

Drug Label Research Across the Product Lifecycle

July 25, 2024

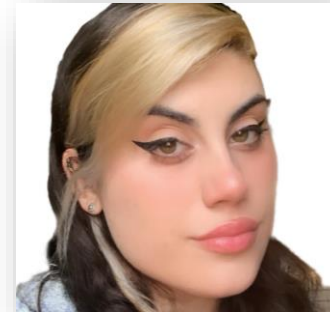


Speakers



Gary Saner

Senior Regulatory
Principal,
Life Sciences,
Reed Tech



Julia Frasch

Account Manager,
Pharma,
Reed Tech

Discussion Topics

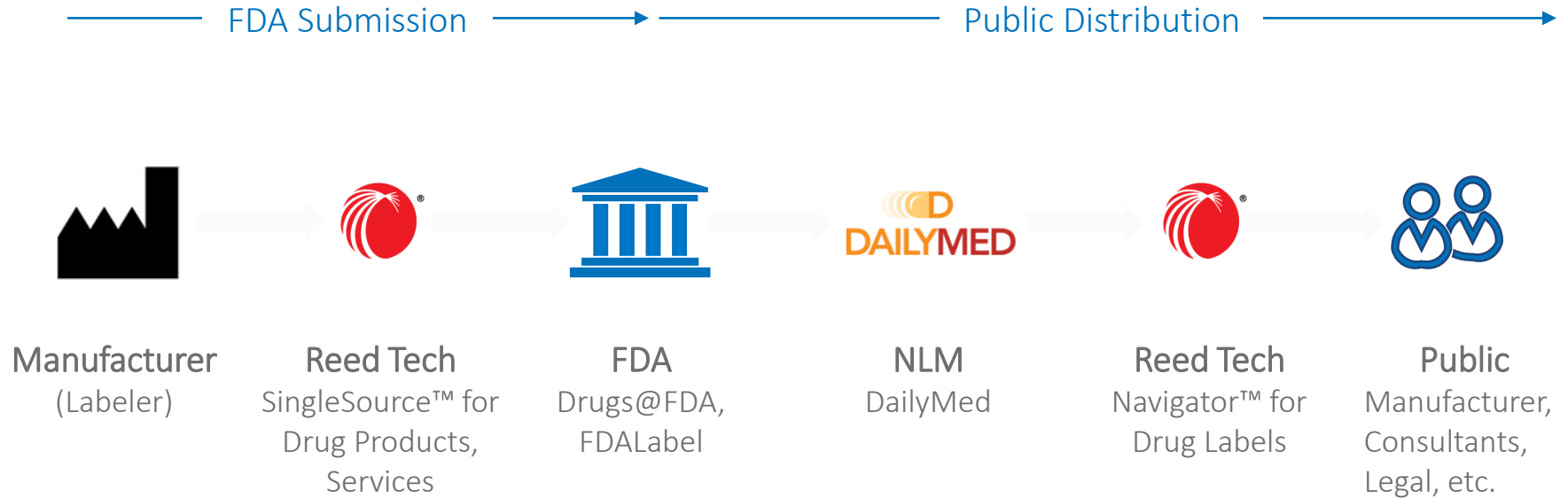


- Drug Label Overview
- Unique Label Research Scenarios
 - Search Products
 - Evaluate Market Labels
 - Track Label Version History
 - Find Competitor and RLD Updates
 - Confirm Delisting
- Reed Tech Support

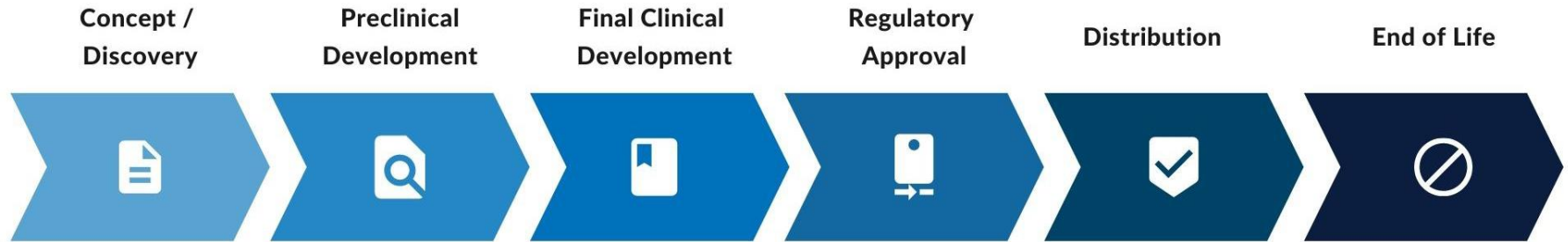
Drug Label Overview



Drug Label Submission and Distribution



Drug Product Lifecycle



Scenario One: Search Products

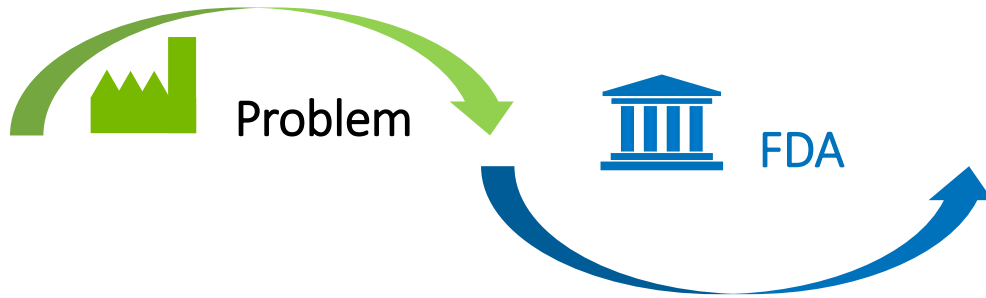


Scenario One: Search Products



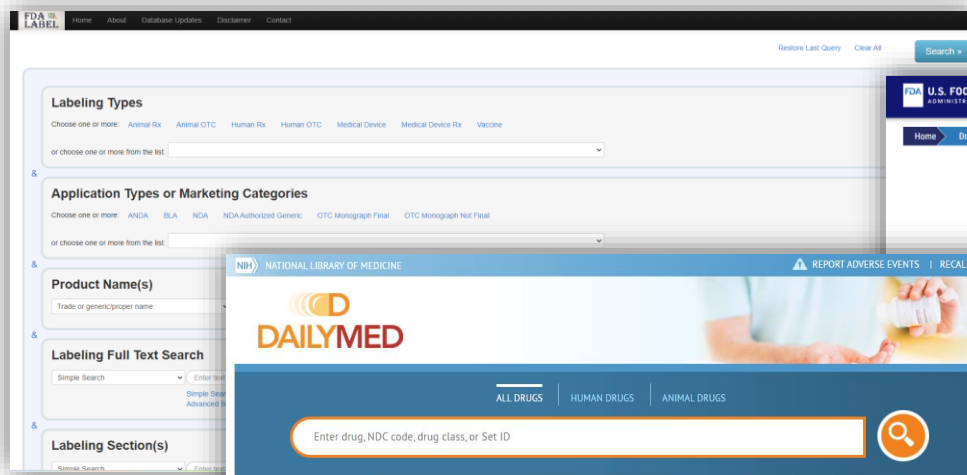
- When Early-stage drug concept and discovery
- Challenge Need to research market for drug products
- Reason(s)
 1. Identify current “state the art” standard for indication or class
 2. Identify the number of manufacturers and competition
 3. Identify existing products and packaging
 4. Identify active ingredients, formulation, dosage form, how it is supplied, etc.

Scenario One: Search Products

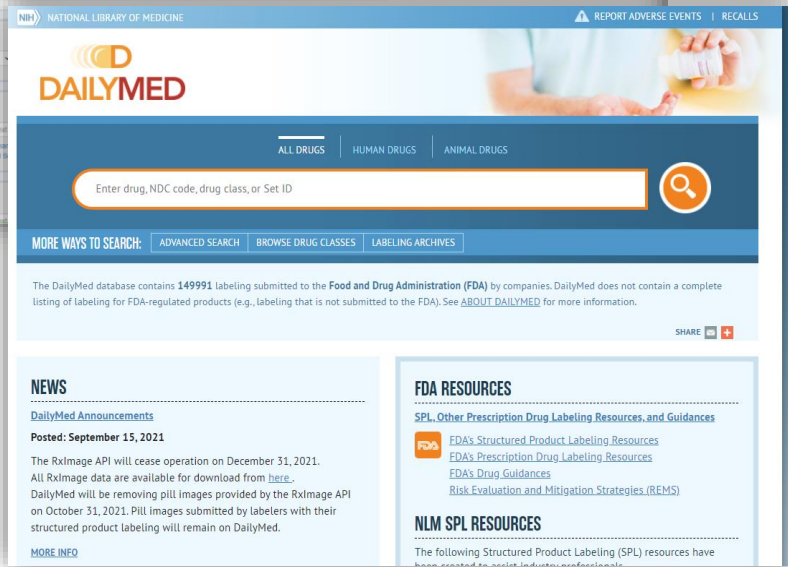


- Tool [FDALabel](#), NLM [DailyMed](#)
- Method Full text search, MedDRA term, search
- Comment FDALabel contains additional links to helpful information, Both FDALabel and DailyMed are providing access to current approved and drug listed versions

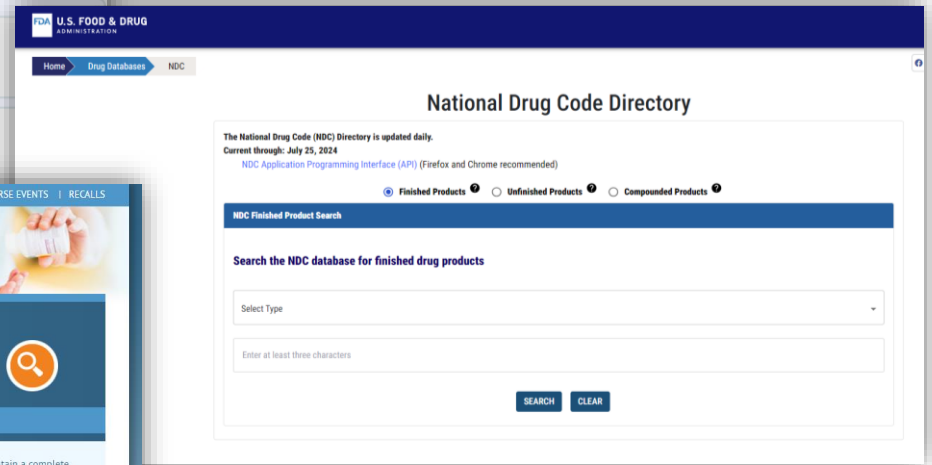
Scenario One: Search Products



The screenshot shows the FDA LABEL search interface. It features a navigation bar with links for Home, About, Database updates, Disclaimer, and Contact. Below the navigation bar, there are several search filters: 'Labeling Types' (Animal Rx, Human Rx, Medical Device, Vaccine), 'Application Types or Marketing Categories' (ANDA, BLA, NDA, OTC Monograph Final, etc.), 'Product Name(s)' (Trade or generic/proper name), 'Labeling Full Text Search' (Simple Search, Advanced Search), and 'Labeling Section(s)'. A 'Search' button is located at the top right of the interface.



The screenshot shows the DAILYMED search interface. It features a navigation bar with links for REPORT ADVERSE EVENTS and RECALLS. Below the navigation bar, there are several search filters: 'ALL DRUGS', 'HUMAN DRUGS', and 'ANIMAL DRUGS'. A search bar is located in the center with the placeholder text 'Enter drug, NDC code, drug class, or Set ID'. Below the search bar, there are links for 'MORE WAYS TO SEARCH: ADVANCED SEARCH, BROWSE DRUG CLASSES, LABELING ARCHIVES'. The main content area contains a news article titled 'DailyMed Announcements' dated September 15, 2021, and a section for 'FDA RESOURCES' with links to 'SPL, Other Prescription Drug Labeling Resources, and Guidances', 'FDA's Structured Product Labeling Resources', 'FDA's Prescription Drug Labeling Resources', 'FDA's Drug Guidances', and 'Risk Evaluation and Mitigation Strategies (REMS)'. There is also a section for 'NLM SPL RESOURCES'.



The screenshot shows the National Drug Code Directory search interface. It features a navigation bar with links for Home, Drug Databases, and NDC. Below the navigation bar, there is a search bar with the placeholder text 'Enter at least three characters'. The main content area contains a section for 'NDC Finished Product Search' with a dropdown menu for 'Select Type' and a 'SEARCH' button. There are also radio buttons for 'Finished Products', 'Unfinished Products', and 'Compounded Products'.

Scenario One: Search Products



- Tool Reed Tech Navigator™ for Drug Labels
- Method Full text search
- Comment Search across current and historical versions of all labels

Scenario One: Search Products

- Indication Search

The screenshot shows the search interface with the following sections:

- Search** (US Labels, PDR Book Archives)
- Drug Name Search**: Search by brand, generic name, or national drug code.
- Text Search**: Search by text across all drug label sections, or create a conditional text search. Includes a search input with "lymphoma" and a dropdown menu set to "INDICATIONS & USAGE SECTION (34067-9)".
- Drug Attribute Search**: Search by drug attributes like ingredient, dosage form, manufacturer, and more.
- Product Characteristic Search**: Search by product characteristics like color, imprint, shape, size or scoring.
- Search Results**: A table with columns: Label#, Brand Name, Generic Name, Company Name, Latest Ver #, Publi..., Dosage Forms, and Category. The first row is B.MOP (Methoxsalen) by Valant Pharmaceuticals.

The screenshot shows a detailed view of the search results table with the following columns:

Label#	Brand Name	Generic Name	Company Name	Latest Ver #	Publi...	Dosage Forms	Category(Appl. Mono...	Product Type
B.MOP	Methoxsalen	Methoxsalen	Valant Pharmaceuticals Nort	Ver: 5 (R4)	Jan 26, 2016	CAPSULE, GELA	NDA (INDA09048)	HUMAN PRESCRIPTION DRU
B.MOP	Methoxsalen	Methoxsalen	ICN Pharmaceuticals, Inc.	Ver: 1 (R3)	Nov 9, 2006	CAPSULE, GELA	[]	HUMAN PRESCRIPTION DRU
ADCE TRIS	brentuximab vedotin	brentuximab vedotin	SEAGEN INC	Ver: 28 (R4)	Dec 17, 2	INJECTION, POW	BLA (BLA125388)	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	Oxcanide Pharmaceuticals	Ver: 8 (R4)	Jun 9, 2020	CAPSULE, LIQU	NDA authorized generic (N	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	Mylan Pharmaceuticals Inc	Ver: 4 (R4)	Oct 13, 2018	CAPSULE, LIQU	ANDA (ANDA2031174)	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	Upsher-Smith Laboratories, Inc	Ver: 2 (R4)	Aug 2, 2018	CAPSULE	ANDA (ANDA209896)	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	Mylan Institutional Inc	Ver: 4 (R4)	Oct 31, 2019	CAPSULE, LIQU	ANDA (ANDA2031174)	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	Amneal Pharmaceuticals NY L	Ver: 10 (R4)	Dec 30, 2	CAPSULE	ANDA (ANDA210105)	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	Hikma Pharmaceuticals USA Inc	Ver: 4 (R4)	Dec 18, 2020	CAPSULE, LIQU	ANDA (ANDA203963)	HUMAN PRESCRIPTION DRU
Bexarotene	Bexarotene	Bexarotene	ANr Pharmaceuticals, Inc	Ver: 4 (R4)	May 27, 20	CAPSULE, LIQU	ANDA (ANDA209861)	HUMAN PRESCRIPTION DRU

Scenario One: Search Products

- Ingredient Search

Reed Tech Navigator™ for Drug Labels

Search

1/1 Labels PDR Book Archives

Drug Name Search Search by brand, generic name, or national drug code

Text Search Search by text across all drug label sections, or create a conditional text search

Drug Attribute Search Search by drug attributes like ingredient, dosage form, manufacturer, and more

Ingredient
Bexarotene

Active Ingredients Inactive Ingredients Both

Company Name

ix, Labels (typically the manufacturer or private label distributor)

Dosage Form

10 Items

e.g., Acetaminophen 500 MG Oral Tablet

Marketing Category

Product Characteristic Search Search by product characteristics like color, imprint, shape, size or scoring

Show only RLD Labels

Search Results

View Compare List (0 of 25) Save Search Excel Export Print

LabelT...	Brand Name	Generic Name	Company Name	Latest Ver.# Publ...	Dosage Forms	Category(Appl./Mono...	Product Type
<input type="checkbox"/>	+ bexarotene	bexarotene	Oceanside Pharmaceuticals	Ver: 8 (R4) Jun 9, 2020	CAPSULE, LIQUI...	NDA authorized generic [N...	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	+ bexarotene	bexarotene	Oceanside Pharmaceuticals	Ver: 2 (R4) Jan 23, 2017	GEL	NDA authorized generic [N...	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Mylan Pharmaceuticals Inc.	Ver: 4 (R4) Oct 13, 2018	CAPSULE, LIQUI...	ANDA [ANDA203174]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Upsher-Smith Laboratories, Inc.	Ver: 2 (R4) Aug 2, 2018	CAPSULE	ANDA [ANDA209886]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Mylan Institutional Inc.	Ver: 4 (R4) Oct 31, 2019	CAPSULE, LIQUI...	ANDA [ANDA203174]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Anneal Pharmaceuticals NY L...	Ver: 10 (R4) Dec 30, 2...	CAPSULE	ANDA [ANDA210105]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	bexarotene	Hikma Pharmaceuticals USA Inc.	Ver: 4 (R4) Dec 18, 2020	CAPSULE, LIQUI...	ANDA [ANDA203663]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	ANI Pharmaceuticals, Inc.	Ver: 4 (R4) May 27, 20...	CAPSULE, LIQUI...	ANDA [ANDA209861]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Targetin	bexarotene	Bausch Health US, LLC	Ver: 13 (R4) May 19, 2...	CAPSULE, LIQUI...	NDA [NDA021055]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	+ Targetin	bexarotene	Eisai Inc.	Ver: 4 (R4) Oct 19, 2011	CAPSULE, LIQUI...	NDA [NDA021055]	HUMAN PRESCRIPTION DRU...

1 of 2 pages (14 Items)

Search Results

View Compare List (0 of 25) Save Search Excel Export Print

LabelT...	Brand Name	Generic Name	Company Name	Latest Ver.# Publ...	Dosage Forms	Category(Appl./Mono...	Product Type
<input type="checkbox"/>	+ bexarotene	bexarotene	Oceanside Pharmaceuticals	Ver: 8 (R4) Jun 9, 2020	CAPSULE, LIQUI...	NDA authorized generic [N...	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	+ bexarotene	bexarotene	Oceanside Pharmaceuticals	Ver: 2 (R4) Jan 23, 2017	GEL	NDA authorized generic [N...	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Mylan Pharmaceuticals Inc.	Ver: 4 (R4) Oct 13, 2018	CAPSULE, LIQUI...	ANDA [ANDA203174]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Upsher-Smith Laboratories, Inc.	Ver: 2 (R4) Aug 2, 2018	CAPSULE	ANDA [ANDA209886]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Mylan Institutional Inc.	Ver: 4 (R4) Oct 31, 2019	CAPSULE, LIQUI...	ANDA [ANDA203174]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	Anneal Pharmaceuticals NY L...	Ver: 10 (R4) Dec 30, 2...	CAPSULE	ANDA [ANDA210105]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	bexarotene	Hikma Pharmaceuticals USA Inc.	Ver: 4 (R4) Dec 18, 2020	CAPSULE, LIQUI...	ANDA [ANDA203663]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Bexarotene	Bexarotene	ANI Pharmaceuticals, Inc.	Ver: 4 (R4) May 27, 20...	CAPSULE, LIQUI...	ANDA [ANDA209861]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	✓ Targetin	bexarotene	Bausch Health US, LLC	Ver: 13 (R4) May 19, 2...	CAPSULE, LIQUI...	NDA [NDA021055]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	+ Targetin	bexarotene	Eisai Inc.	Ver: 4 (R4) Oct 19, 2011	CAPSULE, LIQUI...	NDA [NDA021055]	HUMAN PRESCRIPTION DRU...

1 of 2 pages (14 Items)

Scenario Two: Evaluate Market Labels

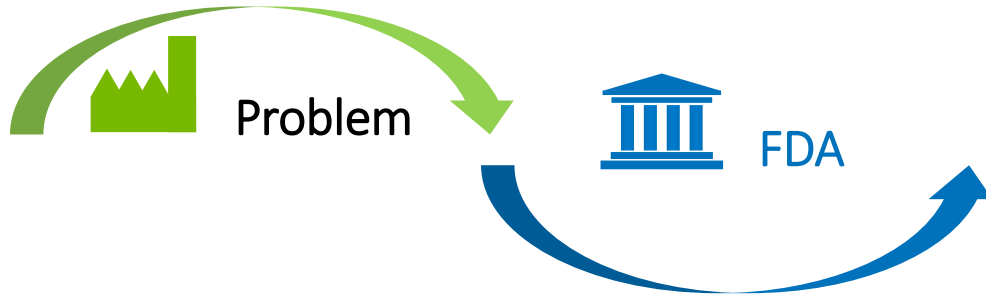


Scenario Two: Evaluate Market Labels



- When Development (Label Authoring)
- Challenge Need to evaluate market labels, including Reference Listed Drugs (RLD)
- Reason(s) 1. Identify the baseline or common label approach in pharmacological class
 2. Identify noteworthy unique content in competitor labels
 3. Identify RLD label content (labeling text, listing metadata, images, patient info, etc.) to duplicate in generic drug label

Scenario Two: Evaluate Market Labels



- Tool [FDALabel](#), NLM [DailyMed](#), [Drugs@FDA](#)
- Method Full text search, Pharma Class, search...
- Comment [Drugs@FDA](#) - latest approved label, but in PDF format (not SPL XML)

Scenario Two: Evaluate Market Labels



- Tool Reed Tech Navigator™ for Drug Labels
- Method Full text search, Unique Ingredient Identifier (UNII) code
- Comment Label comparison (A/B, RLD/Generic)

Scenario Two: Evaluate Market Labels

- Selecting Labels to Compare

Reed Tech Navigator™ for Drug Labels

Dashboard Search Compare Labels My Library Support &

Search

US Labels PDR Book Archives

Drug Name Search Search by brand, generic name, or national drug code

Text Search Search by text across all drug label sections, or create a conditional text search

Drug Attribute Search Search by drug attributes like ingredient, dosage form, manufacturer, and more

Ingredient

Bexarotene

Active Ingredients Inactive Ingredients Both

Company Name

(i.e., Labeler, typically the manufacturer or private label distributor)

Dosage Form

RxNorm 1

(e.g., Acetaminophen 500 MG Oral Tablet)

Marketing Category

Product Characteristic Search Search by product characteristics like color, imprint, shape, size or scoring

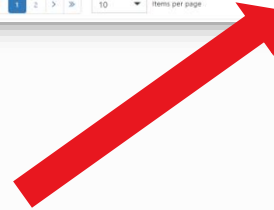
Show only RLD Labels

Search Results

View Compare list (7 of 25) Save Search Excel Export Print

Label...	Brand Name	Generic Name	Company Name	Latest Ver.#	Publi...	Dosage Forms	Category(Appl.Mono...	Product Type
<input type="checkbox"/>	bexarotene	bexarotene	Oceanside Pharmaceuticals	Ver: 8 (R4)	Jun 9, 2020	CAPSULE, LIQUI...	NDA authorized generic [N...	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	bexarotene	bexarotene	Oceanside Pharmaceuticals	Ver: 2 (R4)	Jan 23, 2017	GEL	NDA authorized generic [N...	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	Bexarotene	Mylan Pharmaceuticals Inc.	Ver: 4 (R4)	Oct 13, 2018	CAPSULE, LIQUI...	ANDA [ANDA203174]	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	Bexarotene	Upsher-Smith Laboratories, Inc.	Ver: 2 (R4)	Aug 2, 2016	CAPSULE	ANDA [ANDA209886]	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	Bexarotene	Mylan Institutional Inc.	Ver: 4 (R4)	Oct 31, 2019	CAPSULE, LIQUI...	ANDA [ANDA203174]	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	Bexarotene	Amneal Pharmaceuticals NY L...	Ver: 10 (R4)	Dec 30, 2...	CAPSULE	ANDA [ANDA210105]	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	bexarotene	Hikma Pharmaceuticals USA Inc.	Ver: 4 (R4)	Dec 18, 2020	CAPSULE, LIQUI...	ANDA [ANDA203963]	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	Bexarotene	ANI Pharmaceuticals, Inc.	Ver: 4 (R4)	May 27, 20...	CAPSULE, LIQUI...	ANDA [ANDA209861]	HUMAN PRESCRIPTION DRU...
<input checked="" type="checkbox"/>	Bexarotene	bexarotene	Bausch Health US, LLC	Ver: 13 (R4)	May 19, 2...	CAPSULE, LIQUI...	NDA [NDA021055]	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	Targetin	bexarotene	Eisai Inc.	Ver: 4 (R4)	Oct 19, 2011	CAPSULE, LIQUI...	NDA [NDA021055]	HUMAN PRESCRIPTION DRU...

1 of 2 pages (14 items)



Scenario Two: Evaluate Market Labels

- Comparing Labels

Reed Tech Navigator™ for Drug Labels

Compare Labels

Your compare list is displayed below. Select below to view side by side.

- Brand Name
- Bexarotene
- Bexarotene
- Bexarotene
- Targretin
- Bexarotene
- Bexarotene
- Bexarotene

7 labels selected for side by side view

Synchronize scroller and sections
Synchronize the scrolling and section elements of two or more labels so that they scroll and filter by same sections

Label Name	Labeler Name	Version Number and Date	Label Sections
Bexarotene	Mylan Pharmaceuticals Inc.	Ver: 4 (R4) Oct 13, 2018	Full Label
Bexarotene	Upsher-Smith Laboratories, Inc.	Ver: 2 (R4) Aug 2, 2018	Full Label
Bexarotene	Amneal Pharmaceuticals NY LLC	Ver: 10 (R4) Dec 30, 2020	Full Label
Targretin	Bausch Health US, LLC	Ver: 13 (R4) May 19, 2020	Full Label

BEXAROTENE - bexarotene capsule, liquid filled
Mylan Pharmaceuticals Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BEXAROTENE CAPSULES safely and effectively. See full prescribing information for BEXAROTENE CAPSULES.
BEXAROTENE capsules, for oral use
Initial U.S. Approval: 1999
WARNING: BIRTH DEFECTS
See full prescribing information for complete boxed warning. Bexarotene is a member of the retinoid class of

BEXAROTENE - bexarotene capsule
Upsher-Smith Laboratories, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BEXAROTENE CAPSULES safely and effectively. See full prescribing information for BEXAROTENE CAPSULES.
BEXAROTENE capsules, for oral use
Initial U.S. Approval: 1999
WARNING: BIRTH DEFECTS
See full prescribing information for complete boxed warning. Bexarotene is a member

BEXAROTENE - bexarotene capsule
Amneal Pharmaceuticals NY LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BEXAROTENE CAPSULES safely and effectively. See full prescribing information for BEXAROTENE CAPSULES.
BEXAROTENE capsules, for oral use
Initial U.S. Approval: 1999
WARNING: BIRTH DEFECTS
See full prescribing information for complete boxed warning.

TARGRETIN - bexarotene capsule,
Bausch Health US, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TARGRETIN CAPSULES safely and effectively. See full prescribing information for TARGRETIN capsules, for oral use.
TARGRETIN capsules, for oral use
Initial U.S. Approval: 2009
WARNING: BIRTH DEFECTS
See full prescribing information for complete boxed warning.

Scenario Two: Evaluate Market Labels

- Export Label

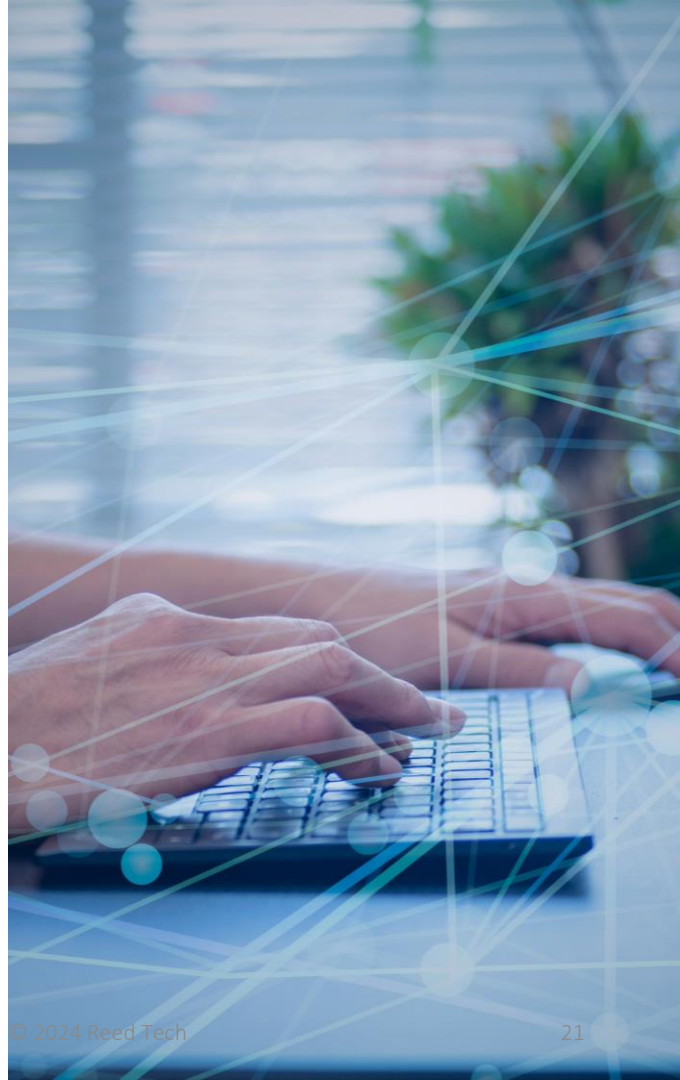
All labels will appear as they were submitted to FDA.

User Name (creator)	Reed Tech
Date and Time of Export	2021-12-14 17:46:00

Save As Print Copy Paste Undo Redo Bold Italic Underline Text Color Background Color Font Size 11pt

Label Name	Label Name	Label Name	Label Name
Bexarotene	Bexarotene	Bexarotene	Targretin
Labeler Name	Labeler Name	Labeler Name	Labeler Name
Mylan Pharmaceuticals Inc.	Upsher-Smith Laboratories, Inc.	Amneal Pharmaceuticals NY LLC	Bausch Health US, LLC
Version Number and Date	Version Number and Date	Version Number and Date	Version Number and Date
Ver: 4 (R4) Oct 13, 2018	Ver: 2 (R4) Aug 2, 2018	Ver: 10 (R4) Dec 30, 2020	Ver: 13 (R4) May 19, 20
BEXAROTENE - bexarotene capsule, liquid filled Mylan Pharmaceuticals Inc.	BEXAROTENE - bexarotene capsule Upsher-Smith Laboratories, Inc.	BEXAROTENE - bexarotene capsule Amneal Pharmaceuticals NY LLC	TARGRETIN- bexarotene Bausch Health US, LLC
<p>-----</p> <p>HIGHLIGHTS OF PRESCRIBING INFORMATION</p> <p>These highlights do not include all the information needed to use BEXAROTENE CAPSULES safely and effectively. See full prescribing information for BEXAROTENE CAPSULES.</p> <p>BEXAROTENE capsules, for oral use Initial U.S. Approval: 1999</p> <div style="border: 1px solid black; padding: 5px;"> <p>WARNING: BIRTH DEFECTS</p> <p>See full prescribing information for complete boxed warning.</p> <p>Bexarotene is a member of the retinoid class of drugs that is associated with birth defects in humans. Bexarotene also caused birth defects when administered orally to pregnant rats. Bexarotene must not be administered to a pregnant woman. (8.1)</p> </div> <p>INDICATIONS AND USAGE</p> <p>Bexarotene is a retinoid indicated for the treatment of cutaneous manifestations of</p>	<p>-----</p> <p>HIGHLIGHTS OF PRESCRIBING INFORMATION</p> <p>These highlights do not include all the information needed to use BEXAROTENE CAPSULES safely and effectively. See full prescribing information for BEXAROTENE CAPSULES.</p> <p>BEXAROTENE capsules, for oral use Initial U.S. Approval: 1999</p> <div style="border: 1px solid black; padding: 5px;"> <p>WARNING: BIRTH DEFECTS</p> <p>See full prescribing information for complete boxed warning.</p> <p>Bexarotene is a member of the retinoid class of drugs that is associated with birth defects in humans. Bexarotene also caused birth defects when administered orally to pregnant rats. Bexarotene must not be administered to a pregnant woman. (8.1)</p> </div> <p>INDICATIONS AND USAGE</p> <p>Bexarotene capsules are a retinoid indicated for the</p>	<p>-----</p> <p>HIGHLIGHTS OF PRESCRIBING INFORMATION</p> <p>These highlights do not include all the information needed to use BEXAROTENE CAPSULES safely and effectively. See full prescribing information for BEXAROTENE CAPSULES.</p> <p>BEXAROTENE capsules, for oral use Initial U.S. Approval: 1999</p> <div style="border: 1px solid black; padding: 5px;"> <p>WARNING: BIRTH DEFECTS</p> <p>See full prescribing information for complete boxed warning.</p> <p>Bexarotene is a member of the retinoid class of drugs that is associated with birth defects in humans. Bexarotene also caused birth defects when administered orally to pregnant rats. Bexarotene must not be administered to a pregnant woman. (8.1)</p> </div> <p>INDICATIONS AND USAGE</p>	<p>-----</p> <p>TARGRETIN- bexarotene</p> <p>Bausch Health US, LLC</p>

Scenario Three: Track Label Version History

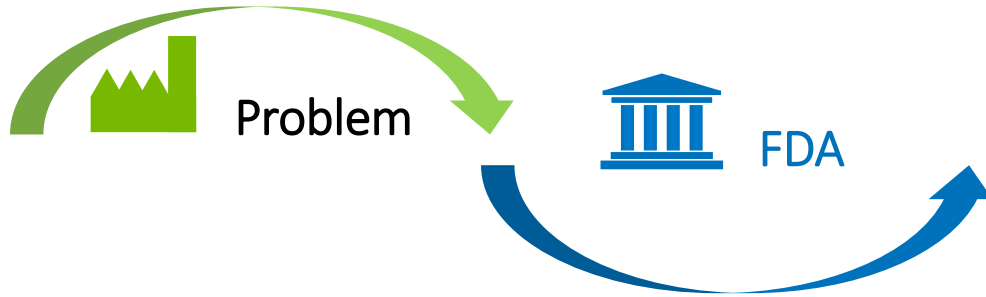


Scenario Three: Track Label Version History



- When Approval and Post-Market Research
- Challenge Need to identify changes across drug label versions
- Reason(s)
 1. Confirm label publication and version accuracy
 2. Establish evolutionary changes to a label
 3. Determine specific content and wording of a particular version or time period for regulatory or legal purposes
 4. Confirm available NDC for assignment

Scenario Three: Track Label Version History



- Tool [FDALabel](#), [Drugs@FDA](#)
- Method Drug name search
- Comment Difficult to search for a drug labels history let alone competitor label history

Scenario Three: Track Label Version History



- Tool Reed Tech Navigator™ for Drug Labels
- Method Drug name search, label compare and highlighted comparison
- Comment Find all label versions and time intervals, compare versions to identify changes, NDC query

Scenario Three: Track Label Version History

- Track Label

Reed Tech Navigator™ for Drug Labels

Dashboard Search Compare Labels My Library Support & Feedback Sign out of Personal Library Sign Out

Search

US Labels PDR Book Archives

Drug Name Search Search by brand, generic name, or national drug code

Text Search Search by text across all drug label sections, or create a conditional text search

Conditional Text Search Simple Text Search

Enter a search term in the first text input, then select if you want to search in/not in one of the categories in the menu.
Include additional search criteria by clicking the Add button. Search terms must be two or more characters long and may only include numbers, letters, dashes, apostrophes, or spaces.

"Covid-19" in INDICATIONS & USAGE SECTION (34067-9)

Drug Attribute Search Search by drug attributes like ingredient, dosage form, manufacturer, and more

Product Characteristic Search Search by product characteristics like color, imprint, shape, size or scoring

Show only RLD Labels

Search Results

View Compare list (7 of 26) Save Search Excel Export Print

<input type="checkbox"/>	Label ID	Brand Name	Generic Name	Company Name	Latest Ver.#	Publi...	Dosage Forms	Category (Appl./Mono...	Product Type
<input type="checkbox"/>	✓	Casirivimab	Casirivimab	Regeneron Pharmaceuticals, I...	Ver: 11 (R4)	Jun 11, 2...	INJECTION, SOL...	UNAPPROVED DRUG OT...	HUMAN PRESCRIPTION DRU...
<input type="checkbox"/>	+	Hand Sanitizer	ALCOHOL	MB Diversity LLC	Ver: 1 (R4)	Jul 9, 2020	LIQUID	OTC monograph not final [...]	HUMAN OTC DRUG LABEL
<input type="checkbox"/>	✓	Janssen COVID-19 Vaccine	Ad26_COV2.S	Janssen Products, LP	Ver: 11 (R4)	Apr 27, 20...	INJECTION, SUS...	Unapproved drug other []	VACCINE LABEL
<input type="checkbox"/>	✓	Pfizer-BioNTech Covid-19 V...	BNT162b2	Pfizer Manufacturing Belgium ...	Ver: 16 (R4)	Jun 29, 2...	INJECTION, SUS...	UNAPPROVED DRUG OT...	VACCINE LABEL
<input type="checkbox"/>	✓	Veklury	remdesivir	Gilead Sciences, Inc.	Ver: 3 (R4)	Mar 12, 2021	INJECTION, INJE...	NDA [NDA214787]	HUMAN PRESCRIPTION DRU...

1 10 items per page 1 of 1 pages (5 items)

Scenario Three: Track Label Version History

- My Library- My LabelTracks notifies you of any updates to these products

The screenshot displays the 'Personal Library' section of the Reed Tech Navigator. At the top, there is a navigation bar with links for 'Dashboard', 'Search', 'Compare Labels', 'My Library', and 'Support & Feedback'. Below this, the 'Personal Library' title is followed by a sub-navigation bar with 'My LabelTracks' (selected), 'My Searches', 'My Account', and 'Reset Password'. The main content area is titled 'Active LabelTracks' and contains a table with the following columns: 'Region', 'Activate Date', 'Label Name', 'Company Name', and 'Delete Alert'. Each row in the table includes a 'Watchlists' button. At the bottom of the table, there is a pagination control showing '1' of 10 items and a '1 of 1 pages (10 items)' indicator.

Region	Activate Date	Label Name	Company Name	Delete Alert	
US	07/25/2024	200C Homeopathic Remedy Kit	Washington Homeopathic Products	Delete Alert	Watchlists
US	07/25/2024	24/7 Life Cold and Flu DayTime Severe	Lif Drug Store Products, Inc.	Delete Alert	Watchlists
US	07/25/2024	24 / 7 Life Extra Strength Pain Reliever	Lif Drug Store Products, Inc.	Delete Alert	Watchlists
US	07/25/2024	24/7 Life IBUPROFEN	Lif Drug Store Products, Inc.	Delete Alert	Watchlists
US	07/25/2024	365 everyday value ibuprofen	Whole Foods Market, INC.	Delete Alert	Watchlists
US	07/25/2024	30C Homeopathic Remedy Kit	Washington Homeopathic Products	Delete Alert	Watchlists
US	07/25/2024	365 everyday value acetaminophen	Whole Foods Market, INC.	Delete Alert	Watchlists
US	07/25/2024	365 everyday value acetaminophen	Whole Foods Market, INC.	Delete Alert	Watchlists
US	07/25/2024	365 everyday value ibuprofen	Whole Foods Market, INC.	Delete Alert	Watchlists
US	07/25/2024	3X Medicated Toothache and Gum Gel	Rite Aid	Delete Alert	Watchlists

Scenario Three: Track Label Version History

- Version History

Reed Tech Navigator™ for Drug Labels | Dashboard | Search | Compare Labels | My Library | Support & Feedback | Sign out of Personal Library | Sign Out

4 Back to Search Results

Label Type: US SPL

Version History

View side by side | Hide side by side view

Compare Labels | Export Labels

Select 2 labels for a combined, full label highlighted view of the differences. ⓘ

Key

- Inserted
- Deleted

Need a hard copy? | Print this comparison

VEKLURY- remdesivir injection
VEKLURY- remdesivir injection, powder, lyophilized, for solution
Gilead Sciences, Inc.

VEKLURY (remdesivir)
IMPORTANT PRESCRIBING INFORMATION

Subject: Updated Emergency Use Authorization (EUA) for hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg with suspected or laboratory-confirmed COVID-19 and variations in carton and vial labeling of VEKLURY (remdesivir)

Dear Healthcare Provider:

Gilead Sciences, Inc., would like to clarify the appropriate use and the variable packaging and labeling of the antiviral VEKLURY (remdesivir).

Gilead's remdesivir (brand name VEKLURY) was approved by the US Food and Drug Administration (FDA) on October 22, 2020, for adults and pediatric patients (12 years and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. Healthcare providers should administer VEKLURY in these patients per the current US Prescribing Information available at www.gilead.com/scienceand-medicine/medicines; please also see Important Safety Information at the end of this letter.

Emergency use of Gilead's remdesivir (brand name VEKLURY) in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg with suspected or laboratory-confirmed COVID-19

On October 22, 2020, FDA revised the Emergency Use Authorization (EUA) for VEKLURY, which now authorizes VEKLURY for use by healthcare providers to treat hospitalized

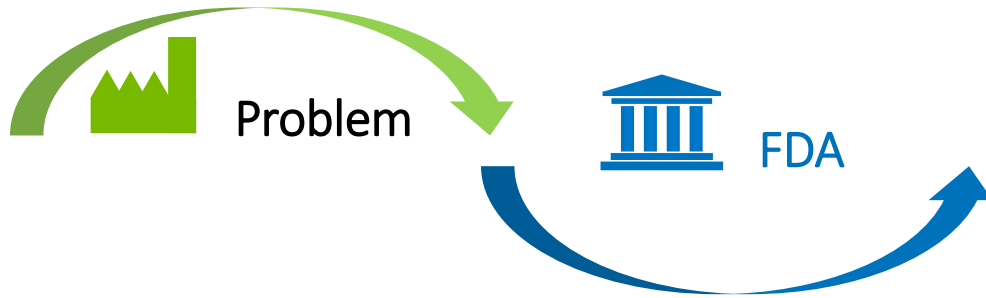
Scenario Four: Competitor and Reference Listed Drug Updates

Scenario Four: Monitor Competitor and RLD Label Updates



- When Post-Market
- Challenge Need to identify changes to competitor and RLD drug labels
- Reason(s)
 1. Market intelligence of changes to box warnings, updated indications, how supplied, dosage form, etc.
 2. Monitor for updates due to regulations requiring generic drug labels are updated to match RLD updates

Scenario Four: Monitor Competitor and RLD Label Updates



- Tool [FDALabel](#), Drug Safety – related labeling changes
- Method Drug name search, FDA email updates
- Comment Latest version of label, notification of what labels have had drug safety related changes

Scenario Four: Monitor Competitor and RLD Label Updates



- Tool Reed Tech Navigator™ for Drug Labels
- Method Search, My Library LabelTraks, view side-by-side
- Comment Find latest label versions as well as historical versions, compare versions to identify changes, saved searches using and alerts using the Navigator™ library functions

Scenario Four: Monitor Competitor and RLD Label Updates

The screenshot displays the Reed Tech Navigator for Drug Labels search interface. The search results are filtered for 'sertraline hydrochloride'. The results table shows the following data:

Label...	Brand Name	Generic Name	Company Name	Latest Ver.#	Publi...	Dosage Forms	Category[Appl./Mono...	Product Type
<input type="checkbox"/>	Zoloft	sertraline hydrochloride	Roerig	Ver. 57 (R4)	Jul 15, 2021	SOLUTION, CON...	NDA [NDA020990, ...]	HUMAN PRESCRIPTION DRU...

A red circle highlights the '1' in the pagination controls, indicating the current page. A red arrow points to this circle from the left side of the interface.

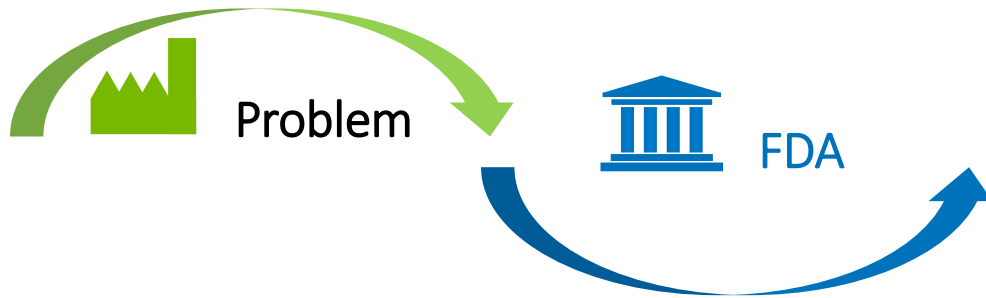
Scenario Five: Confirm Delisting

Scenario Five: Confirm Delisting



- When Post-Market (end commercial distribution)
- Challenge Need to confirm drug label was delisted
- Reason(s) Verify label has completed final step, i.e. delisted, to ensure compliance with FDA regulation

Scenario Five: Confirm Delisting



- Tool NLM [DailyMed](#), FDA NDC Directory
- Method DailyMed: drug name search, NDC code search and advanced search
NDC Directory: drug name, application number, NDC code, labeler name and database files
- Comment Once the Marketing End Date has passed these records are archived

Scenario Five: Confirm Delisting



- Tool Reed Tech Navigator™ for Drug Labels
- Method Drug name search and NDC code search
- Comment NDC code search results provide all active and delisted or expired listings

Scenario Five: Confirm Delisting

Search Results

[View Compare list \(0 of 25\)](#) [Save Search](#) [Excel Export](#) [Print](#)

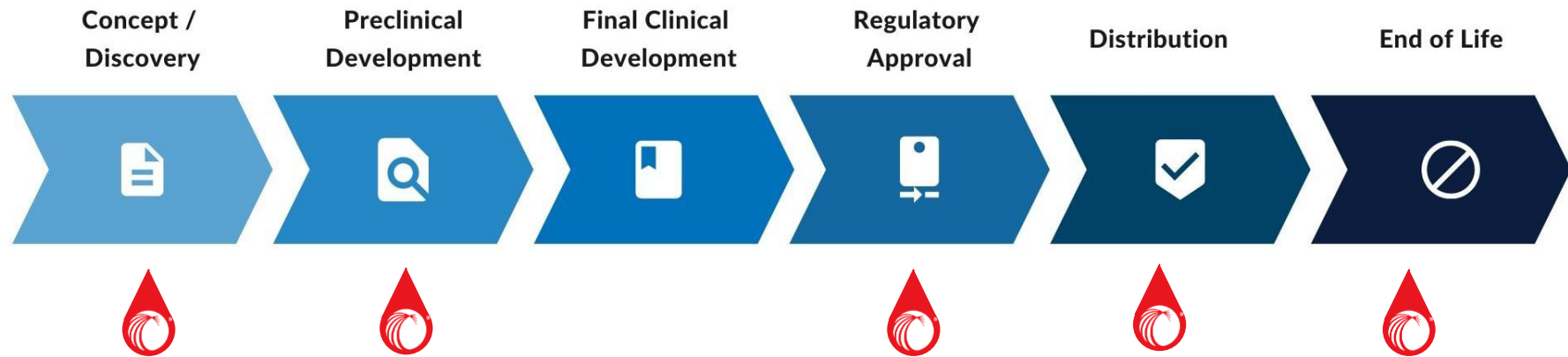
Label	Brand Name	Generic Name	NDC Package Codes	Company Name	Latest Ver.# P...	Dosage Fo...	Category[Appl./M...	Product Type	Synonyms
			57520						
<input type="checkbox"/>	+ 10 Stomach	Condurango, Antimoniu...	57520-0249-1	Apotheca Company	Ver: 1 (R4) Nov 9, ...	LIQUID	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA
<input type="checkbox"/>	+ 11 Thyroid Adrenal	Iodium, Phytolacca dec...	57520-0251-1	Apotheca Company	Ver: 2 (R4) Aug 6, ...	LIPSTICK	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA
<input type="checkbox"/>	+ 8 Small Intestine	Condurango, Phytolacc...	57520-0246-1	Apotheca Company	Ver: 2 (R4) Nov 10...	LIQUID	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA
<input type="checkbox"/>	+ 9 Spleen Pancreas	Ceanothus americanus...	57520-0248-1	Apotheca Company	Ver: 1 (R4) Aug 4, ...	LIQUID	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA
<input type="checkbox"/>	+ Bowel Nosode B Faecalis	Bowel Nosode B Faecalis	57520-0323-1	Apotheca Company	Ver: 3 (R4) Jan 20...	LIQUID	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA
<input type="checkbox"/>	+ Endo Pure Testos (for ...	DNA, RNA, Sabal serru...	57520-0527-1	Apotheca Company	Ver: 1 (R4) Jun 29...	LIQUID	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA
<input type="checkbox"/>	+ Flexible	Rhododendron chrysan...	57520-0059-1	Apotheca Company	Ver: 2 (R4) May 13...	LIQUID	unapproved homeopa...	HUMAN OTC DRUG LABEL	CA

[Search All](#) [Clear Search](#)

LexisNexis Reed Tech Navigator™ for Drug Labels



Reed Tech Product Lifecycle Support



Regulatory Strategy Support

- Reed Tech Navigator™ for Drug Labels supports market research (sponsors/products) and scientific due diligence

Regulatory Affairs Support

- Reed Tech Navigator™ for Drug Labels supports competitive evaluation, i.e., baseline labeling, indications, etc. and confirms label publications

Regulatory Operations Support

- Reed Tech Navigator™ for Drug Labels supports market intelligence (alerts, version history, cross-label comparisons and export)

Reed Tech Benefits of Experience



Reed Tech Can Help



Do More with
Existing
Resources



Save Time



Save with
Automated
Functionality



Industry Thought
Leaders

Getting it done right. On time.
The first time.

Simplifies management of data

- Secure environments for SPL, drug label data, and FDA document preparation
- Version control and audit trail - all current and historical versions

Streamlines workflow

- Improved communication between the client & Reed Tech and between colleagues at client organization
- Orders can be placed and tracked
- Users within client organization can be assigned roles and tasks

Reduces required resources

- Accurate & consistent use of companies & contacts
- Enter data once & use repeatedly
- On-demand SPL creation and updating
- Instant validation of entries
- Up-to-date with current FDA business rules
- Cloning of product listing metadata

Thank You



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+1-215-557-3010

Or visit us at: www.ReedTech.com

