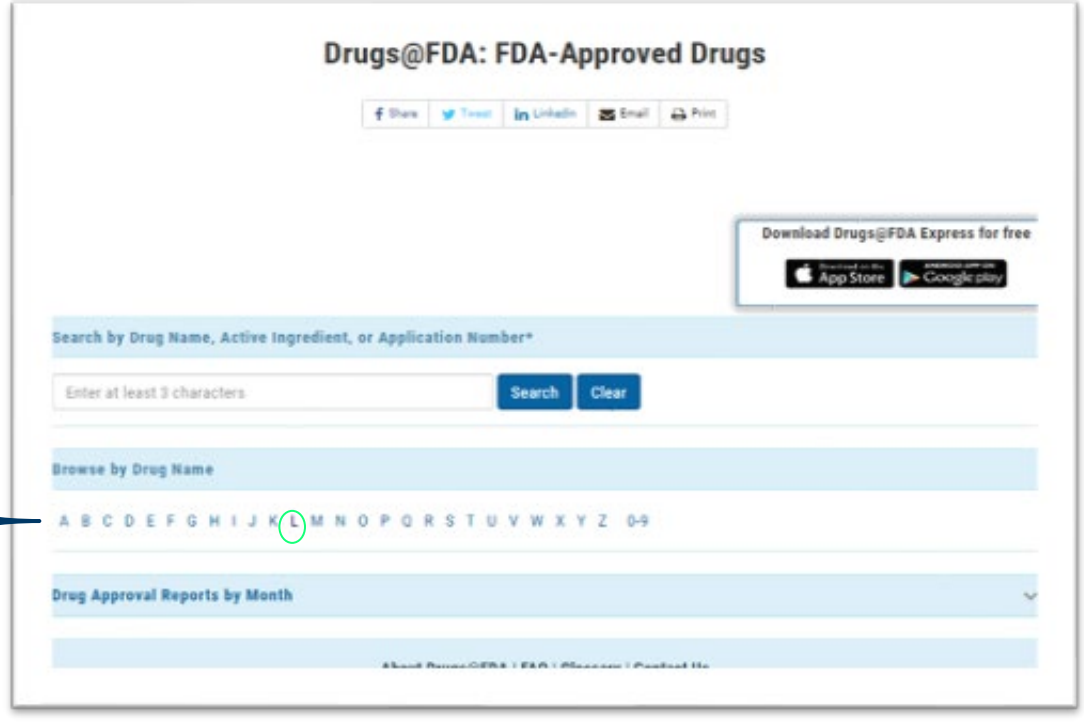
Drugs@FDA: How to search?

- Search Drugs@FDA in the following ways:
- Use the search box on the home page to search by:
  - Drug name(s)
  - Active ingredient(s)
  - Application number (NDA, ANDA, or BLA number)



Drugs@FDA: How to search?

- Browse by drug name (in alphabetical order) using the A-Z Index.
  - Unlike the search box results, the A-Z "Drug Name" search results for an active ingredient will not include brand name drugs for this active ingredient or drugs that contain this active ingredient and other active ingredient(s).
  - For example, the search results for "LISINOPRIL" (using the A-Z "Drug Name" search) will not include PRINIVIL, ZESTRIL, or QBRELIS and will not include ZESTORETIC (lisinopril and hydrochlorothiazide tablets).



Formulation searching using the Drugs@FDA website:

Sample formulation claim language:

An orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer, said composition having **15mg-30mg of lansoprazole** and (ii) **an additive**.

Drugs@FDA: active ingredient search

Search results shown on next slide. →

Search results: active ingredient search

Lansoprazole was searched as the active ingredient. Two products identified from search, 15 mg and 30 mg formulations identified in orally disintegrating forms:

Products on NDA 021428

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
PREVACID	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	AB	Yes	No
PREVACID	LANSOPRAZOLE	30MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	AB	Yes	Yes

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021428

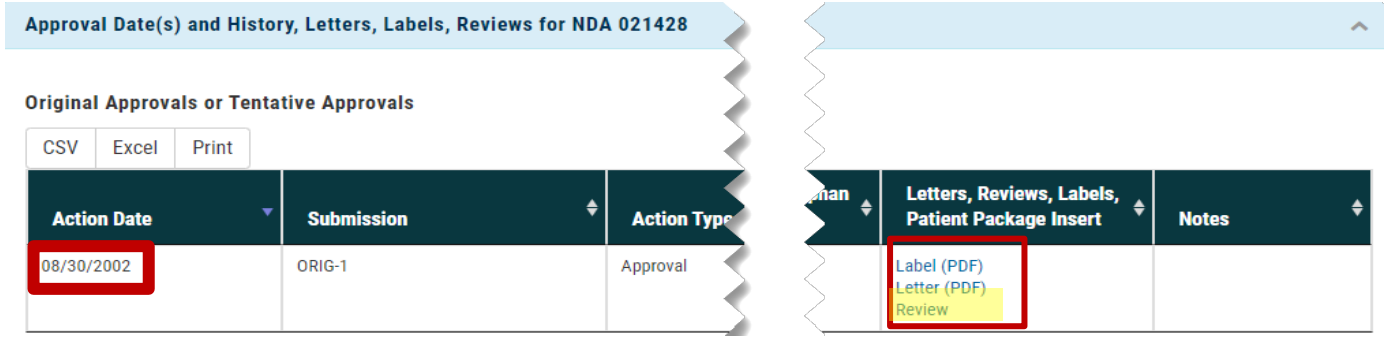
Labels for NDA 021428

Therapeutic Equivalents for NDA 021428

Search results: approval date, drug approval package

The Approval Date and History, Letter, Labels, Reviews link provides a listing of documents associated with the approval process.

Drug Approval dates are provided, patient packaging insert information, labels and the letters of approval are listed.



Drug approval documents (cont.)

In addition to approval letters and labeling, the Drug Approval package site also provides clinical and non-clinical reviews of the drug, and chemistry reviews providing dosing and formulation information.

Drug approval documents (cont.)

The approval letter for Prevacid (having lansoprazole as the active agent) provides the approval date, dosage information, and the indications for use of the drug.

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
21-428

Trade Name: Prevacid SoluTab Delayed-Release Orally Disintegrating Tablets, 15 mg and 30 mg.

Generic Name: lansoprazole

Sponsor: TAP Pharmaceutical Products, Inc.

Approval Date: August 30, 2002

Indications: Provides for a new dosage form of Prevacid to treat:

1) Short-Term Treatment of Active Duodenal Ulcer
2) *H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
3) Maintenance of Healed Duodenal Ulcers
4) Short-Term Treatment of Active Benign Gastric Ulcer
5) Healing of NSAID-Associated Gastric Ulcer
6) Risk Reduction of NSAID-Associated Gastric Ulcer
7) Gastroesophageal Reflex Disease (GERD)
8) Maintenance of Healing of Erosive Esophagitis
9) Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome

Search result: label for NDA

The search of an active ingredient, drug name, or new drug application number will produce a results page as shown to the right. Selecting the Labels for NDA link provides a direct link to the label for that drug, and the approval date.

Products on NDA 021428

CSV Excel Print

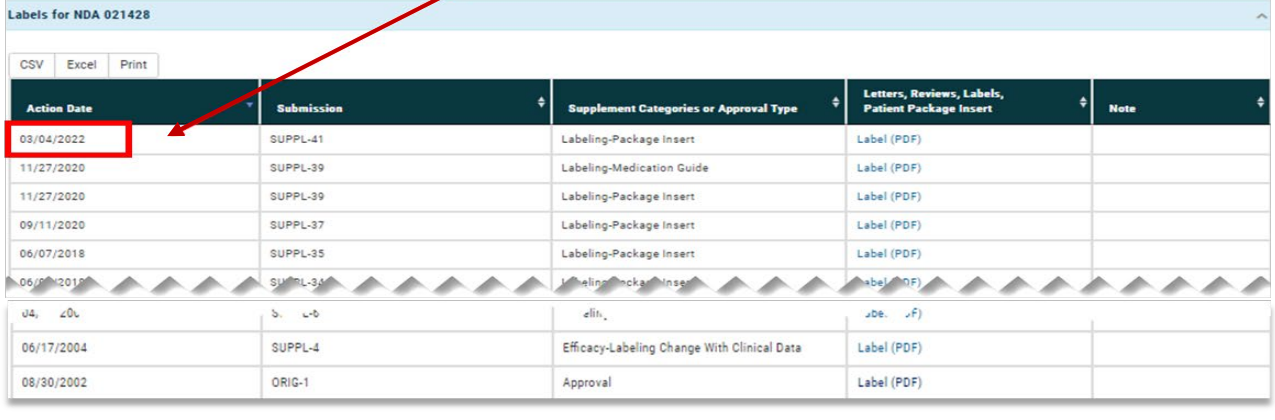
Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
PREVACID	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	AB	Yes	No
PREVACID	LANSOPRAZOLE	30MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	AB	Yes	Yes

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 021428

Labels for NDA 021428

Therapeutic Equivalents for NDA 021428



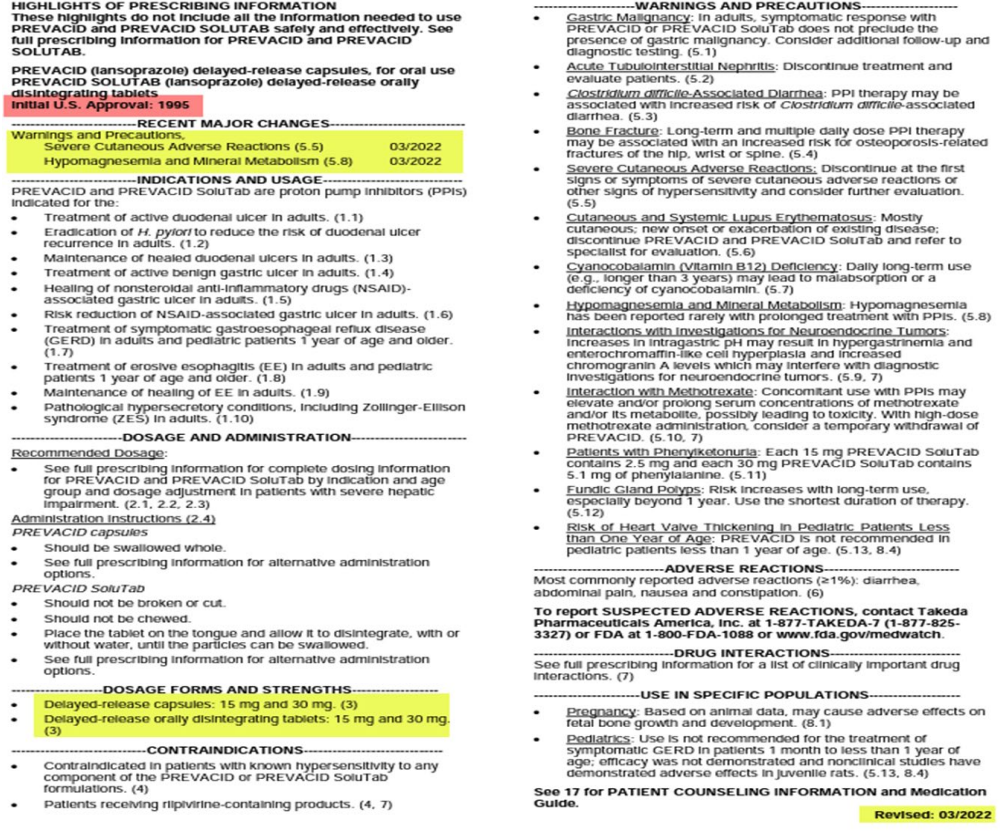
Labels for NDA 021428

CSV Excel Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
03/04/2022	SUPPL-41	Labeling-Package Insert	Label (PDF)	
11/27/2020	SUPPL-39	Labeling-Medication Guide	Label (PDF)	
11/27/2020	SUPPL-39	Labeling-Package Insert	Label (PDF)	
09/11/2020	SUPPL-37	Labeling-Package Insert	Label (PDF)	
06/07/2018	SUPPL-35	Labeling-Package Insert	Label (PDF)	
06/17/2004	SUPPL-4	Efficacy-Labeling Change With Clinical Data	Label (PDF)	
08/30/2002	ORIG-1	Approval	Label (PDF)	

Label PDF provides initial approval year and revision date

The label for Prevacid (having lansoprazole as the active agent) provides approval year, dosage information, indications for use of the drug, and warnings for drug use. Revisions to the Label month and year provided.



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PREVACID and PREVACID SOLUTAB safely and effectively. See full prescribing information for PREVACID and PREVACID SOLUTAB.

PREVACID (lansoprazole) delayed-release capsules, for oral use
PREVACID SOLUTAB (lansoprazole) delayed-release orally disintegrating tablets
Initial U.S. Approval: 1995

----------RECENT MAJOR CHANGES----------

Warnings and Precautions,	
Severe Cutaneous Adverse Reactions (5.5)	03/2022
Hypomagnesemia and Mineral Metabolism (5.8)	03/2022

----------INDICATIONS AND USAGE----------

PREVACID and PREVACID SoluTab are proton pump inhibitors (PPIs) indicated for the:

- Treatment of active duodenal ulcer in adults. (1.1)
- Eradication of *H. pylori* to reduce the risk of duodenal ulcer recurrence in adults. (1.2)
- Maintenance of healed duodenal ulcers in adults. (1.3)
- Treatment of active benign gastric ulcer in adults. (1.4)
- Healing of nonsteroidal anti-inflammatory drugs (NSAID)-associated gastric ulcer in adults. (1.5)
- Risk reduction of NSAID-associated gastric ulcer in adults. (1.6)
- Treatment of symptomatic gastroesophageal reflux disease (GERD) in adults and pediatric patients 1 year of age and older. (1.7)
- Treatment of erosive esophagitis (EE) in adults and pediatric patients 1 year of age and older. (1.8)
- Maintenance of healing of EE in adults. (1.9)
- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome (ZES) in adults. (1.10)

----------DOSAGE AND ADMINISTRATION----------

Recommended Dosage:

- See full prescribing information for complete dosing information for PREVACID and PREVACID SoluTab by indication and age group and dosage adjustment in patients with severe hepatic impairment. (2.1, 2.2, 2.3)

Administration Instructions (2.4)

PREVACID capsules

- Should be swallowed whole.
- See full prescribing information for alternative administration options.

PREVACID SoluTab

- Should not be broken or cut.
- Should not be chewed.
- Place the tablet on the tongue and allow it to disintegrate, with or without water, until the particles can be swallowed.
- See full prescribing information for alternative administration options.

----------DOSAGE FORMS AND STRENGTHS----------

- Delayed-release capsules: 15 mg and 30 mg. (3)
- Delayed-release orally disintegrating tablets: 15 mg and 30 mg. (3)

----------CONTRAINDICATIONS----------

- Contraindicated in patients with known hypersensitivity to any component of the PREVACID or PREVACID SoluTab formulations. (4)
- Patients receiving rilpivirine-containing products. (4, 7)

----------WARNINGS AND PRECAUTIONS----------

- Gastric Malignancy: In adults, symptomatic response with PREVACID or PREVACID SoluTab does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing. (5.1)
- Acute Tubulointerstitial Nephritis: Discontinue treatment and evaluate patients. (5.2)
- *Clostridium difficile*-Associated Diarrhea: PPI therapy may be associated with increased risk of *Clostridium difficile*-associated diarrhea. (5.3)
- Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. (5.4)
- Severe Cutaneous Adverse Reactions: Discontinue at the first signs or symptoms of severe cutaneous adverse reactions or other signs of hypersensitivity and consider further evaluation. (5.5)
- Cutaneous and Systemic Lupus Erythematosus: Mostly cutaneous; new onset or exacerbation of existing disease; discontinue PREVACID and PREVACID SoluTab and refer to specialist for evaluation. (5.6)
- Cyanocobalamin (Vitamin B12) Deficiency: Daily long-term use (e.g., longer than 3 years) may lead to malabsorption or a deficiency of cyanocobalamin. (5.7)
- Hypomagnesemia and Mineral Metabolism: Hypomagnesemia has been reported rarely with prolonged treatment with PPIs. (5.8)
- Interactions with Investigations for Neuroendocrine Tumors: Increases in intragastric pH may result in hypergastrinemia and enterochromaffin-like cell hyperplasia and increased chromogranin A levels which may interfere with diagnostic investigations for neuroendocrine tumors. (5.9, 7)
- Interaction with Methotrexate: Concomitant use with PPIs may elevate and/or prolong serum concentrations of methotrexate and/or its metabolite, possibly leading to toxicity. With high-dose methotrexate administration, consider a temporary withdrawal of PREVACID. (5.10, 7)
- Patients with Phenylketonuria: Each 15 mg PREVACID SoluTab contains 2.5 mg and each 30 mg PREVACID SoluTab contains 5.1 mg of phenylalanine. (5.11)
- Fundic Gland Polyps: Risk increases with long-term use, especially beyond 1 year. Use the shortest duration of therapy. (5.12)
- Risk of Heart Valve Thickening in Pediatric Patients Less than One Year of Age: PREVACID is not recommended in pediatric patients less than 1 year of age. (5.13, 8.4)

----------ADVERSE REACTIONS----------

Most commonly reported adverse reactions (≥1%): diarrhea, abdominal pain, nausea and constipation. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals America, Inc. at 1-877-TAKEDA-7 (1-877-825-3327) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

See full prescribing information for a list of clinically important drug interactions. (7)

----------USE IN SPECIFIC POPULATIONS----------

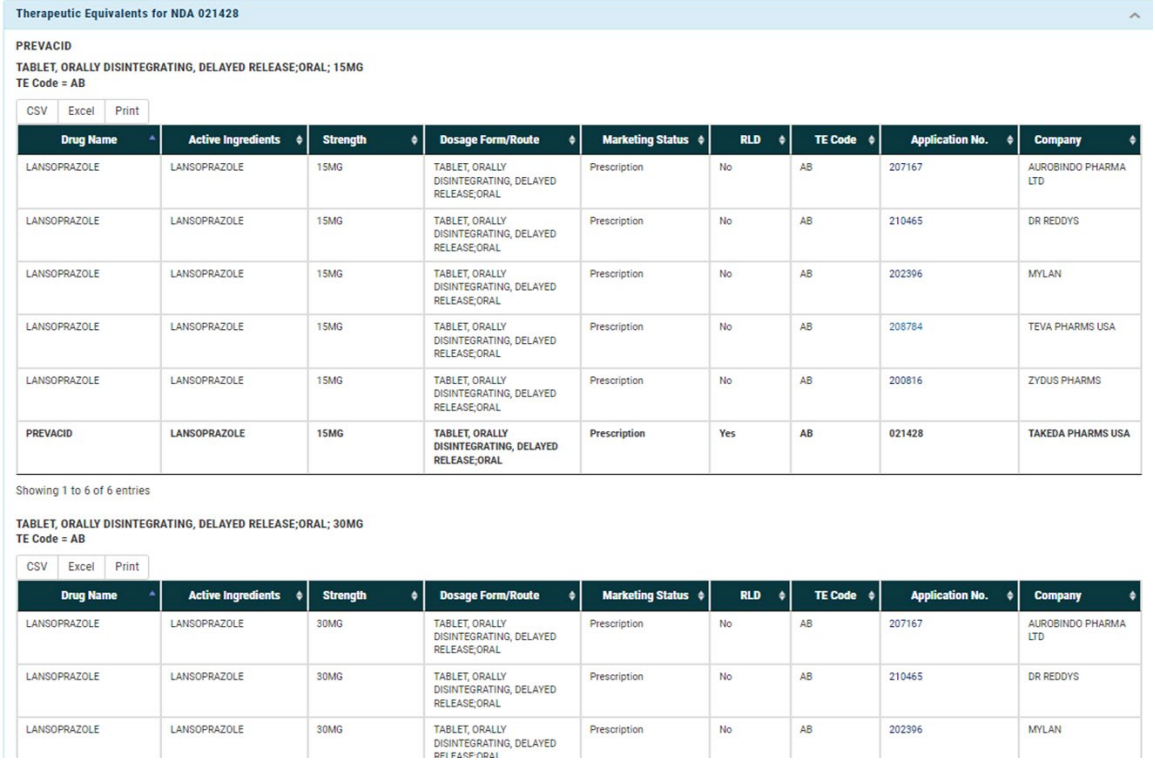
- Pregnancy: Based on animal data, may cause adverse effects on fetal bone growth and development. (8.1)
- Pediatrics: Use is not recommended for the treatment of symptomatic GERD in patients 1 month to less than 1 year of age; efficacy was not demonstrated and nonclinical studies have demonstrated adverse effects in juvenile rats. (5.13, 8.4)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 03/2022

Therapeutic equivalents for NDA: PREVACID (lansoprazole)

In addition to providing documents relating to the approval and labeling of the drug/active searched, Drugs@FDA also provides access to information relating to Therapeutic Equivalents of the drug/active searched.



Therapeutic Equivalents for NDA 021428

PREVACID

TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL; 15MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
LANSOPRAZOLE	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	207167	AUROBINDO PHARMA LTD
LANSOPRAZOLE	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	210465	DR REDDYS
LANSOPRAZOLE	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	202396	MYLAN
LANSOPRAZOLE	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	208784	TEVA PHARMS USA
LANSOPRAZOLE	LANSOPRAZOLE	15MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	200816	ZYDUS PHARMS
PREVACID	**LANSOPRAZOLE**	**15MG**	**TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL**	**Prescription**	**Yes**	**AB**	**021428**	**TAKEDA PHARMS USA**

Showing 1 to 6 of 6 entries

TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL; 30MG
TE Code = AB

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
LANSOPRAZOLE	LANSOPRAZOLE	30MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	207167	AUROBINDO PHARMA LTD
LANSOPRAZOLE	LANSOPRAZOLE	30MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	210465	DR REDDYS
LANSOPRAZOLE	LANSOPRAZOLE	30MG	TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE;ORAL	Prescription	No	AB	202396	MYLAN

Recordation of these searches

Make sure to add any of these FDA searches to your search notes:

Search Notes	
Search Notes	**Date**
Inventor/Assignee Search in PALM/PE2E	02/24/2023
FDALabel, DailyMed, Drugs@FDA: Lansoprazole or prevacid	02/24/2023

Google “FDA.gov”

Google — a powerful tool

You may know you can limit with various operators and dates, but did you know that you can limit to specific ‘domains’?

Google to search FDA.gov

- A Google search can be forced to target one or more specific web domains by including “site:” in the search query.
  - Example:

Note that it is important to omit www. as there are many URLs at FDA.gov that have a different string of characters immediately preceding “fda.gov.”

Google to search FDA.gov

Sometimes it's possible to target certain subsets of data:

- 'Drugs@FDA' database files:
  - *site:accessdata.fda.gov/drugsatfda_docs/*
- 'DAILYMED' database (NIH) Drug Labels (CURRENT labels only):
  - *site:dailymed.nlm.nih.gov/dailymed/*

Google to search FDA.gov

'Drug Safety Communications' (2010 to present only):

site:fda.gov/drugs/drug-safety-and-availability/

- Intended to provide important information to patients and health care professionals about new safety issues.
- Side effects not discovered during the clinical trials.
- Data from available clinical trials or other studies, case reports, and medical literature are reviewed; based on what is found, changes may be required to the prescribing information or the patient Medication Guide.

Google to search FDA.gov

'New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products' (2015 to present only):

site:fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/

- Some of these products have never been used in clinical practice; others are the same as, or related to, previously approved products, and they will compete with those products in the marketplace.
- Many of these products contain active moieties that FDA had not previously approved, either as a single ingredient drug or as part of a combination product. These products frequently provide important new therapies for patients.
- No vaccines, allergenic products, blood and blood products, plasma derivatives, cellular and gene therapy products.

Google to search FDA.gov

- CBER entities are not located in Drugs@FDA; use *site:fda.gov/vaccines-blood-biologics/*
  - It can be helpful to search for a name only and view the CBER record.
- To search for a CBER entity in combination with other terms such as claim limitations, consider searching within the entirety of the FDA domain
  - *site:fda.gov*

Google to search FDA.gov

It's possible to **omit** certain subsets of data:

- For example, to search all of fda.gov, *except* the 'Drugs@FDA' database: *site:fda.gov -site:accessdata.fda.gov/drugsatfda_docs/*

It's possible to search **multiple** subsets of data simultaneously:

- For example to search both 'Drug Safety Communications' and 'New Drugs at FDA':

  (site:fda.gov/drugs/drug-safety-and-availability/ ***OR*** *site:fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/)*

Google to search FDA.gov

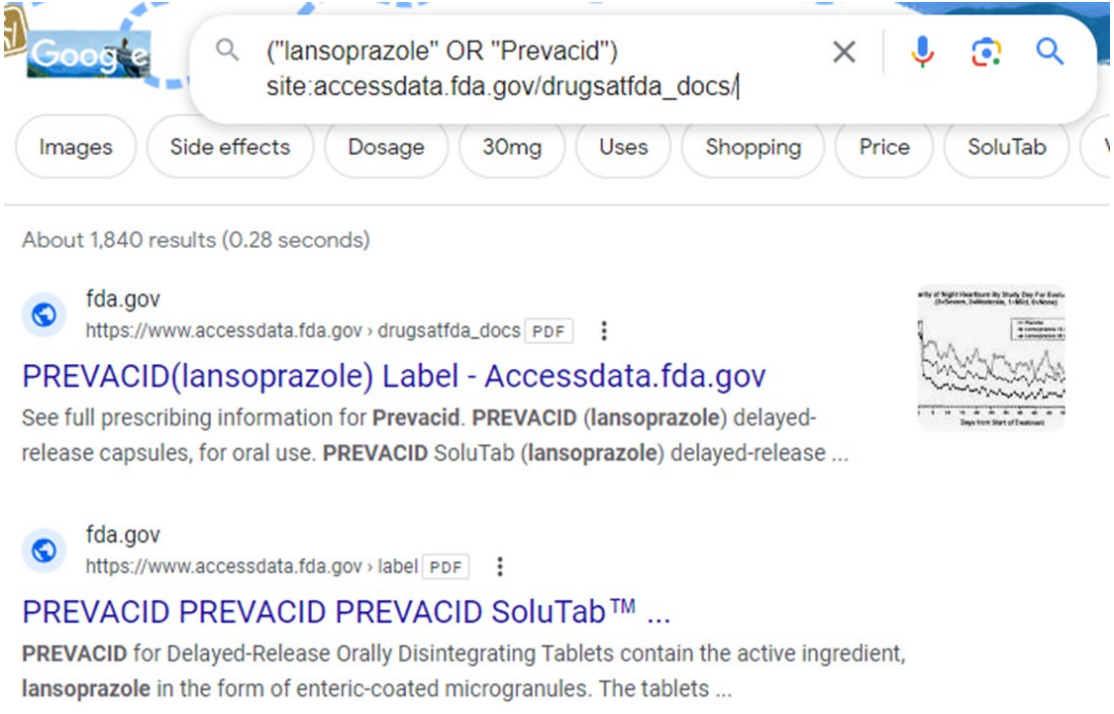
- Claims can be searched, or broad drug information perused.

Sample claim:

An orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer, said composition having **15mg-30mg of lansoprazole** and (ii) an additive.

Google to search FDA.gov

- Search of **Drugs@FDA** broadly, to peruse hits
- Adding quotes forces Google to avoid "synonyms" for the drug names, often associated with drug function



Google to search FDA.gov

- Search of the **entire FDA.gov** domain with **orally disintegrating** terms and "**enteric**" yields 10 hits

- Search of the **entire FDA.gov domain** with **microgranule** and **enteric coat*** terms yields 58 hits

Generate Google history: QRG Chrome extension “Search History Generator”

- The search history in Google can be obtained the usual way

Web Search History

date, time	web site	search string
10/2/2023 5:04:30 PM	Google	("lansoprazole" OR "Prevacid") site:accessdata.fda.gov/drugsatfda_docs/
10/2/2023 5:04:57 PM	Google	("lansoprazole" OR "Prevacid") site:dailymed.nlm.nih.gov/dailymed/
10/2/2023 5:05:12 PM	Google	("lansoprazole" OR "Prevacid") site:fda.gov/drugs/drug-safety-and-availability/
10/2/2023 5:05:35 PM	Google	("lansoprazole" OR "Prevacid") site:fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/
10/2/2023 5:05:50 PM	Google	("lansoprazole" OR "Prevacid") site:fda.gov -site:accessdata.fda.gov/drugsatfda_docs/
10/2/2023 5:06:01 PM	Google	("lansoprazole" OR "Prevacid") (site:fda.gov/drugs/drug-safety-and-availability/ OR site:fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/)
10/2/2023 5:07:07 PM	Google	("lansoprazole" OR "Prevacid") (ODT OR disintegr*) enteric site:fda.gov
10/2/2023 5:12:55 PM	Google	("lansoprazole" OR "Prevacid") microgranule enteric coated site:fda.gov

Followed up by an edit to your Search notes too:

Search Notes	
Search Notes	**Date**
Inventor/Assignee Search in PALM/PE2E	02/24/2023
Google: Lansoprazole or prevacid (see history)	02/24/2023

Summary of labeling databases (www.fda.gov 1 of 2)

	Drugs@FDA	DailyMed	FDALabel
Source of data	FDA-approved labeling	Current labeling submitted by firms	Current labeling submitted by firms
Format	PDF	Structured Product Labeling	Structured Product Labeling
Products include			
CDER-approved prescription and nonprescription human drugs and biologics (under NDAs, ANDAs, and BLAs)	Yes (generic labeling rarely present)	Yes	Yes
CBER-approved human drugs and biologics (e.g., vaccines, gene-therapy products)	No	Yes	Yes
Unapproved human drugs (e.g., homopathics)	No	Yes	Yes

Labeling databases (2 of 2):

	Drugs@FDA	DailyMed	FDALabel
Information included			
Approved labeling, scientific reviews	Yes	No	No
Carton and container labeling	Rarely	Yes	Yes
Repackager, relabeler, and authorized generic labeling	No	Yes	Yes
Search features			
Seach by application number or drug name	Yes	Yes	Yes
Search by drug class, NDC number, and/or by active or inactive ingredient	No	Yes	Yes
Search by labeling section	No	Somewhat	Yes
Search by application type or marketing category (e.g., ANDA, BLA, NDA), DEA schedule, and/or market status and ability to export results to an Excel Spreadsheet	No	No	Yes

In conclusion

- Examiners are now able to search and utilize results from important FDA websites and resources through various search tools available to USPTO.
- Further examiners can narrow searches to specific dates, drugs and product sheets.
- Lastly, examiners can perform a complete and correct search for a drug, use, dose or formulation in compliance with the Examiner PAP, MPEP, and best practices.

Additional information/resources

User guides

- FDALabel Handout
- FDALabel Quick Start Guide
- Simple Search Guide
- Advanced Search Guide
- Query Logic Guide
- DailyMed Help
- DailyMed Index

Demos/Search Examples

- FDALabel Demo
- FDALabel Presentation

Thank you!

www.uspto.gov