

**Small Business &
Industry Assistance (SBIA)
January 26, 2023, Webinar**



FDA's Labeling Resources for Human Prescription Drugs

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Disclaimer



- The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.
- The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.

Learning Objectives (1 of 2)



- Provide an overview of FDA's labeling resources for human prescription drugs
- Distinguish between *current* labeling and the *last FDA-approved* labeling
- Discuss available searchable labeling and product databases
- Locate specific Prescribing Information (PI) resources including a sample PI template

Learning Objectives (2 of 2)



- Describe resources for Instructions for Use, Medication Guides, and Patient Package Inserts
- Identify carton and container labeling resources
- Discuss labeling resources for specific product categories including generic drugs and biological products
- Discuss a resource for Structured Product Labeling (SPL) developers in selecting the appropriate SPL codes for human prescription drug labeling

Redesigned *FDA's Labeling Resources* for *Human Prescription Drugs*



- FDA's prescription drug labeling resources were previously located on one lengthy webpage entitled "*Prescription Drug Labeling Resources*"
- Reorganized this previous single webpage into:
 - 7 webpages for industry
 - 1 webpage for healthcare practitioners and patients¹

¹ See the December 2022 webinar about the *Frequently Asked Questions about Labeling for Prescription Medicines* webpage for healthcare practitioners and patients at <https://www.fda.gov/media/163893/download>

Webpage #1: FDA's Labeling Resources for Human Prescription Drugs

FDA's Labeling Resources for Human Prescription Drugs

[Prescribing Information Resources](#)

[Patient Labeling Resources](#)

[Carton and Container Labeling Resources](#)

[Selection of Appropriate SPL Codes for Human Prescription Drug Labeling](#)

[Generic Drugs - Specific Labeling Resources](#)

[Biological Products - Specific Labeling Resources](#)

FDA's Labeling Resources for Human Prescription Drugs

For Industry



FDA's labeling resources for human prescription drugs are primarily directed to industry staff who develop human prescription drug labeling. Human prescription drug labeling (1) contains a summary of the essential scientific information needed for the safe and effective use of the drug; and (2) includes the Prescribing Information, FDA-approved patient labeling (Medication Guides, Patient Package Inserts, and/or Instructions for Use), and/or carton and container labeling.

If you are a healthcare professional, patient, or caregiver, visit [Frequently Asked Questions about Labeling for Prescription Medicines](#).

[Searchable Labeling Databases](#) ▼

[How May "Current" Labeling Be Different Than "FDA-Approved" Labeling](#) ▼

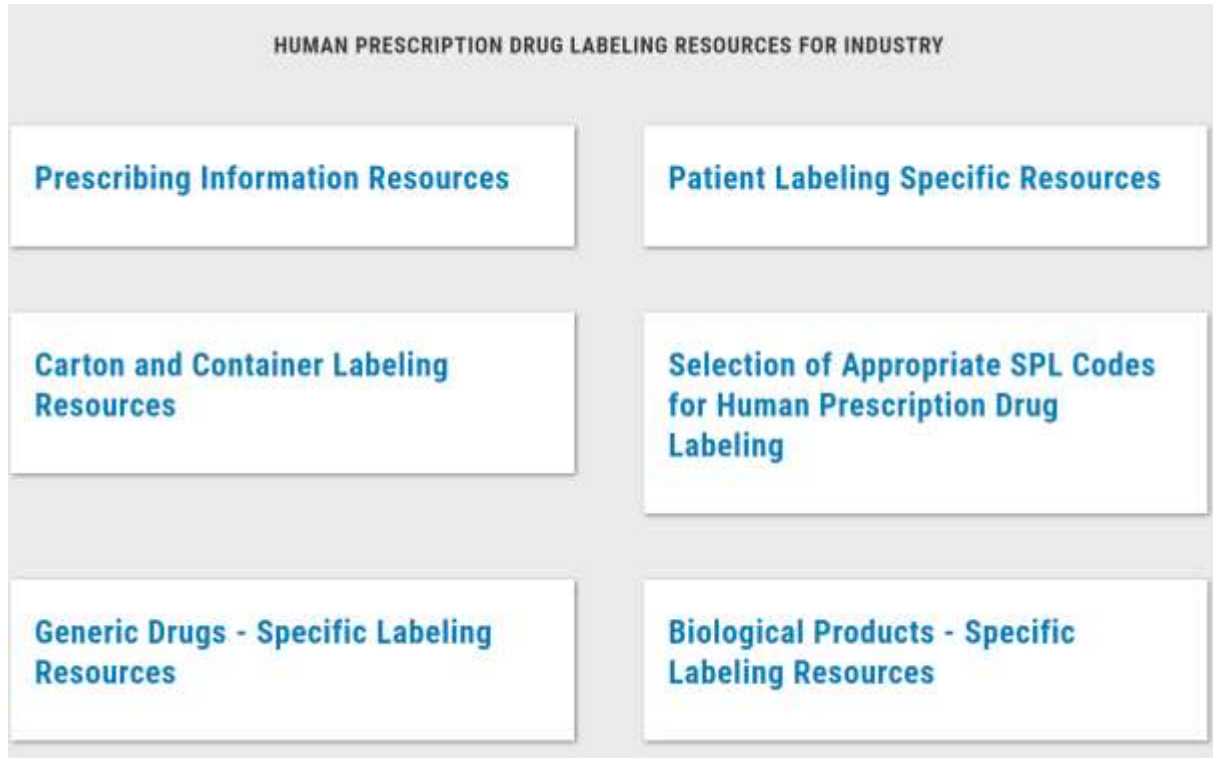
[Searchable Product Databases](#) ▼

[Imported-Drug Specific Labeling Resources](#) ▼

[Resources for Promotional Labeling and Other FDA-Regulated Products](#) ▼

Left-sided box with links to other webpages

FDA's Labeling Resources for Human Prescription Drugs





Convenient Links to Promotional Labeling and Resources for Other FDA-Regulated Products¹

- [Promotional labeling resources](#) for human prescription drugs, and
- Labeling resources for other FDA-regulated products such as [nonprescription drug products](#) ("over-the-counter" drugs), [medical devices](#), [homeopathic products](#), [dietary supplements](#), [foods](#), [cosmetics](#), [tobacco](#), or [animal drugs](#).

¹ Available under the “**Resources for Promotional Labeling and Other FDA-Regulated Products**” heading on *the FDA’s Labeling Resources for Human Prescription Drugs* webpage at <https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs>

How May *Current* Labeling Be Different Than *FDA-Approved* Labeling¹



- Minor changes in an annual reportable change
- Moderate changes in a “Changes Being Effected” (CBE) labeling supplement that is undergoing FDA review

¹ See the “How May ‘Current’ Labeling Be Different Than ‘FDA-Approved’ Labeling” heading on the FDA’s Labeling Resources for Human Prescription Drugs webpage (see <https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs>)



Searchable Labeling Databases¹

- **DailyMed:** NIH's labeling tool designed to search over 140,000 labeling documents for prescription drugs, nonprescription drugs, animal drugs, and other products (e.g., animal nonprescription and animal prescription drugs, cosmetics, dietary supplements, medical devices, medical foods).
- **Drug Safety-Related Labeling Changes Database:** Includes recent updates to safety information in labeling including labeling changes from efficacy supplements and labeling supplement approvals. These labeling changes include changes:
 - Recommended by the FDA or initiated by companies, and
 - Required by the FDA under Section 505(o)(4) of the FD&C Act (safety labeling changes).
- **Drugs@FDA:** Includes information about drugs approved for human use in the United States:
 - Drug information,
 - Regulatory history,
 - Most recent FDA-approved Prescribing Information and patient labeling, and
 - Reviews by FDA staff that evaluate the safety and effectiveness of the drug.Drugs@FDA does not include information about FDA-approved products regulated by the Center for Biologics Evaluation and Research (vaccines, allergenic products, blood and blood products, plasma derivatives, and cellular and gene therapy products) or products not approved by the FDA.
- **FDALabel:** FDA's web-based application designed to perform customizable searches of over 140,000 labeling for human prescription drug; nonprescription drugs; and labeling for other products (e.g., animal nonprescription and animal prescription drugs, cosmetics, dietary supplements, medical devices, medical foods). FDALabel and DailyMed have the same database but have different search functions and different displays of search results. For the similarities and differences between FDALabel and DailyMed see Slides 42-44 in the Prescription Drug Labeling Updates [presentation](#).
- **Medication Guides:** Includes Medication Guides approved by the Center for Drug Evaluation and Research.
- **Pediatric Labeling Information Database:** Includes labeling recently updated with pediatric use information.

¹ See the “**Searchable Labeling Databases**” heading on the FDA’s Labeling Resources for Human Prescription Drugs webpage (see <https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs>)

FDALabel: Full-Text Search of Labeling for Human Drugs¹

FDALabel [Home](#) [About](#) [Database Updates](#) [Disclaimer](#) [Contact](#)

Labeling Types

Choose one or more: [Animal Rx](#) [Animal OTC](#) [Human Rx](#) [Human OTC](#) [Medical Device](#) [Medical Device Rx](#) [Vaccine](#)

or choose one or more from the list:

&

Application Types or Marketing Categories

Choose one or more: [ANDA](#) [BLA](#) [NDA](#) [NDA Authorized Generic](#) [OTC Monograph Final](#) [OTC Monograph Not Final](#)

or choose one or more from the list:

&

Product Name(s)

Trade or generic/proper name contains Enter any part(s) of product name

&

Labeling Full Text Search

Simple Search Enter text (e.g., search for NAUSEA OR VOMITING retrieves labeling containing the phrase "nausea or vomiting")

[Simple Search](#): Search for exact text using complete words/phrases (ignores non-alphanumeric characters, e.g., ignores ":", "%")
[Advanced Search](#) (from drop-down menu): Conduct a Boolean and/or partial word search

¹ See the “**Searchable Labeling Databases**” heading on the *FDA’s Labeling Resources for Human Prescription Drugs* webpage (see <https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs>). To find FDALabel directly, see <https://nctr-crs.fda.gov/fdalabel/ui/search>.

Labeling Section(s) Search in FDALabel¹



Additional Fields

Product Title (123788 labeling)

Initial U.S. Approval [4 Digit Year] (20124 labeling)

Highlights [Excluding Product Title] (20169 labeling)

Full Prescribing Information (PLR & Non-PLR)

BOXED WARNING (16256 labeling)

1 INDICATIONS AND USAGE (134992 labeling)

2 DOSAGE AND ADMINISTRATION (134718 labeling)

3 DOSAGE FORMS AND STRENGTHS (22409 labeling)

4 CONTRAINDICATIONS (44651 labeling)

5 WARNINGS AND PRECAUTIONS (24350 labeling)

6 ADVERSE REACTIONS (45722 labeling)

7 DRUG INTERACTIONS (33587 labeling)

8 USE IN SPECIFIC POPULATIONS (21765 labeling)

8.1 Pregnancy (33915 labeling)

8.2 Lactation (7271 labeling)

8.2 Labor and Delivery (8638 labeling)

8.3 Females and Males of Reproductive Potential (2430 labeling)

8.3 Nursing Mothers (23384 labeling)

¹ See the “**Searchable Labeling Databases**” heading on the *FDA’s Labeling Resources for Human Prescription Drugs* webpage (see <https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs>). To find FDALabel directly, see <https://nctr-crs.fda.gov/fdalabel/ui/search>.

Labeling Databases (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	SPL	SPL
Products Include:			
CDER-approved prescription and nonprescription human drugs and biologics (under NDAs and BLAs)	Yes	Yes	Yes
CDER-approved prescription and nonprescription human drugs (under ANDAs)	Rarely	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			
Search by application # or drug name	Yes	Yes	Yes
Search by drug class, NDC #, and/or by active or inactive ingredient	No	Yes	Yes
Search by labeling section	No	Yes	Yes
Search by application type or marketing category (e.g., ANDA, BLA, NDA), DEA schedule, and/or market status; can export results to an Excel Spreadsheet	No	No	Yes

Searchable Product Databases¹



- Animal Rule Approvals
- Biosimilar Product Information
- CBER's Novel Biological Products
- CDER's Novel Drugs and Biological Products
- Drug Safety Communications
- Drug Trials Snapshots
- Emergency Use Authorization
- National Drug Code (NDC) Directory
- Orange Book
- Purple Book
- REMS@FDA
- United States Pharmacopeia-National Formulary Resources

¹ See the “**Searchable Product Databases**” heading on the FDA’s Labeling Resources for Human Prescription Drugs webpage (see <https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs>).

CDER's Novel Drug and Biological Products Database

New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products



Innovative drugs often mean new treatment options for patients and advances in health care for the American public. When it comes the development of new drugs and therapeutic biological products, FDA's Center for Drug Evaluation and Research (CDER) provides clarity to drug developers on the necessary study design elements and other data needed in the drug application to support a full and comprehensive assessment. To do so, CDER relies on its understanding of the science used to create new products, testing and manufacturing procedures, and the diseases and conditions that new products are designed to treat.



Content current as of:
01/10/2023

Regulated Product(s)
Drugs



Webpage #2: Prescribing Information Resources

Prescribing Information Resources

For Industry

[f Share](#)
[t Tweet](#)
[in LinkedIn](#)
[✉ Email](#)
[🖨 Print](#)

Who is the Audience for This Webpage?

FDA's Prescribing Information (PI) resources on this webpage are primarily directed to industry staff who develop PI. For other prescription drug[®] labeling resources for industry such as those for FDA-approved patient labeling, carton and container labeling, generic drug labeling, biological product labeling, labeling databases, and product databases visit [FDA's Labeling Resources for Human Prescription Drugs](#). If you are a healthcare professional, patient, or caregiver, visit [Frequently Asked Questions about Labeling for Prescription Medicines](#).

What is the Prescribing Information?



When Should Prescribing Information Be Updated?



Prescribing Information Resources¹



What is the Prescribing Information? 

When Should Prescribing Information Be Updated? 


What Are the Formats for the Prescribing Information? 

What Are the Advantages of PLR Format? 

Prescribing Information Regulations 

Prescribing Information Guidances and MAPPs 

Format Tools and Sample Templates 

General Labeling Presentations 

Publications 

¹ Available at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>

FDA Encourages Submission of Voluntary PLR Conversions¹



- “PLR format represents a **more useful ... approach** for communicating accurate and up-to-date information on the safe and effective use of drugs and makes prescription information more accessible for use with electronic prescribing tools”²
- “FDA **strongly encourages** all applicants to voluntarily convert the labeling of their drug products to the PLR format, regardless of the date of approval”²

Over 300 voluntary PLR conversions approved to date in CDER!

¹ Discussed under the “**What Are the Advantages of PLR Format?**” heading on the Prescribing Information Resources webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

² See 78 FR 8446 (February 6, 2013); also see final rule (PLR) “Requirements on Content and Format of Labeling For Human Prescription Drug and Biological Products” 71 FR 3922 (January 24, 2006)

Converting Labeling for Older Drugs from the Old Format to the PLR Format

Farrokh Sohrabi, MD

Labeling Development Team, Office of New Drugs

Center for Drug Evaluation and Research (CDER)

Food and Drug Administration (FDA)

Labeling Policy Team was previously known as the Labeling Development Team

¹ Available under the **“What Are the Advantages of PLR Format?”** heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

Updated Sample Prescribing Information Template¹



Template located under the “Format Tools and Sample Templates” heading:

- Consider using when developing PLR-formatted labeling
- Does not contain all labeling regulatory requirements or guidance recommendations

¹ Available under the “**Format Tools and Sample Templates**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

WARNING: TITLE OF WARNING

[[Include a boxed warning for contraindications or serious adverse reactions or risks, particularly those that may lead to death or serious injury. Include a boxed warning when (1) an adverse reaction is so serious in proportion to the potential benefit from the drug that it is essential that it be considered in assessing the drug's benefits and risks, (2) a serious adverse reaction can be prevented or reduced in frequency or severity by appropriate use of the drug, or (3) the drug has been approved with restrictions for use because the drug can be safely used only if distribution or use is restricted (e.g., Elements to Assure Safe Use (ETASU)).

Provide a brief, concise summary of critical information from the CONTRAINDICATIONS and/or WARNINGS AND PRECAUTIONS section(s). Cross-reference to more detailed discussion in other sections (e.g., CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS) and use bold font.]]

1 INDICATIONS AND USAGE

PROPRIETARY NAME is indicated for ...

Limitations of Use

[[Limitations of Use are included when there is reasonable concern or uncertainty about a drug's risk-benefit profile in certain settings (e.g., use of drug may be inadvisable, drug should generally not be used).]]

2 DOSAGE AND ADMINISTRATION

[[When certain dosage- or administration-related information is particularly critical to the safe and effective use of the drug that health care practitioners need to be alerted to such information prior to drug initiation, include this information prior the recommended dosage and administration information ordinarily placed at the beginning of this section (e.g., critical tests, procedures, and/or evaluations needed prior to administration).

14 CLINICAL STUDIES

[[Discuss the clinical studies that are important to a health care practitioner's understanding of the safe and effective use of the drug. Include a description and results of the clinical studies (adequate and well-controlled studies) that (1) provided the primary support for the approved indication(s) (2) provided other important information about the drug's effectiveness not furnished by the studies that provided primary support for effectiveness (e.g., studies that suggested differential effects in subpopulations) and/or (3) prospectively evaluated a safety endpoint. Include information about clinical studies that suggested lack of effectiveness in a clinical situation or lack of effect on an endpoint.

For the study design description include:

- *Major design characteristics*
- *Study treatment arms, including the dosage and route(s) of administration*
- *Eligibility criteria important for understanding the treatment effect or for understanding if the results can be generalized (it may be more important to describe the important baseline disease characteristics of the studied population rather than the protocol/study eligibility criteria)*
- *Important concomitant therapy that helps understand the effects of the drug*
- *Endpoints critical to establish effectiveness*
- *Limitations of the study design and statistical analysis plan, and uncertainties with the endpoint(s)*

When summarizing study findings include:

- *Number enrolled*
- *Baseline demographics (age, sex, racial subgroups (e.g., White, Black or African American, American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander), and ethnic subgroups (i.e., Hispanic or Latino vs. Not Hispanic or Latino))*

Required “Manufacturer Information” in Labeling



For NDAs must include at least one of the following: the manufacturer’s name (e.g., Firm-M) and their place of business; distributor’s name (e.g., Firm-D) and their place of business, or packer’s name (e.g., Firm-P) and their place of business:

- The manufacturer’s, distributor’s, and/or packer’s name may be the name of a parent, subsidiary, or affiliate company where the related companies are under common ownership and control.
- The place of business must include the street address, city, state, and zip code; however, may omit the street address if the address is shown in a current city or telephone directory. For a foreign manufacturer must also include the country and any applicable mailing code.
- If the manufacturer information is included and there are joint manufacturers must state: “Jointly Manufactured By [insert name of all of the manufacturers]”
- If the distributor is included, must use one of the following phrases: “Manufactured for Firm-D”, “Distributed by Firm-D”, “Manufactured by Firm-M for Firm-D”, “Manufactured for Firm-D by Firm-M”, “Distributor: Firm-D”, “Marketed by Firm-D”.
- If the packer is included, must use one of the following phrases: “Packed by Firm-P” or “Packaged by Firm-P”

For BLAs must include the license manufacturer’s name (i.e., the applicant on Form 356h) along with the license manufacturer’s address and U.S. license number.

- The distributor’s name and address may also be included.
- If the distributor is included must include one of the following phrases: “Manufactured for Firm-D”, “Distributed by Firm-D”, “Manufactured by Firm-M for Firm-D”, “Manufactured for Firm-D by Firm-M”, “Distributor: Firm-D”, or “Marketed by Firm-D”.]

FDA Regulatory Education for Industry Conference June 2022



U.S. FOOD & DRUG
ADMINISTRATION



Prescription Drug Labeling Updates

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Office of New Drug Policy, Office of New Drugs
CDER | US FDA

Regulatory Education for Industry Annual Conference 2022

¹ Available under the “**General Labeling Presentations**” heading on the Prescribing Information Resources webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

Consistency in Labeling and Methods to Optimize Communication in Labeling

Eric Brodsky, MD
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Office of New Drugs
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

¹ Available under the “**General Labeling Presentations**” heading on the Prescribing Information Resources webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

Prescribing Information Resources¹ (1 of 3)



Highlights of Prescribing Information



Boxed Warning



1 Indications and Usage



2 Dosage and Administration



3 Dosage Forms and Strengths



4 Contraindications



5 Warnings and Precautions



6 Adverse Reactions



7 Drug Interactions



¹ Available at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>

Prescribing Information Resources¹ (2 of 3)

8 Use in Specific Populations



8.1 Pregnancy, 8.2 Lactation, and 8.3 Females and Males Reproductive Potential



8.4 Pediatric Use



8.5 Geriatric Use



9 Drug Abuse and Dependence



10 Overdosage



11 Description



¹ Available at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>

Prescribing Information Resources¹ (3 of 3)



12 Clinical Pharmacology	▼
12.1 Mechanism of Action, 12.2 Pharmacodynamics, and 12.3 Pharmacokinetics	▼
12.4 Microbiology	▼
12.5 Pharmacogenomics	▼
12.6 Immunogenicity	▼
13 Nonclinical Toxicology	▼
14 Clinical Studies	▼
15 References	▼
16 How Supplied/Storage and Handling	▼
17 Patient Counseling Information	▼

¹ Available at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>

Product Titles in Highlights of Prescribing Information Consistent with Requirements Under 21 CFR 201.57(a)(2) and Recommendations in Draft Guidance for Industry: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products - Content and Format*

<p>OTHER INJECTION DOSAGE FORMS</p>	<p>INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension, for intramuscular use ABILIFY MAINTENA (aripiprazole) for extended-release injectable suspension, for intramuscular use ARISTADA (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use CINVANTI (aprepitant) injectable emulsion, for intravenous use OMEGAVEN (fish oil triglycerides) injectable emulsion, for intravenous use CLINOLIPID (lipid injectable emulsion), for intravenous use VARITHENA (polidocanol injectable foam), for intravenous use SIGNIFOR LAR (pasireotide) for injectable suspension, for intramuscular use VARITHENA (polidocanol injectable foam), for intravenous use</p>
<p>TRANSDERMAL SYSTEMS</p>	<p>OXYTROL (oxybutynin transdermal system) IONSYS (fentanyl iontophoretic transdermal system), CII MINIVELLE (estradiol transdermal system) NEUPRO (rotigotine transdermal system) EMSAM (selegiline transdermal system)</p>
<p>DOSAGE FORMS FOR TOPICAL USE</p>	<p>ULESFIA (benzyl alcohol) lotion, for topical use CENTANY (mupirocin) ointment, for topical use XERESE (acyclovir and hydrocortisone) cream, for topical use ESKATA (hydrogen peroxide) topical solution ULESFIA (benzyl alcohol) lotion, for topical use PLIAGLIS (lidocaine and tetracaine) cream, for topical use BACTROBAN (mupirocin calcium) cream, for topical use RHOFADÉ (oxymetazoline hydrochloride) cream, for topical use XEPI (ozonoxacin) cream, for topical use MIRVASO (brimonidine) topical gel</p>

¹ The “Example Product Titles” document under the “Product Title and Initial U.S. Approval” subheading under the “**Highlights of Prescribing Information**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

Established Pharmacologic Class



FDA Listing of Established Pharmacologic Class Text Phrases January 2023	
Active Moiety Name	FDA EPC Text Phrase PLR regulations require that the following statement is included in the Highlights Indications and Usage heading if a drug is a member of an EPC [see 21 CFR 201.57(a)(6)]: “(Drug) is a (FDA EPC Text Phrase) indicated for [indication(s)].” For each listed active moiety, the associated FDA EPC text phrase is included in this document. For more information about how FDA determines the EPC Text Phrase, see the 2009 "Determining EPC for Use in the Highlights" guidance and 2013 "Determining EPC for Use in the Highlights" MAPP 7400.13.

TELAPREVIR	hepatitis C virus (HCV) NS3/4A protease inhibitor
VOXILAPREVIR	hepatitis C virus (HCV) NS3/4A protease inhibitor
DACLATASVIR	hepatitis C virus (HCV) NS5A inhibitor
ELBASVIR	hepatitis C virus (HCV) NS5A inhibitor
LEDIPASVIR	hepatitis C virus (HCV) NS5A inhibitor
OMBITASVIR	hepatitis C virus (HCV) NS5A inhibitor
PIBRENTASVIR	hepatitis C virus (HCV) NS5A inhibitor
VELPATASVIR	hepatitis C virus (HCV) NS5A inhibitor
SOFOSBUVIR	hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor

¹ Available under the “Established Pharmacologic Class (EPC)” subheading under the “**Highlights of Prescribing Information**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)³³

1 Indications and Usage¹





Guidance

- Indications and Usage Section of Labeling ([draft guidance](#))

Related Guidances

- Labeling for Human Prescription Drugs and Biological Products Under the Accelerated Approval Regulatory Pathway ([final guidance](#))
- Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations ([draft guidance](#))

Presentations

- Considerations for Developing Indications and Usage Section ([2017 presentation](#) and [video](#) ) and ([2015 presentation](#))
- Indications and Usage Section of Labeling ([2019 presentation](#) and [video](#) )
- Labeling Case Study - Transformation of an Indication ([2019 presentation](#) and [video](#))

¹ Available under the “1 Indications and Usage” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)



Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Eric Brodsky at (301) 796-0855, or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

**January 2023
Labeling
Revision 1**

Please submit
comments by
March 14, 2023

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dosage-and-administration-section-labeling-human-prescription-drug-and-biological-products-content>

¹ Available under the “2 Dosage and Administration” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)



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Including Grouped Term Information in the ADVERSE REACTIONS Section of the Prescribing Information

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Center for Evaluation and Research, FDA

¹ Available under the “**6 Adverse Reactions**” heading on the *Prescribing Information Resources* webpage
(see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

8.4 Pediatric Use¹



Scenario 1: Evidence Supports Safety and Effectiveness of Drug for a Pediatric Indication



<https://paintingvalley.com/clipart-child-drawing/clipart-child-drawing-25.jpg>

¹ “Pediatric Information in Labeling” presentation and video under the “**8.4 Pediatric Use**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

8.4 Pediatric Use¹



Scenarios 2, 3, and 4: Evidence Does Not Support Safety and Effectiveness of Drug for a Pediatric Indication



<https://www.shutterstock.com/search/say-no>; <http://clipartportal.com/child-saying-no-clipart-6/>

¹ “Pediatric Information in Labeling” presentation and video under the “8.4 Pediatric Use” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)



8.5 Geriatric Use¹



Geriatric Labeling Rule and Guidance

- “Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of ‘Geriatric Use’ Subsection in the Labeling,” (21 CFR 201; 62 FR 45313) published August 27, 1997. ([Geriatric Labeling Rule](#)).
- Geriatric Information in Human Prescription Drug and Biological Product Labeling ([draft guidance](#)).

Presentation

- Geriatric Patients - Promoting Safe and Effective Prescription Drug Use (2020 [presentation](#)  and [video](#) )

¹ Available under the “8.5 Geriatric Use” heading on the Prescribing Information Resources webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

12.1 Mechanism of Action, 12.2 Pharmacodynamics, and 12.3 Pharmacokinetics (1 of 2)¹

Guidances

- Clinical Pharmacology Section of Labeling ([final guidance](#))

Related Guidances



- Assessing the Effects of Food on Drugs in INDs and NDAs – Clinical Pharmacology Considerations ([final guidance](#))
- Assessment of Pressor Effects of Drugs ([draft guidance](#))
- Clinical Drug Interactions Studies – Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions ([final guidance](#))
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data, Data Analysis, and Impact on Dosing ([draft guidance](#))
- Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments ([draft guidance](#))

¹ Available under the “**12.1 Mechanism of Action, 12.2 Pharmacodynamics, and 12.3 Pharmacokinetics**” heading on *the Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

12.1 Mechanism of Action, 12.2 Pharmacodynamics, and 12.3 Pharmacokinetics (2 of 2)¹

...

Presentations

- Clinical Pharmacology Information in Labeling ([2017 presentation](#)) and (2019 [presentation](#) and [video](#) )
- Clinical Pharmacology Section of Labeling Guidance Webinar ([2017 webinar](#))
- Clinical Pharmacology Section of Labeling (2017 [presentation](#) and [video](#) )
- Drug Interaction Information in Labeling (2020 [presentation](#) and [video](#))

¹ Available under the “**12.1 Mechanism of Action, 12.2 Pharmacodynamics, and 12.3 Pharmacokinetics**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

16 How Supplied/Storage and Handling (1 of 2)¹



Related Guidances

- Child-Resistant Packaging Statements in Drug Product Labeling ([final guidance](#))
- Metered Dose Inhaler and Dry Powder Inhaler Drug Products - Quality Considerations ([draft guidance](#))
- Naming of Drug Products Containing Salt Drug Substances ([final guidance](#)) and [MAPP](#)
- Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex ([final guidance](#))
- Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use ([final guidance](#))
- Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation ([final guidance](#))
- Transdermal and Topical Delivery Systems - Product Development and Quality Considerations ([draft guidance](#))



¹ Available under the “**16 How Supplied/Storage and Handling**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

16 How Supplied/Storage and Handling (2 of 2)¹



...

Presentations

- Considerations for Product Quality Information in the Prescribing Information ([2017 presentation](#))
- Drug Product Nomenclature (2019 [presentation](#) and [video](#) )
- Improving Consistency of Information Between Carton-Container Labeling and Prescribing Information (2019 [presentation](#) and [video](#) )

¹ Available under the “**16 How Supplied/Storage and Handling**” heading on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

Labeling Considerations for Product Quality Information in the Prescribing Information

Eric Brodsky, MD
Associate Director, Labeling Development Team
Office of New Drugs
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

¹ This presentation is available under Product Titles” document available under the “**Highlights of Prescribing Information, 3 Dosage Forms and Strengths, 11 Description, and 16 How Supplied/Storage and Handling**” headings on the *Prescribing Information Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources>)

Webpage #3: Patient Labeling Resources

Patient Labeling Resources

For Industry

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On this page

- [Who is the audience for this webpage?](#)
- [What are Instructions for Use?](#)
- [What are Medication Guides?](#)
- [What are Patient Package Inserts?](#)
- [Contact information](#)

Who is the audience for this webpage?

FDA's patient labeling specific resources on this webpage are primarily directed to industry staff who develop patient labeling for prescription drugs. For more information about:



Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products — Content and Format

Guidance for Industry

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products (OCP)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**July 2022
Labeling**

¹ Available under the *Patient Labeling Resources* webpage (see <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources>)



**INSTRUCTIONS FOR USE
MYDRUG [mye-drug]
(drugoxide injection)
for intramuscular use**

This Instructions for Use contains information on how to take MYDRUG.

Important Information You Need to Know Before Taking MYDRUG

...

Preparing to Take MYDRUG

...

Taking MYDRUG

...

Storing MYDRUG

...

Disposing of MYDRUG

...

Drug Company X, City, State, zip code

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: MM/YYYY



MEDICATION GUIDE
DRUG-X [drug X]
(drugimab-cznm)
injection, for intramuscular use

What is the most important information I should know about DRUG-X? ...
What is DRUG-X? ...
Who should not take DRUG-X? ...
Before taking DRUG-X, tell your healthcare provider about all of your medical conditions, including if you: ...
How should I take DRUG-X? ...
What should I avoid while taking DRUG-X? ...
What are the possible side effects of DRUG-X? ... Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
How should I store DRUG-X? ...
General information about the safe and effective use of DRUG-X. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DRUG-X for a condition for which it was not prescribed. Do not give DRUG-X to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DRUG-X that is written for health professionals.
What are the ingredients in DRUG-X? Active ingredients: Inactive ingredients:
Manufactured for: Manufactured by:

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: MM/YYYY



PATIENT INFORMATION
DRUG-X [drug X]
(drugoxide-a and drugoxide-b tablets)
for oral use

What is DRUG-X?

....

Do not take DRUG-X if you:

....

Before taking DRUG-X, tell your healthcare provider about all of your medical conditions, including if you:

....

How should I take DRUG-X?

What should I avoid while taking DRUG-X?

....

What are the possible side effects of DRUG-X?

....

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DRUG-X?

....

General information about the safe and effective use of DRUG-X.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DRUG-X for a condition for which it was not prescribed. Do not give DRUG-X to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about DRUG-X that is written for health professionals.

What are the ingredients in DRUG-X?

Active ingredients:

Inactive ingredients:

Manufactured for:

Manufactured by:

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: MM/YYYY

A prescription drug may have a PPI or a MG (but not both)

Webpage #4: Carton and Container Labeling Resources

Carton and Container Labeling Resources

For Industry

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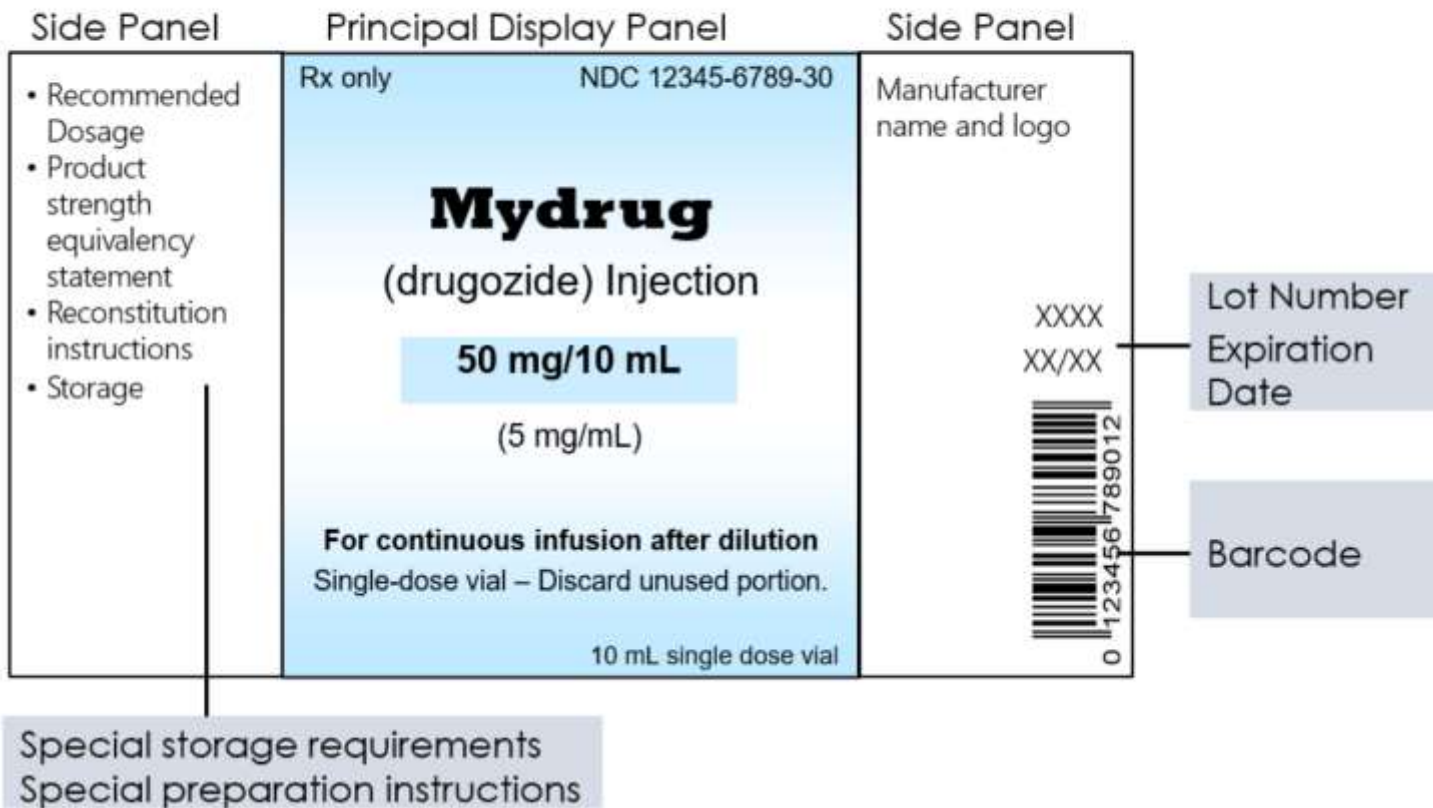
On this webpage

- [Who Is the Audience for This Website?](#)
- [General Carton and Container Labeling Statutory/Regulatory Provisions](#)
- [Specific Container Label Statement Requirements](#)
- [Carton and Container Labeling Guidances and MAPPs](#)
- [Other Carton and Container Labeling Resources](#)
- [Example Container Label](#)
- [Contact Information](#)

Who Is the Audience for This Website?

FDA's carton and container labeling specific resources on this webpage are primarily directed to industry staff who develop carton and container labeling for prescription drugs. For other prescription drug labeling resources for industry such as those for the

Example Container Label



Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors

Guidance for Industry

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**May 2022
Drug Safety**

Improving Consistency of Information Between Prescribing Information and Carton/Container Labeling

Eric Brodsky, M.D.

Associate Director, Labeling Policy Team*, Office of New Drug Policy,
Office of New Drugs, Center for Drug Evaluation and Research, FDA

* Labeling Policy Team (previously known as the Labeling Development Team)

Webpage #5: Generic Drugs – Specific Labeling Resources

Generic Drugs - Specific Labeling Resources

For Industry

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Who Is the Audience for This Website?

FDA's generic drug-specific labeling resources are primarily directed to industry staff who develop generic drug labeling. For more information about:

- Other prescription drug labeling resources for industry such as those for the Prescribing Information, FDA-approved patient labeling, carton and container labeling, biological product labeling, labeling databases, and product databases visit [FDA's Labeling Resources for Human Prescription Drugs](#).
- Drug labeling resources for healthcare professionals, patients, and caregivers, visit [Frequently Asked Questions about Labeling for Prescription Medicines](#)

Generic Drug Labeling

Generic drug labeling [labeling under an abbreviated new drug application (ANDA)] must be the "same as" the last approved reference listed drug (RLD) labeling except for permissible differences (e.g., manufacturer/packer/distributor information, package size, inactive ingredients, omission of information protected by patent or exclusivity, differences due to an approved suitability petition).

ANDA Holder Responsibility to Update Their Labeling¹

- Routinely review the last approved reference listed drug (RLD) labeling on Drugs@FDA to ensure that their generic drug labeling meets the “same as” requirements
- Promptly update their generic drug labeling after FDA has approved changes to associated RLD labeling
- Additional methods to follow RLD labeling changes:
 - Subscribe to CDER Drug Safety Labeling Changes
 - Online, fax, or mail request to FDA’s Division of Freedom of Information

¹ Available at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/generic-drugs-specific-labeling-resources>

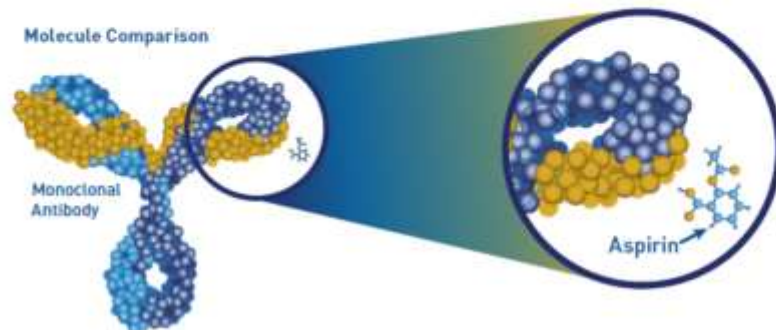
Webpage #6: Biological Products – Specific Labeling Resources

Biological Products - Specific Labeling Resources

For Industry



Biological products, including biosimilar and interchangeable biosimilars, are large and generally complex molecules. A biological product may weigh more than 800 times than a drug product (e.g., aspirin). See the figure below.



Webpage #7: Selection of Appropriate SPL Codes for Human Prescription Drug Labeling

Improving the Accuracy of SPL Submissions: “The Missing LOINC”

Farrokh Sohrabi, M.D.

Labeling Policy Team, Office of New Drug Policy

Office of New Drugs, Center for Drug Evaluation and Research, FDA

SPL = Structured Product Labeling; LOINC = Logical Observation Identifiers Names and Codes

LOINC for Human Prescription Drug and Biological Product Labeling¹

Table 1: HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS PLR FORMAT PRESCRIBING INFORMATION*		
Full Prescribing Information		
LOINC Code	LOINC Name	Section/Subsection Name as Per 21 CFR 201.56(d) and 201.57(c) or by Guidance
34066-1	BOXED WARNING SECTION	BOXED WARNING section
34067-9	INDICATIONS & USAGE SECTION	1 INDICATIONS AND USAGE section
34068-7	DOSAGE & ADMINISTRATION SECTION	2 DOSAGE AND ADMINISTRATION section
43678-2	DOSAGE FORMS & STRENGTHS SECTION	3 DOSAGE FORMS AND STRENGTHS section
34070-3	CONTRAINDICATIONS SECTION	4 CONTRAINDICATIONS section
43685-7	WARNINGS AND PRECAUTIONS SECTION	5 WARNINGS AND PRECAUTIONS section
34084-4	ADVERSE REACTIONS SECTION	6 ADVERSE REACTIONS section
90374-0	CLINICAL TRIALS EXPERIENCE SECTION	6.1 Clinical Trials Experience subsection
88830-5	IMMUNOGENICITY	Immunogenicity subsection
90375-7	POSTMARKETING EXPERIENCE SECTION	Postmarketing Experience subsection
34073-7	DRUG INTERACTIONS SECTION	7 DRUG INTERACTIONS section
43684-0	USE IN SPECIFIC POPULATIONS SECTION	8 USE IN SPECIFIC POPULATIONS section
42228-7	PREGNANCY SECTION	8.1 Pregnancy subsection

LOINC = Logical Observation Identifiers Names and Codes

Available on the *Selection of Appropriate SPL Codes for Human Prescription Drug Labeling* webpage at <https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/selection-appropriate-spl-codes-human-prescription-drug-labeling>

Challenge Question #1

The last FDA-approved labeling and “current” labeling [*labeling most recently submitted by applicants to FDA’s electronic system*] (choose the most accurate answer):

- A. Both appear on FDALabel
- B. Both appear on DailyMed
- C. May differ because of major labeling changes (e.g., adding a new dosage regimen)
- D. May differ because of minor labeling changes (e.g., changing the name and address of the distributor)

Challenge Question #1

The last FDA-approved labeling and “current” labeling [*labeling most recently submitted by applicants to FDA’s electronic system*] (choose the most accurate answer):

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- B. Both appear on DailyMed
- C. May differ because of major labeling changes (e.g., adding a new dosage regimen)
- D. May differ because of minor labeling changes (e.g., changing the name and address of the distributor)

Challenge Question #2

FDA's Labeling Resources for Human Prescription Drugs

seven webpages contain the following resources:

(select all that apply)

- A. Examples of product titles in the Highlights of Prescribing Information
- B. Established Pharmacologic Class Text Phrases for the Highlights of Prescribing Information
- C. Labeling resources specific for generic drugs and biological products
- D. Searchable labeling databases

Challenge Question #2

FDA's Labeling Resources for Human Prescription Drugs

seven webpages contain the following resources:

(select all that apply)

- A. Examples of product titles in the Highlights of Prescribing Information
- B. Established Pharmacologic Class Text Phrases for the Highlights of Prescribing Information
- C. Labeling resources specific for generic drugs and biological products
- D. Searchable labeling databases

Challenge Question #3

Sample Prescribing Information Template on the Prescribing Information Resources webpage:

- A. Contains all the required elements to develop a Prescribing Information
- B. May be used to develop labeling for an upcoming labeling supplement submission
- C. Is required to be used for labeling submissions for original NDAs and BLAs (not for supplements)
- D. None of the above

Challenge Question #3

Sample Prescribing Information Template on the Prescribing Information Resources webpage:

- A. Contains all the required elements to develop a Prescribing Information
- B. May be used to develop labeling for an upcoming labeling supplement submission
- C. Is required to be used for labeling submissions for original NDAs and BLAs (not for supplements)
- D. None of the above

Closing Thoughts



FDA dedicated to providing, maintaining, and updating labeling resources for human prescription drugs

Questions?

Eric Brodsky

Associate Director, Labeling Policy Team
Office of New Drug Policy, Office of New Drugs
CDER | US FDA



U.S. FOOD & DRUG
ADMINISTRATION

Extra Slides

Prescription Drug Labeling Guidances Published in the Last Year (February 2022 to January 2023)



Recently Published Labeling Guidances¹ (1 of 3)

- (Draft) Assessment of Pressor Effects of Drugs (February 2022)
- (Draft) Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling (February 2022)
- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (May 2022)
- Assessing the Effects of Food on Drugs in INDs and NDAs - Clinical Pharmacology Considerations (June 2022)

Recently Published Labeling Guidances¹ (2 of 3)

- Instructions for Use - Patient Labeling for Human Prescription Drug and Biological Products - Content and Format (July 2022)
- (Draft) Human Prescription Drug and Biological Products — Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers — “Dose Banding” (July 2022)
- (Draft) Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over the-Counter and Prescription Drug Products (September 2022)
- (Draft) Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials (October 2022)



Recently Published Labeling Guidances¹ (3 of 3)

- Cross Labeling Oncology Drugs in Combination Regimens (November 2022)
- (Draft) Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations (December 2022)
- (Revised Draft) Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products - Content and Format (January 2023)

Future Draft Labeling Guidances and Future Finalization of Draft Labeling Guidances

Notable Labeling Draft Guidances on CDER's Guidance Agenda¹



- Repackagers and Relabelers of Human Drugs: Labeling; Registration and Listing, Safety Reporting, Supply Chain Security, and Good Manufacturing Practice (Draft)
- Labeling for Biosimilar Products and Interchangeable Biosimilar (Revised Draft)
- Combined Hormonal Contraceptives for Prevention of Pregnancy — Labeling for Health Care Providers and Patients (Revised Draft)
- Regulatory Considerations and Drug Labeling Recommendations for Prescription Drug Use-Related Software for Combination Products (Draft)

Notable Labeling Draft Guidances We Are Working to Finalize¹



Pregnancy, Lactation, and Females and Males of Reproductive Potential: Labeling for Human Prescription Drug and Biological Products

Challenge Question #4



Labeling on Drugs@FDA and FDALabel have the following in common:

- A. Contains most up-to-date labeling submitted to FDA
- B. Almost always includes carton and container labeling
- C. Includes historically approved labeling
- D. Almost always includes generic drug labeling
- E. None of the above