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

November 2023
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.
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)
Old FDA documents are archived at archive-it.org/organizations/1137
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.
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

<table>
<thead>
<tr>
<th></th>
<th>Search multiple terms</th>
<th>Current drug labels</th>
<th>Retired drug labels</th>
<th>Generic drug labels</th>
<th>Non-label content</th>
<th>Structure search</th>
<th>“Publicly available” date</th>
<th>Document location clarity</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDALabel</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs@FDA (CDER)</td>
<td></td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td>Y</td>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>DailyMed</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>DailyMed Archive</td>
<td></td>
<td></td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
</tr>
<tr>
<td>Google search of FDA.gov</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
What information is contained in the FDALabel Database?

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

<table>
<thead>
<tr>
<th>Labeling Types</th>
<th>Number of Labeling as of February 21, 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human OTC Drugs*</td>
<td>90,518</td>
</tr>
<tr>
<td>Human Prescription Drugs and Biological Products**</td>
<td>53,188</td>
</tr>
<tr>
<td>Animal Prescription and Animal OTC Products</td>
<td>3,390</td>
</tr>
</tbody>
</table>

* 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, allergens (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, UNIIIs, 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

<table>
<thead>
<tr>
<th>Links</th>
<th>Labeling Type</th>
<th>Dosage Form(s)</th>
<th>Route(s) of Administration</th>
<th>Marketing Category</th>
<th>Application Number(s)</th>
<th>Trade Name</th>
<th>Generic/Proper Name(s)</th>
<th>Most Recent SPL Date (YYYY/MM/DD)</th>
<th>Marketing Date(s) (YYYY/MM/DD)</th>
<th>Established Pharmacologic Class(es)</th>
<th>NDA(s)</th>
<th>Initial U.S. Approval</th>
<th>Company</th>
<th>NDC(s)</th>
<th>Active Ingredient UNII(s)</th>
<th>MedDRA Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPL Document</td>
<td>HUMAN PRESCRIPT...</td>
<td>CAPSULE, DELAYED RELEASE</td>
<td>ORAL</td>
<td>NDA</td>
<td>20200066</td>
<td>Devamprazole delayed release</td>
<td>DEKLANZOPRAZOLE</td>
<td>2023/05/10</td>
<td>2022/12/01</td>
<td>1995</td>
<td>AS MEDICATION SOLUTIONS</td>
<td>30000-4514</td>
<td>UYE4T978X</td>
<td>Excel CSV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DailyMed (SPL)</td>
<td>PDF</td>
<td>Drugs@FDA [OPEN][OPEN]; Orange Book [OPEN][OPEN];</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>SPL Document</td>
<td>HUMAN PRESCRIPT...</td>
<td>CAPSULE, DELAYED RELEASE</td>
<td>ORAL</td>
<td>NDA</td>
<td>2022024</td>
<td>Devamprazole delayed release</td>
<td>DEKLANZOPRAZOLE</td>
<td>2023/05/10</td>
<td>2022/12/01</td>
<td>1995</td>
<td>AS MEDICATION SOLUTIONS</td>
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<td>DailyMed (SPL)</td>
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<td></td>
</tr>
</tbody>
</table>

Sort ascending or descending by clicking any column heading.

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
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)

The DailyMed database contains 145853 labeling submitted to the Food and Drug Administration (FDA) by companies. DailyMed does not contain a complete listing of labeling for FDA-regulated products (e.g., labeling that is not submitted to the FDA). See ABOUT DAILYMED for more information.

- 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/daily med/)
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

This archive allows the user to retrieve the label current for a given date. By default, only archived labels for this year are returned.

Labeling Archives Search

prevacid
Enter date (mm/dd/yyyy)

If you wish to request all labels for a given date, please visit our customer support. Include your email address and the desired date in the request form for a response.
### Results within labeling archive

<table>
<thead>
<tr>
<th>DATE POSTED</th>
<th>DRUG NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 18, 2023</td>
<td>PREVACID (lansoprazole) capsule, delayed release</td>
</tr>
<tr>
<td>Jan 02, 2023</td>
<td>PREVACID (lansoprazole) capsule, delayed release</td>
</tr>
<tr>
<td>Jun 27, 2022</td>
<td>PREVACID (lansoprazole) capsule, delayed release</td>
</tr>
<tr>
<td>Jun 01, 2022</td>
<td>PREVACID 24 HR (lansoprazole) capsule, delayed release</td>
</tr>
<tr>
<td>Mar 16, 2012</td>
<td>PREVACID (lansoprazole) capsule, delayed release</td>
</tr>
</tbody>
</table>

Archive label search results: show all labels with earlier dates and can be date limited if needed to overcome a priority date.
# Drugs@FDA vs. DailyMed: labeling differences

<table>
<thead>
<tr>
<th></th>
<th>Drugs@FDA</th>
<th>DailyMed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Labeling Type</strong></td>
<td>Last FDA-approved PI&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Most recent labeling submitted to FDA (may not be FDA-approved)</td>
</tr>
<tr>
<td><strong>Format</strong></td>
<td>PDF</td>
<td>SPL (hyperlinks, allows indexing)</td>
</tr>
<tr>
<td><strong>Includes recent PI updates:</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>• Annual reportable changes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pending CBE-0 supplements</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Includes carton/container labeling</strong></td>
<td>Sometimes</td>
<td>Always</td>
</tr>
<tr>
<td><strong>Includes previously approved labeling, regulatory history, and FDA reviews</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>FDA reviews labeling prior to posting</strong></td>
<td>Always</td>
<td>Generally, no</td>
</tr>
</tbody>
</table>

<sup>1</sup> 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

Insert Active Ingredient or first letter of Active

Search results shown on next slide.
Lansoprazole was searched as the active ingredient. Two products identified from search, 15 mg and 30 mg formulations identified in orally disintegrating forms:
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.
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
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.
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.
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.
Recordation of these searches

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

<table>
<thead>
<tr>
<th>Search Notes</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventor/Assignee Search in PALM/PE2E</td>
<td>02/24/2023</td>
</tr>
<tr>
<td>FDALabel, DailyMed, Drugs@FDA: Lansoprazole or prevacid</td>
<td>02/24/2023</td>
</tr>
</tbody>
</table>
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.
‘New Drugs at FDA: CDER’s New Molecular Entities and New Therapeutic Biological Products’ (2015 to present only):


- 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’:
  
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

Followed up by an edit to your Search notes too:
# Summary of labeling databases

(www.fda.gov 1 of 2)

<table>
<thead>
<tr>
<th>Source of data</th>
<th>Drugs@FDA</th>
<th>DailyMed</th>
<th>FDALabel</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FDA-approved labeling</td>
<td>Current labeling submitted by firms</td>
<td>Current labeling submitted by firms</td>
</tr>
<tr>
<td>Format</td>
<td>PDF</td>
<td>Structured Product Labeling</td>
<td>Structured Product Labeling</td>
</tr>
</tbody>
</table>

**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):

<table>
<thead>
<tr>
<th>Information included</th>
<th>Drugs@FDA</th>
<th>DailyMed</th>
<th>FDALabel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved labeling, scientific reviews</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Carton and container labeling</td>
<td>Rarely</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Repackager, relabeler, and authorized generic labeling</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Search features**

| Search 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!

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