



Prescription Drug Labeling Updates

Eric Brodsky

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

Regulatory Education for Industry Annual Conference 2022

Learning Objectives



- Understand the status of required and voluntary Physician Labeling Rule (PLR) conversions
- Provide an overview of key recommendations in recently published labeling guidances
- Learn about new prescription drug labeling resources
 - Distinguish between labeling databases (i.e., Drugs@FDA, DailyMed, and FDALabel)



Physician Labeling Rule (PLR) Conversions

Prescribing Information



“Old” Format¹ Labeling Sections

1979

BOXED WARNING
DESCRIPTION
CLINICAL PHARMACOLOGY
INDICATIONS AND USAGE
CONTRAINDICATIONS
WARNINGS
PRECAUTIONS
ADVERSE REACTIONS
DRUG ABUSE AND DEPENDENCE
OVERDOSAGE
DOSAGE AND ADMINISTRATION
HOW SUPPLIED



PLR Format ² (Full Prescribing Information Sections)	
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	
8 USE IN SPECIFIC POPULATIONS	2006
8.1 Pregnancy	
8.2 Lactation	
8.3 Females and Males of Reproductive Potential	
8.4 Pediatric Use	
8.5 Geriatric Use	
9 DRUG ABUSE AND DEPENDENCE	
9.1 Controlled Substance	
9.2 Abuse	
9.3 Dependence	
10 OVERDOSAGE	
11 DESCRIPTION	
12 CLINICAL PHARMACOLOGY	
12.1 Mechanism of Action	
12.2 Pharmacodynamics	
12.3 Pharmacokinetics	
13 NONCLINICAL TOXICOLOGY	
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility	
13.2 Animal Toxicology and/or Pharmacology	
14 CLINICAL STUDIES	
15 REFERENCES	
16 HOW SUPPLIED/STORAGE AND HANDLING	
17 PATIENT COUNSELING INFORMATION	

¹“Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs”; 44 FR 37434 (June 26, 1979), 21 CFR 201.80

²“Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,”; 71 FR 392221 (January 24, 2006), CFR 201.56(d) and 21 CFR 201.57

CDER-Regulated NDA/BLA Prescribing Information with PLR Format¹



Month/Year	Proportion of CDER PI With PLR Format (NDAs/BLAs only)
January 2014	~ 45%
January 2016	~ 56%
January 2017	~ 61%
January 2018	~ 63%
March 2019	~ 66%
August 2020	~ 70%
April 2022	~ 71%

NDAs = New Drug Applications; BLAs = Biologics License Applications; PI = Prescribing Information;

¹ Analyses based on Structured Product Labeling (SPL) - generally only includes marketed products; excludes labeling from repackagers, relabelers, and authorized generics

CDER NDA/BLA Labeling in PLR Format (Required and Voluntary PLR Conversions)¹



	NDA, BLA, and/or ESs	Proportion of Labeling with PLR Format
Required	NDA/BLA/ESs approved on or after 6/30/2001	100%
Voluntary	NDA/BLAs approved from 1938 to 6/29/2001 (without an ES approved on or after 6/30/2001)	~26%

In 2013 ~71%
in PLR format

In 2012 ~1%
in PLR format

CDER has approved 320 voluntary PLR conversions!

ESs = efficacy supplements
¹ Data in table as of April 2022.

CDER Encourages Submission of Voluntary PLR Conversions



- “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”¹
- “FDA **strongly encourages** all applicants to voluntarily convert the labeling of their drug products to the PLR format, regardless of the date of approval”¹

320 voluntary PLR conversions approved to date in CDER!

¹ 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)



Recently Published Notable Labeling Guidances

Pediatric Information Incorporated Into Human Prescription Drug and Biological Product Labeling 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)**

**March 2019
Labeling**



Full Prescribing Information Sections and Subsections¹

BOXED WARNING
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
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12.2 Pharmacodynamics
12.3 Pharmacokinetics
12.4 Microbiology
12.5 Pharmacogenomics
12.6 Immunogenicity

¹ Several required sections (i.e., Sections 13, 14, 15, 16, and 17) are not shown for presentation purposes

Four Scenarios for Including Pediatric Use Information in Labeling



- Evidence supports safety and effectiveness of drug for a pediatric indication (**Scenario 1**)
- Evidence does **not** support safety and effectiveness of a drug for a pediatric indication:
 - Results of pediatric studies were negative or inconclusive (**Scenario 2**)
 - No evidence available - studies not conducted or are ongoing (**Scenario 3**)
 - Drug is contraindicated (**Scenario 4**)

Ensure a Consistent Message in the Labeling About the Approved Pediatric Age Groups



1 INDICATIONS AND USAGE

DRUG X is indicated for the treatment of Indication Y in adults and pediatric patients **aged 6 years and older**.

8 USE IN SPECIFIC POPULATIONS

...

8.4 Pediatric Use

The safety and effectiveness of DRUG X (for Indication Y) have **been established** in pediatric patients **aged 6 years and older**.

The safety and effectiveness of DRUG X (for Indication Y) have **not been established** in pediatric patients **younger than 6 years old**.

Pediatric Use Subsection: “Pediatric Use Statements”¹



- Generally, “pediatric use statements” are required in the *Pediatric Use* subsection²
- Include “pediatric use statements” for all indications in adult and pediatric patients and all pediatric populations

¹ Pediatric use statement is a statement explaining whether the safety and effectiveness of a drug for a specific use or indication have (or have not) been established in the entire pediatric population or in a pediatric subpopulation

² 21 CFR 201.57(c)(9)(iv)

Pediatric Use Subsection: Examples of “Pediatric Use Statements”



- “The safety and effectiveness of DRUG X (for Indication Y) have been established in pediatric patients aged 6 years and older.” ✓
- “The safety and effectiveness of DRUG X have not been established in pediatric patients (for Indication Y).” ✓
- “DRUG X is contraindicated in pediatric patients ...”¹ ✓
- ~~“DRUG X was studied in 98 pediatric patients 6 years old and older with Disease A”~~ ✗

¹ For a contraindication in pediatric patients, an alternative recommended pediatric use statement is shown (instead of stating that safety and effectiveness have not been established in pediatric patients) [see 21 CFR 201.57(c)(9)(iv)(G)]



Geriatric Information in Human Prescription Drug and Biological Product Labeling 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.

Full Prescribing Information Sections and Subsections¹

For the purposes of prescription drug labeling, the geriatric population is defined as patients 65 years of age and older²

¹ Several required sections (i.e., Sections 13, 14, 15, 16, and 17) are not shown for presentation purposes

² 21 CFR 201.57(c)(9)(v)(A)

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Geriatric Exposure Data Examples in *Geriatric Use* Subsection¹



- “Of the total number of DRUG X-treated patients in these studies, n (x%) were 65 to 74 years of age, n (y%) were 75 to 84 years of age, and n (z%) were 85 years of age and older.”
- “Of the total number of DRUG X-treated patients in clinical studies for Disease A, n (y%) were 65 to 74 years of age, and n (z%) were 75 years of age and older [see *Clinical Studies (14)*].”

¹ The *Geriatric Use* subsection can also include information on the total number of geriatric patients in the clinical studies. For example: “There were n patients 65 years of age and older in the clinical studies for Disease A, Disease B, and Disease C [see *Clinical Studies (14.1, 14.2, 14.3)*].”

Develop *Geriatric Use* Subsection Based on Sufficiency of Information To Detect Differences in Safety and/or Effectiveness Between Geriatric and Younger Adult Patients

- ***Insufficient*** information to detect differences in safety and/or effectiveness between geriatric and younger adult patients
- ***Sufficient*** information to detect differences in safety and/or effectiveness between geriatric and younger adult patients and:
 - Differences observed
 - No differences observed

Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products — Content and Format

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Iris Masucci, 301-796-2500, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

<https://www.fda.gov/media/128443/download>





Full Prescribing Information Sections and Subsections¹

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¹ Several required sections (i.e., Sections 13, 14, 15, 16, and 17) are not shown for presentation purposes

Controlled Substance Subsection¹ (scheduled drug)



If a drug is **scheduled** under the Controlled Substances Act (CSA),² the *Controlled Substance* subsection (subsection 9.1) must state that the drug is a controlled substance and identify the schedule. For example:

9 ABUSE AND DEPENDENCE

9.1 Controlled Substance

DRUG-X contains active ingredient-Y, a Schedule II controlled substance.

¹ 21 CFR 201.57(c)(10) and draft guidance for industry: *Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* (July 2019) When final this guidance, will represent the FDA's current thinking on this topic. Available at <https://www.fda.gov/media/128443/download>.

² The list of all scheduled substances can be found at 21 CFR part 1308 (see <https://www.ecfr.gov/current/title-21/chapter-II/part-1308>)

Controlled Substance Subsection¹ **(scheduled drug)**



If a drug is not scheduled but there is information about abuse, dependence, or tolerance in the DRUG ABUSE AND DEPENDENCE subsection,² the *Controlled Substance* subsection should state that the drug is not controlled. For example:

9 ABUSE AND DEPENDENCE

9.1 Controlled Substance

DRUG-X contains active ingredient-Y, which is not a controlled substance.

¹ 21 CFR 201.57(c)(10) and draft guidance for industry: *Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* (July 2019) When final this guidance, will represent the FDA's current thinking on this topic. Available at <https://www.fda.gov/media/128443/download>.

Definitions: *Abuse* Subsection¹



- **Abuse** is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects.
- **Misuse** is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed.
- **Drug addiction** is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence.

¹ See draft guidance for industry: [Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format](#) (July 2019)
When final this guidance, will represent the FDA's current thinking on this topic.

Abuse Subsection in the DRUG ABUSE AND DEPENDENCE Section¹



3. Must identify susceptible patient populations

9 ABUSE AND DEPENDENCE

9.2 Abuse

Abuse is the intentional, non-therapeutic use of a drug, even once, for its desirable psychological or physiological effects. Signs and symptoms of central nervous system stimulant abuse include the following: tachycardia, tachypnea, hypertension, sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, tremors, and vomiting. Patients at high risk of DRUG-X abuse include those with a history of prolonged use of products containing active ingredient-Y and those who use DRUG-X in combination with other abused drugs.

¹ 21 CFR 201.57(c)(10) and draft guidance for industry: [Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format](#) (July 2019) When final this guidance, will represent the FDA's current thinking on this topic.

Definitions: *Dependence* Subsection¹



- **Physical dependence** is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.
- **Tolerance** is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

¹ See draft guidance for industry: [Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format](#) (July 2019)
When final this guidance, will represent the FDA's current thinking on this topic.

Dependence Subsection¹

3. Must include principles of treating or mitigating effects of abrupt withdrawal

9 ABUSE AND DEPENDENCE

...

9.3 Dependence

Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. If DRUG-X is abruptly discontinued in a physically dependent patient, a withdrawal syndrome may occur, typically characterized by restlessness, rhinorrhea, perspiration, chills, myalgia, and mydriasis. **Discontinue DRUG-X by gradual taper over a 2-week period to reduce the risk of symptoms of withdrawal [see *Dosage and Administration (2.x)*].**

¹ 21 CFR 201.57(c)(10) and draft guidance for industry: [Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format](#) (July 2019) When final this guidance, will represent the FDA's current thinking on this topic.

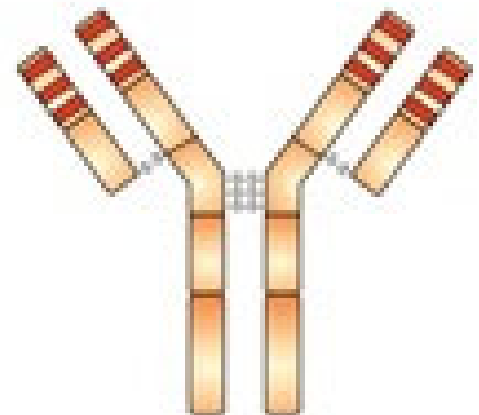
Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling — Content and Format Guidance for Industry

DRAFT GUIDANCE

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HUMAN

Historical Placement of Immunogenicity Information in Labeling¹



Review of 71 therapeutic proteins and drug products approved by CDER during a recent five-year period (2014-2018) with immunogenicity information in labeling

- 98% of labeling included immunogenicity information in the ADVERSE REACTIONS section
- 30% of labeling did not include any statements regarding the immunogenicity impact on safety or effectiveness²

¹ Guinn, D., Madabushi, R., Wang, Y., Brodsky, E., Zineh, I., and Maxfield, K. *Communicating Immunogenicity-Associated Risk in Current U.S. FDA Prescription Drug Labeling: A Systematic Evaluation*. Ther Innov Regul Sci (2020).

<https://doi.org/10.1007/s43441-020-00161-z>

² Categories of impact on safety or effectiveness include observed or potential impact, unknown impact, or no observed impact ²⁸


Immunogenicity Labeling Draft Guidance



Presenting immunogenicity information in a consistent manner will enable health care practitioners to more easily identify and differentiate between:



Products associated with clinically significant immunogenicity



Products whose ADA are not associated with clinically significant effects on PK, PD, safety, or effectiveness

FDA Recommends a Dedicated *Immunogenicity* Subsection

Reserve other sections for description of only clinically significant effects of immunogenicity

Allows for a consistent location for summarizing immunogenicity data and its PK and PD effects

BOXED WARNING
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12.6 Immunogenicity
13 NONCLINICAL TOXICOLOGY
14 CLINICAL STUDIES
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION



Future Draft Labeling Guidances and Finalization of Draft Labeling Guidances

Notable Labeling Draft Guidances on CDER's Guidance Agenda¹



- Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format (Revised Draft)
- Labeling for Biosimilar Products (Revised Draft)
- Human Prescription Drugs and Biological Products – Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers – “Dose Banding” (Draft)

Notable Labeling Draft Guidances We Are Working to Finalize¹



- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors
- Pregnancy, Lactation, and Females and Males of Reproductive Potential: Labeling for Human Prescription Drug and Biological Products
- Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products — Content and Format

FDA's Labeling Resources for Human Prescription Drugs

<u>Prescribing Information Resources</u> For industry	<u>Patient Labeling Resources</u> For industry
<u>Carton and Container Labeling Resources</u> For industry	<u>Selection of Appropriate SPL Codes for Human Prescription Drug Labeling</u> For SPL drug developers
<u>Generic Drugs - Specific Labeling Resources</u> For industry	<u>Biological Products - Specific Labeling Resources</u> For industry
<u>FAQs About Labeling for Prescription Medicines</u> For healthcare professionals, patients, and caregivers	<u>Contact Information</u> For specific application or supplement questions or for general questions about human prescription drug labeling


FDA's Labeling Resources for Human Prescription Drugs

for Industry

 Share

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Searchable Labeling Databases



Searchable Product Databases



Imported-Drug Specific Labeling Resources



Resources for Promotional Labeling and Other FDA-Regulated Products



Prescribing Information Resources

for Industry



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	▼

Drugs@FDA¹



FDA U.S. FOOD & DRUG ADMINISTRATION

Home > Drug Databases > Drugs@FDA

Drugs@FDA: FDA-Approved Drugs

f SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

Search by Drug Name, Active Ingredient, or Application Number*

Enter at least 3 characters [Search] [Clear]

¹ FDA's Drugs@FDA available at www.fda.gov/drugsatfda

Drugs@FDA FAQs¹



Drugs@FDA Frequently Asked Questions



1. [What are the main uses of Drugs@FDA?](#)
2. [What products are in Drugs@FDA?](#)
3. [What products are *not* in Drugs@FDA?](#)
4. [Why doesn't Drugs@FDA include dietary supplements?](#)
5. [What information is typically available for a product in Drugs@FDA?](#)
6. [How can I search Drugs@FDA?](#)
7. [How do searches work in Drugs@FDA?](#)
8. [How can I find out if a generic drug is available for a brand-name drug that is approved under a New Drug Application \(NDA\)?](#)
9. [How often do you update Drugs@FDA?](#)
10. [Where does the information in Drugs@FDA come from?](#)
11. [How does Drugs@FDA compare with the *Orange Book*?](#)
12. [How does Drugs@FDA compare with the *Purple Book*?](#)
13. [How are BLAs that were formerly approved under an NDA and subsequently deemed a BLA on March 23, 2020, displayed on drugs@FDA?](#)
14. [What do the submission classification codes for NDAs and review designation codes stand for?](#)
15. [Can I get a copy of the Drugs@FDA database?](#)
16. [How can I get further assistance?](#)

¹ FDA's Drugs@FDA FAQs available at <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page>

DailyMed¹



NIH NATIONAL LIBRARY OF MEDICINE REPORT ADVERSE EVENTS | RECALLS

ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS

Enter drug, NDC code, drug class, or Set ID

MORE WAYS TO SEARCH: [ADVANCED SEARCH](#) [BROWSE DRUG CLASSES](#) [LABELING ARCHIVES](#)

The DailyMed database contains **142816** 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.

SHARE

NEWS

[DailyMed Announcements](#)

Posted: September 15, 2021

The RxImage API will cease operation on December 31, 2021.

FDA RESOURCES

[SPL, Other Prescription Drug Labeling Resources, and Guidances](#)

- [FDA's Structured Product Labeling Resources](#)
- [FDA's Prescription Drug Labeling Resources](#)

¹ Accessed on May 14, 2022. From the National Library of Medicine at the National Institute of Health. See <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

FDALabel: Full-Text Search of Labeling for Human Drugs¹

The screenshot displays the FDALabel search interface. At the top, a dark navigation bar contains the following links: **FDALabel**, **Home**, **About**, **Database Updates**, **Disclaimer**, and **Contact**.

The main content area is divided into four sections, each separated by an ampersand (&):

- Labeling Types:** Includes a "Choose one or more:" section with links for [Animal Rx](#), [Animal OTC](#), [Human Rx](#), [Human OTC](#), [Medical Device](#), [Medical Device Rx](#), and [Vaccine](#). Below this is a dropdown menu labeled "or choose one or more from the list:".
- Application Types or Marketing Categories:** Includes a "Choose one or more:" section with links for [ANDA](#), [BLA](#), [NDA](#), [NDA Authorized Generic](#), [OTC Monograph Final](#), and [OTC Monograph Not Final](#). Below this is a dropdown menu labeled "or choose one or more from the list:".
- Product Name(s):** Features a dropdown menu for "Trade or generic/proper name", a dropdown menu for "contains", and a text input field labeled "Enter any part(s) of product name".
- Labeling Full Text Search:** Includes a dropdown menu for "Simple Search" and a text input field with the placeholder "Enter text (e.g., search for NAUSEA OR VOMITING retrieves labeling containing the phrase 'nausea or vomiting')".

At the bottom of the search section, there are two explanatory lines:
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 FDA's FDALabel. See <https://nctr-crs.fda.gov/fdalabel/ui/search>

Labeling Section(s) Search in FDALabel¹



Additional Fields

Product Title (123154 labeling)

Initial U.S. Approval [4 Digit Year] (19411 labeling)

Full Prescribing Information (PLR & Non-PLR)

BOXED WARNING (16037 labeling)

1 INDICATIONS AND USAGE (134291 labeling)

2 DOSAGE AND ADMINISTRATION (134060 labeling)

3 DOSAGE FORMS AND STRENGTHS (21331 labeling)

4 CONTRAINDICATIONS (43837 labeling)

5 WARNINGS AND PRECAUTIONS (23509 labeling)

6 ADVERSE REACTIONS (44956 labeling)

7 DRUG INTERACTIONS (32879 labeling)

8 USE IN SPECIFIC POPULATIONS (20976 labeling)

8.1 Pregnancy (33318 labeling)

8.2 Lactation (6873 labeling)

8.2 Labor and Delivery (8464 labeling)

8.3 Females and Males of Reproductive Potential (2363 labeling)

8.3 Nursing Mothers (23469 labeling)

8.4 Pediatric Use (33292 labeling)

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	Structured Product Labeling	Structured Product Labeling
Products include			
CDER-approved prescription and nonprescription human drugs and biologics (under NDAs, ANDAs, and BLAs)	Yes (generic labeling rarely present)	Yes	Yes
CDER-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 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

Challenge Question #1



FDA recommends all applicants of NDAs/BLAs (labeling is in “old” format), voluntarily PLR convert their labeling in the following situation(s):

- A. Only when there are known medication errors
- B. Only when there is high drug use
- C. When there are known medication errors, high risk for consequences of medication errors, or high drug use
- D. Only when the drug was approved on or after June 30, 2001 (effective date of the Physician Labeling Rule)

Challenge Question #1



FDA recommends all applicants of NDAs/BLAs (labeling is in “old” format), voluntarily PLR convert their labeling in the following situation(s):

- A. Only when there are known medication errors
- B. Only when there is high drug use
- C. When there are known medication errors, high risk for consequences of medication errors, or high drug use
- D. Only when the drug was approved on or after June 30, 2001 (effective date of the Physician Labeling Rule)

Challenge Question #2



If a drug is approved for Indication-A in adults and pediatric patients, Indication-B in adults only, and Indication-C in pediatric patients only; include a pediatric use statement in the *Pediatric Use* subsection for:

- A. Indication-A
- B. Indication-B
- C. Indication-C
- D. Indication-A, Indication-B, and Indication-C



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- B. Indication-B
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Challenge Question #3



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

Challenge Question #3



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Closing Thoughts



- FDA strongly encourages NDA/BLA applicants to voluntarily convert the labeling of their drugs to the PLR format, if applicable
- When developing prescription drug labeling, refer to FDA's updated prescription drug labeling resources¹ (e.g., newly published FDA labeling guidances)



Questions?

Eric Brodsky

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

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