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
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

<table>
<thead>
<tr>
<th>Section</th>
<th>1979</th>
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</thead>
<tbody>
<tr>
<td>BOXED WARNING</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION</td>
<td></td>
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<tr>
<td>CLINICAL PHARMACOLOGY</td>
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<tr>
<td>INDICATIONS AND USAGE</td>
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<tr>
<td>CONTRAINDICATIONS</td>
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<tr>
<td>WARNINGS</td>
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<tr>
<td>PRECAUTIONS</td>
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<tr>
<td>ADVERSE REACTIONS</td>
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<tr>
<td>DRUG ABUSE AND DEPENDENCE</td>
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<tr>
<td>OVERDOSAGE</td>
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<tr>
<td>DOSAGE AND ADMINISTRATION</td>
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<tr>
<td>HOW SUPPLIED</td>
<td></td>
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</tbody>
</table>

PLR Format² (Full Prescribing Information Sections)

<table>
<thead>
<tr>
<th>Section</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>BOXED WARNING</td>
<td></td>
</tr>
<tr>
<td>1 INDICATIONS AND USAGE</td>
<td></td>
</tr>
<tr>
<td>2 DOSAGE AND ADMINISTRATION</td>
<td></td>
</tr>
<tr>
<td>3 DOSAGE FORMS AND STRENGTHS</td>
<td></td>
</tr>
<tr>
<td>4 CONTRAINDICATIONS</td>
<td></td>
</tr>
<tr>
<td>5 WARNINGS AND PRECAUTIONS</td>
<td></td>
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<tr>
<td>6 ADVERSE REACTIONS</td>
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</tr>
<tr>
<td>7 DRUG INTERACTIONS</td>
<td></td>
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<tr>
<td>8 USE IN SPECIFIC POPULATIONS</td>
<td></td>
</tr>
<tr>
<td>8.1 Pregnancy</td>
<td></td>
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<tr>
<td>8.2 Lactation</td>
<td></td>
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<tr>
<td>8.3 Females and Males of Reproductive Potential</td>
<td></td>
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<tr>
<td>8.4 Pediatric Use</td>
<td></td>
</tr>
<tr>
<td>8.5 Geriatric Use</td>
<td></td>
</tr>
<tr>
<td>9 DRUG ABUSE AND DEPENDENCE</td>
<td></td>
</tr>
<tr>
<td>9.1 Controlled Substance</td>
<td></td>
</tr>
<tr>
<td>9.2 Abuse</td>
<td></td>
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<tr>
<td>9.3 Dependence</td>
<td></td>
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<tr>
<td>10 OVERDOSAGE</td>
<td></td>
</tr>
<tr>
<td>11 DESCRIPTION</td>
<td></td>
</tr>
<tr>
<td>12 CLINICAL PHARMACOLOGY</td>
<td></td>
</tr>
<tr>
<td>12.1 Mechanism of Action</td>
<td></td>
</tr>
<tr>
<td>12.2 Pharmacodynamics</td>
<td></td>
</tr>
<tr>
<td>12.3 Pharmacokinetics</td>
<td></td>
</tr>
<tr>
<td>13 NONCLINICAL TOXICOLOGY</td>
<td></td>
</tr>
<tr>
<td>13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility</td>
<td></td>
</tr>
<tr>
<td>13.2 Animal Toxicology and/or Pharmacology</td>
<td></td>
</tr>
<tr>
<td>14 CLINICAL STUDIES</td>
<td></td>
</tr>
<tr>
<td>15 REFERENCES</td>
<td></td>
</tr>
<tr>
<td>16 HOW SUPPLIED/STORAGE AND HANDLING</td>
<td></td>
</tr>
<tr>
<td>17 PATIENT COUNSELING INFORMATION</td>
<td></td>
</tr>
</tbody>
</table>

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 Format

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

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 repackers, relabelers, and authorized generics.
### CDER NDA/BLA Labeling in PLR Format (Required and Voluntary PLR Conversions)¹

<table>
<thead>
<tr>
<th></th>
<th>NDAs, BLAs, and/or ESs</th>
<th>Proportion of Labeling with PLR Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required</td>
<td>NDAs/BLAs/ESs approved on or after <strong>6/30/2001</strong></td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Voluntary</td>
<td>NDAs/BLAs approved from <strong>1938 to 6/29/2001</strong> (without an ES approved on or after 6/30/2001)</td>
<td><strong>~26%</strong></td>
</tr>
</tbody>
</table>

CDER has approved 320 voluntary PLR conversions!

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**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”

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

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

https://www.fda.gov/media/84949/download
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)

[www.fda.gov](http://www.fda.gov)
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.
For the purposes of prescription drug labeling, the geriatric population is defined as patients 65 years of age and older.

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)
Geriatric Exposure Data Examples in Geriatric Use Subsection

- “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
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 Subsection

- **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.

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1 See draft guidance for industry: [Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format](https://www.fda.gov/drugs/guidance-compliance-information/guidances) (July 2019) When final this guidance, will represent the FDA’s current thinking on this topic.
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.

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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](https://www.fda.gov/规制规定/Labeling) (July 2019) When final this guidance, will represent the FDA’s current thinking on this topic.
Definitions: Dependence Subsection

- **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](https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm) (July 2019)

When final this guidance, will represent the FDA’s current thinking on this topic.
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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See https://www.fda.gov/media/155871/download
Historical Placement of Immunogenicity Information in Labeling

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 effectiveness


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

ADA = antidrug antibodies; PK = pharmacokinetic; PD = pharmacodynamic
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
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)

¹ See CDER guidance agenda at https://www.fda.gov/media/134778/download
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

¹ We are actively considering the comments to these draft guidances and will work to finalize them as appropriate.
FDA’s Labeling Resources for Prescription Drugs
# FDA’s Labeling Resources for Human Prescription Drugs

<table>
<thead>
<tr>
<th>Prescribing Information Resources</th>
<th>Patient Labeling Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>For industry</td>
<td>For industry</td>
</tr>
</tbody>
</table>

**Carton and Container Labeling Resources**
For industry

**Selection of Appropriate SPL Codes for Human Prescription Drug Labeling**
For SPL drug developers

**Generic Drugs - Specific Labeling Resources**
For industry

**Biological Products - Specific Labeling Resources**
For industry

**FAQs About Labeling for Prescription Medicines**
For healthcare professionals, patients, and caregivers

**Contact Information**
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

1. Searchable Labeling Databases
2. Searchable Product Databases
3. Imported-Drug Specific Labeling Resources
4. Resources for Promotional Labeling and Other FDA-Regulated Products

www.fda.gov

# Prescribing Information Resources for Industry

1. **Highlights of Prescribing Information**
2. **Boxed Warning**
3. **1 Indications and Usage**
4. **2 Dosage and Administration**
5. **3 Dosage Forms and Strengths**
6. **4 Contraindications**
7. **5 Warnings and Precautions**
8. **6 Adverse Reactions**
9. **7 Drug Interactions**
Drugs@FDA: FDA-Approved Drugs

Search by Drug Name, Active Ingredient, or Application Number

Enter at least 3 characters

Search Clear

FDA's Drugs@FDA available at www.fda.gov/drugsatfda
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
FDALabel: Full-Text Search of Labeling for Human Drugs

FDALabel.

See https://nctr-crs.fda.gov/fdalabel/ui/search
Labeling Section(s) Search in FDALabel

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

### Source of data
- **Drugs@FDA**: FDA-approved labeling
- **DailyMed**: Current labeling submitted by firms
- **FDALabel**: Current labeling submitted by firms

### Format
- **Drugs@FDA**: PDF
- **DailyMed**: Structured Product Labeling
- **FDALabel**: Structured Product Labeling

### Products include

<table>
<thead>
<tr>
<th>Category</th>
<th>Drugs@FDA</th>
<th>DailyMed</th>
<th>FDALabel</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDER-approved prescription and nonprescription human drugs and biologics</td>
<td>Yes (generic labeling rarely present)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>(under NDAs, ANDAs, and BLAs)</td>
<td></td>
<td></td>
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<tr>
<td>CBER-approved human drugs and biologics (e.g., vaccines, gene-therapy products)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Unapproved human drugs (e.g., homeopathics)</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
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## Labeling Databases (2 of 2)

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

### Search features

<table>
<thead>
<tr>
<th>Search features</th>
<th>Drugs@FDA</th>
<th>DailyMed</th>
<th>FDALabel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search by application number or drug name</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Search by drug class, NDC number, and/or by active or inactive ingredient</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Search by labeling section</td>
<td>No</td>
<td>Somewhat</td>
<td>Yes</td>
</tr>
<tr>
<td>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</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
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)
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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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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
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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).

¹ https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources