FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
SMALL BUSINESS AND INDUSTRY ASSISTANCE

CDER's Review of the Prescribing Information

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May 30, 2019

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.
- Reference to any marketed products is for illustrative purposes only and does not constitute endorsement by the FDA.

Learning Objectives

Understand:

- Regulatory requirements for the Prescribing Information
- Roles and responsibilities of select CDER staff in the review of the Prescribing Information
- Importance of clear, concise, and applicable information in the Prescribing Information
- Content of recently published labeling guidances
- Where to find resources for developing the Prescribing Information

Labeling Review Goals

Ensure that drug* labeling

- Meets statutory/regulatory requirements and is appropriately consistent with guidance recommendations
- Is clinically meaningful and scientifically accurate
- Is concise and clear for healthcare providers

Prescription drug labeling is FDA's primary tool for communicating drug information

* The term "drug" as used in this presentation refers to both human prescription drug and biological products.

Words Are Powerful!

- Marie Antoinette (1755-1793)
- Queen of France before French Revolution

- Supposedly said: (English translation)“**Let them eat cake!”**

- Original French phrase: Qu'ils mangent de la brioche” : **“Let them eat brioche!”**

Words Can Be Misinterpreted!

Punctuations can potentially save lives!

"Let's eat, grandma."

versus

"Let's eat grandma."

Prescribing Information

- Must contain a summary of the essential information needed for the safe and effective use of the drug
- Must be informative and accurate
- Must not be promotional in tone
- Must not be false or misleading
- Must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading
- Must be based whenever possible on human data

(21CFR 201.56(a))

Sections of the Prescribing Information

Highlights of Prescribing Information (Highlights)

Table of Contents (Contents)

Full Prescribing Information (FPI)

Sections/ Subsections of the Full 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
8 USE IN SPECIFIC POPULATIONS
- 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
- 12.4 Microbiology (designated by guidance)
- 12.5 Pharmacogenomics (designated by guidance)

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

*Required unless clearly inapplicable(21CFR 201.56(d)(1) and (4))

Contents

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed

Highlights

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NAME OF DRUG PRODUCT safely and effectively. See full prescribing information for NAME OF DRUG PRODUCT.

PROPRIETARY NAME (non-proprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: YYYY

WARNING: SUBJECT OF WARNING
See full prescribing information for complete boxed warning.

- **Text (5.1)**
- **Text (5.2)**

----------RECENT MAJOR CHANGES----------
Section title, Subsection Title (X.X) M/201Y
Section title, Subsection Title (X.X) M/201Y

----------INDICATIONS AND USAGE----------
PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for … (1)

----------DOSAGE AND ADMINISTRATION----------
- Text (2.1)
- Text (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Dosage form: strength(s) (3)

----------CONTRAINDICATIONS----------
- Text (4)
- Text (4)

----------WARNINGS AND PRECAUTIONS----------
- Text (5.x)
- Text (5.x)

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence > x%) are text (6)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Text (7)
- Text (7)

----------USE IN SPECIFIC POPULATIONS----------
- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/201Y

CDER's Review of the Prescribing Information is a Collaborative Process

CDER Prescribing Information Reviewers Include……

- Division/Office Director (includes Deputy): Signatory authority;
- Cross-Discipline Team Lead (CDTL): Oversees review to ensure labeling is clinically meaningful and scientifically accurate
- Regulatory Project Manager (RPM): Manages administrative functions; Performs format (Selected Requirements of Prescribing Information) review during filing period
- Associate Director for Labeling: Ensures entire labeling conforms with labeling regulations, statutory requirements, and applicable guidance recommendations

CDER Prescribing Information Reviewers Include…… (cont.)

- Clinical Reviewers
- Pharmacology/Toxicology Reviewers
- Clinical Pharmacology Reviewers
- Product Quality Reviewers
- Biostatistics Reviewers
- Clinical Microbiology Reviewers
- Risk Management Reviewers
- Medication Error and Prevention and Analysis Reviewers

Other Subject Matter Experts As Needed……

- Labeling Development Team (LDT) Reviewers: develop/implement labeling policy initiatives to promote consistency in and improve labeling review practices (across review divisions)
- Pediatric Reviewers
- Maternal Health Reviewers
- Prescription Drug Promotion Reviewers
- Controlled Substance Staff Reviewers
- Center for Devices and Radiological Health (CDRH) Reviewers

Prescribing Information Focused Review Example

Highlights: Product Title *

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (non-proprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: YYYY

WARNING: TITLE OF WARNING
See full prescribing information for complete boxed warning.

- **Text (4)**
- **Text (5.x)**

----------RECENT MAJOR CHANGES----------
Section Title, Subsection Title (x.x) M/201Y
Section Title, Subsection Title (x.x) M/201Y

----------INDICATIONS AND USAGE----------
PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for … (1)

Limitations of Use: Text (1)

----------DOSAGE AND ADMINISTRATION----------
- Text (2.x)
- Text (2.x)

----------DOSAGE FORMS AND STRENGTHS----------
Dosage form(s): strength(s) (3)

----------CONTRAINDICATIONS----------
- Text (4)
- Text (4)

----------WARNINGS AND PRECAUTIONS----------
- Text (5.x)
- Text (5.x)

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence > x%) are text (6.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Text (7.x)
- Text (7.x)

----------USE IN SPECIFIC POPULATIONS----------
- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/201Y

* 21 CFR 201.57(a)(2)

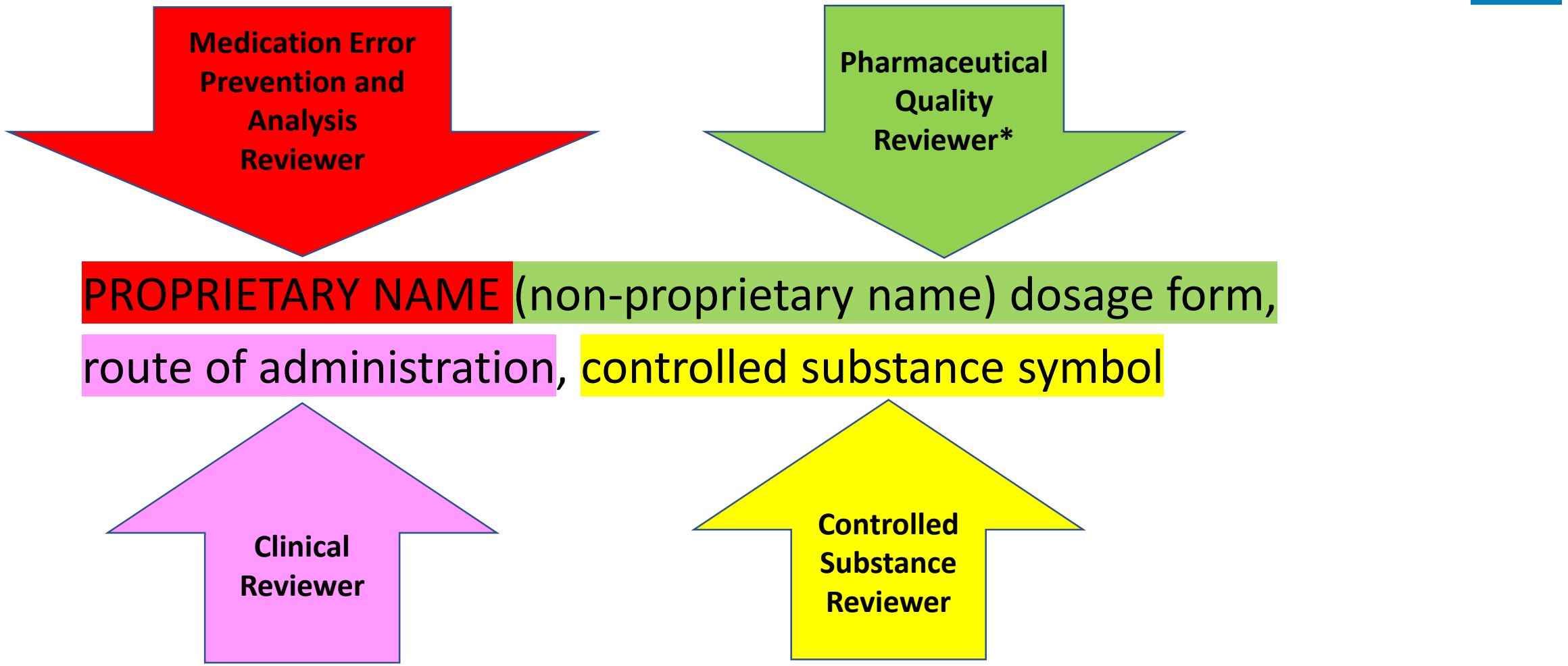
Product Title

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol

Example:

MYDRUG (drugoxide) tablets, for oral use, CV

Product Title Review Involves Several Disciplines



*For drug and biological products

Data From Some Sections Supports Recommendations in Other Sections

Efficacy Review: Clinical and Biostats Focused Review

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
9 DRUG ABUSE AND DEPENDENCE
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
13 NONCLINICAL TOXICOLOGY
14 CLINICAL STUDIES
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

Sections 1 and 2 Informed by Content of Section 14

CLINICAL STUDIES Section Informs Other Labeling Sections

Example 1

14 CLINICAL STUDIES	OTHER LABELING SECTIONS
14 CLINICAL STUDIES STUDY ABC enrolled adult patients with **metastatic small cell lung cancer (SCLC)** who had progressed **after receiving platinum-based chemotherapy and at least one other prior line of therapy…..**	**1 INDICATIONS and USAGE** **Drug-X is indicated** for the treatment of adult patients **with metastatic small cell lung cancer (SCLC)** with **progression after platinum-based chemotherapy and at least one other line of therapy** (Indications or uses must not be implied or suggested in other sections of the labeling -21CFR 201.57(c)(2)(iv) and (v))

Example 2

14 CLINICAL STUDIES	OTHER LABELING SECTIONS
14 CLINICAL STUDIES In Study DEF patients who received **DRUG-Y 20 mg orally once daily** showed improvement in Mayo scores compared to patients who received placebo at week 6 as shown in Table 1.	**2 DOSAGE AND ADMINISTRATION** The recommended dosage of **DRUG-Y is 20 mg orally once daily.** (Dosing regimens must not be implied or suggested in other sections of the labeling- 21CFR 201.57(c)(3)(ii))

How You Say It Matters As Much as What You Say

Text Should be Consistent with Applicable Guidance Recommendations

- INDICATIONS AND USAGE (include age groups in the Indication) [1]
  - Ex: *"DRUG-X is indicated for the treatment of adult and pediatric patients 12 years of age and older with moderate to severe plaque psoriasis."*
- CONTRAINDICATIONS (use term, "contraindicated" when describing)
  - Ex: *"Drug X is contraindicated in patients with condition Y."* [2]
- ADVERSE REACTIONS: (classify adverse reactions using meaningful and specific terms) [3]
  - Ex: Avoid terms such as, "infestations"

1. FDA draft Guidance: *Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products —Content and Format (when finalized this guidance will represent the FDA's current thinking)*
1. FDA Guidance: *Warnings and Precautions, Contraindications, and Boxed Warnings Sections of Labeling for Human Prescription Drug and Biological Products-Content and Format*
2. FDA Guidance: *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products-Content and Format*

Ensure Information is Clear; Concise; and Applicable

- Omit information that is not pertinent for healthcare providers to use the drug safely and effectively
  - Ex:*"Daily dosing and continued treatment are critical."*
- Use directive statements
  - Ex: *"Prepare and reconstitute DRUG-X as described in Table 1."*
- Omit clearly inapplicable content*
  - Ex: Omit the *Geriatric Use* subsection for a drug only approved for use in neonates

*21CFR 201.56(d)(4)

Format Review

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DRUG-X safely and effectively. See full prescribing information for DRUG-X.

DRUG-X (drugoxide) capsules, for oral use

Initial U.S. Approval: 2005

WARNING: EMBRYO-FETAL TOXICITY
See full prescribing information for complete boxed warning.

DRUG-X can cause embryo-fetal toxicity. Obtain pregnancy testing in females of reproductive potential before initiating treatment with DRUG-X. Advise females of reproductive potential to use effective contraception during treatment with DRUG-X and for at least 30 days after the last dose.

Format Review

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DRUG-X safely and effectively. See full prescribing information for DRUG-X.

DRUG-X (drugoxide) capsules, for oral use
Initial U.S. Approval: 2005

Bolded; Removed White Space

WARNING: EMBRYO-FETAL TOXICITY
See full prescribing information for complete boxed warning.

DRUG-X can cause embryo-fetal toxicity. Obtain pregnancy testing in females of reproductive potential before initiating treatment with DRUG-X. Advise females of reproductive potential to use effective contraception during treatment with DRUG-X and for at least 30 days after the last dose (2.1, 5.1).

Added Cross References

Format Review Tool

Selected Requirements of Prescribing Information (SRPI)*

- 41-item, drop-down checklist of important format elements of the prescribing information based on labeling regulations (21 CFR 201.56 and 201.57) and guidances

*https://www.fda.gov/drugs/laws-acts-and-rules/plr-requirements-prescribing-information

Highlights

See Appendix for a sample tool illustrating Highlights format.

HIGHLIGHTS GENERAL FORMAT

NO 1. Highlights (HL) must be in a minimum of 8-point font and should be in two-column format, with ½ inch margins on all sides and between columns.

Comment:

NO 2. The length of HL must be one-half page or less unless a waiver has been granted in a previous submission. The HL Boxed Warning does not count against the one-half page requirement. Instructions to complete this item: If the length of the HL is one-half page or less, select "YES" in the drop-down menu because this item meets the requirement. However, if HL is longer than one-half page, select "NO" unless a waiver has been granted.

Comment:

NO 3. A horizontal line must separate:
- HL from the Table of Contents (TOC), **and**
- TOC from the Full Prescribing Information (FPI).

Comment:

NO 4. All headings in HL (from Recent Major Changes to Use in Specific Populations) must be **bolded** and presented in the center of a horizontal line. (Each horizontal line should extend over the entire width of the column.) The HL headings (from Recent Major Changes to Use in Specific Populations) should be in UPPER CASE letters. See Appendix for HL format.

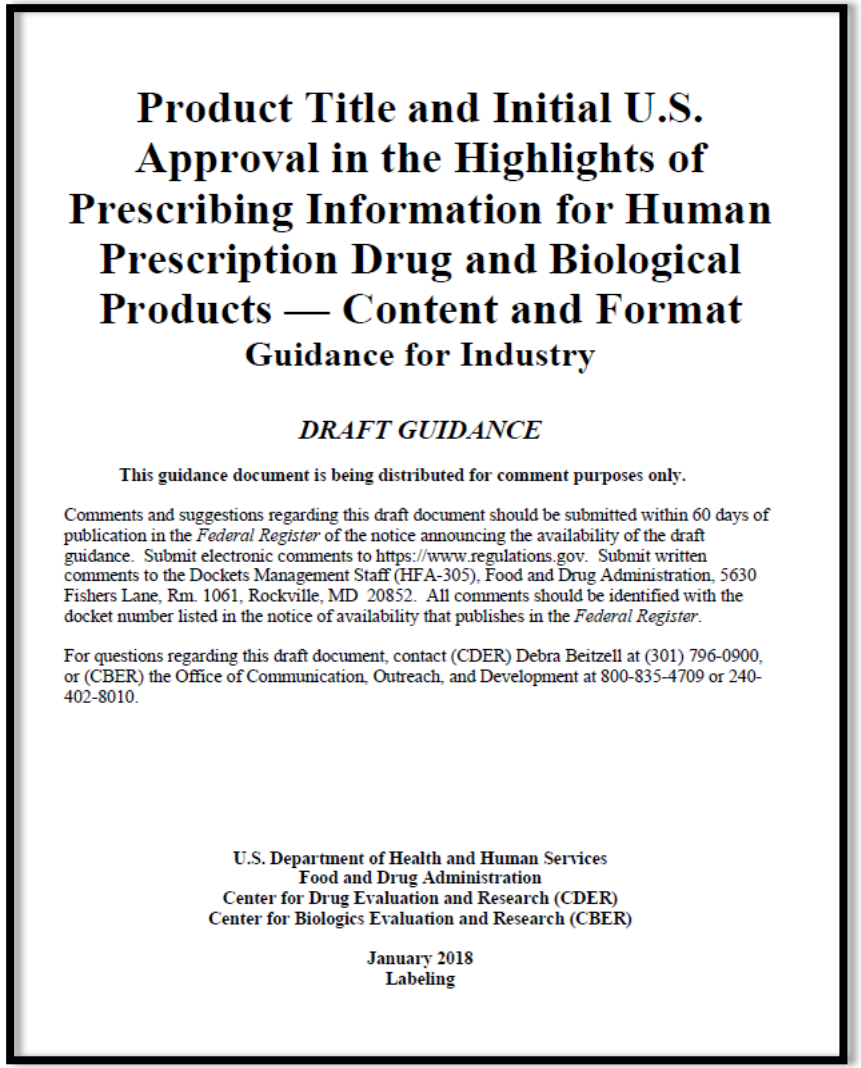
Comment:

NO

What's New!

- FDA Draft Guidance*: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products-Content and Format* (January 2018)
- FDA Draft Guidance*: *Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products-Content and Format* (July 2018)
- FDA Guidance: *Pediatric Information Incorporated Into Human Prescription Drug and Biological Product Labeling* (March 2019)

*When finalized these guidances will represent FDA's current thinking.



Product Title and Initial U.S. Approval in the Highlights of Prescribing Information 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) Debra Beitzell at (301) 796-0900, or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

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)

January 2018
Labeling

- Provides recommended format, content, and terminology sources for the required elements of the product title in Highlights (drug names, dosage form, route of administration, controlled substance symbol)
- Includes appendices for dosage form and route of administration terminology to assist in selecting proper terminology for use in the product title and other human drug and biological product labeling
- Provides recommendations for determining the initial U.S. approval date in Highlights

Draft Product Title Guidance: Dosage Form Appendix

Terminology

Aerosol

Aerosols are packaged under pressure. All aerosols are assumed to be metered except topical aerosols. Topical aerosols are assumed not to be metered unless labeling indicates they are metered.

inhalation aerosol — assumed to be for oral inhalation
lingual aerosol
nasal aerosol
topical aerosol

Bead — not preferred, see "Pellet"

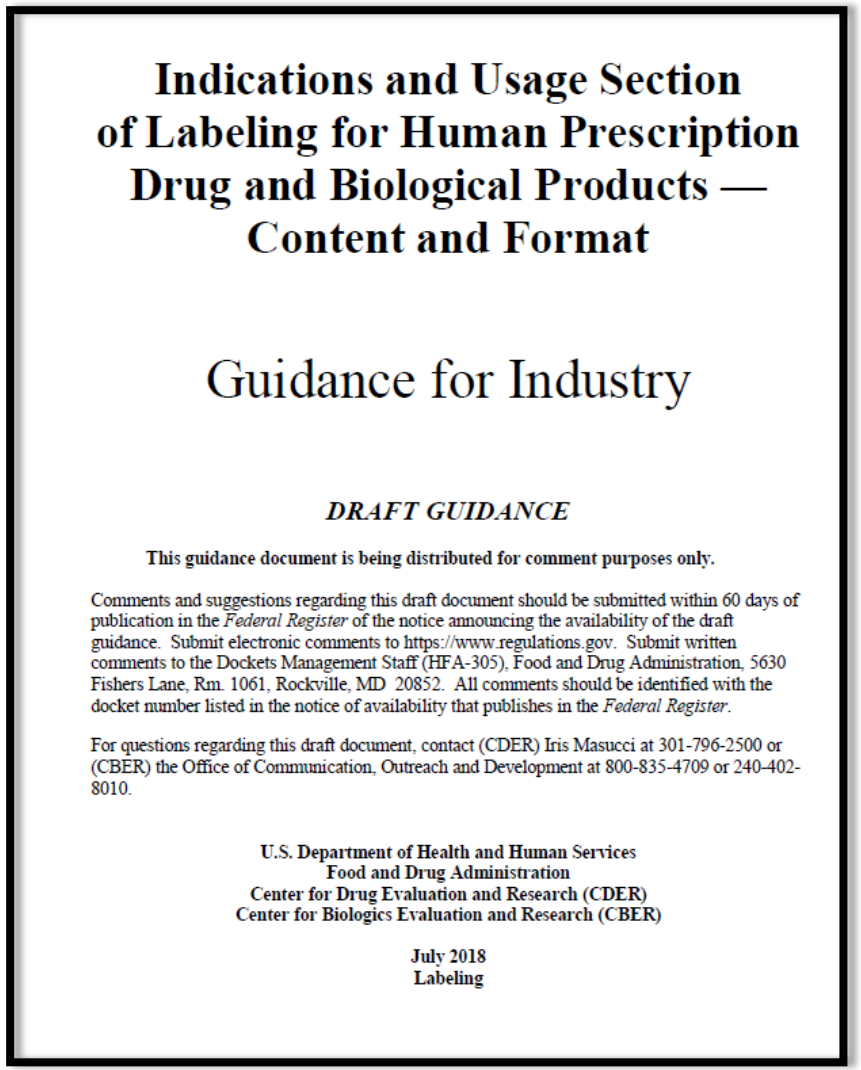
Caplet — not preferred, see "Tablet"

Capsule

Capsules are assumed to be oral.
Note: In the past, the terminology "vaginal capsules" was used, but these drug products are now referred to as "vaginal inserts."

capsules
delayed-release capsules
extended-release capsules

Collodion — not preferred, see "Solution"



Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format

Guidance for Industry

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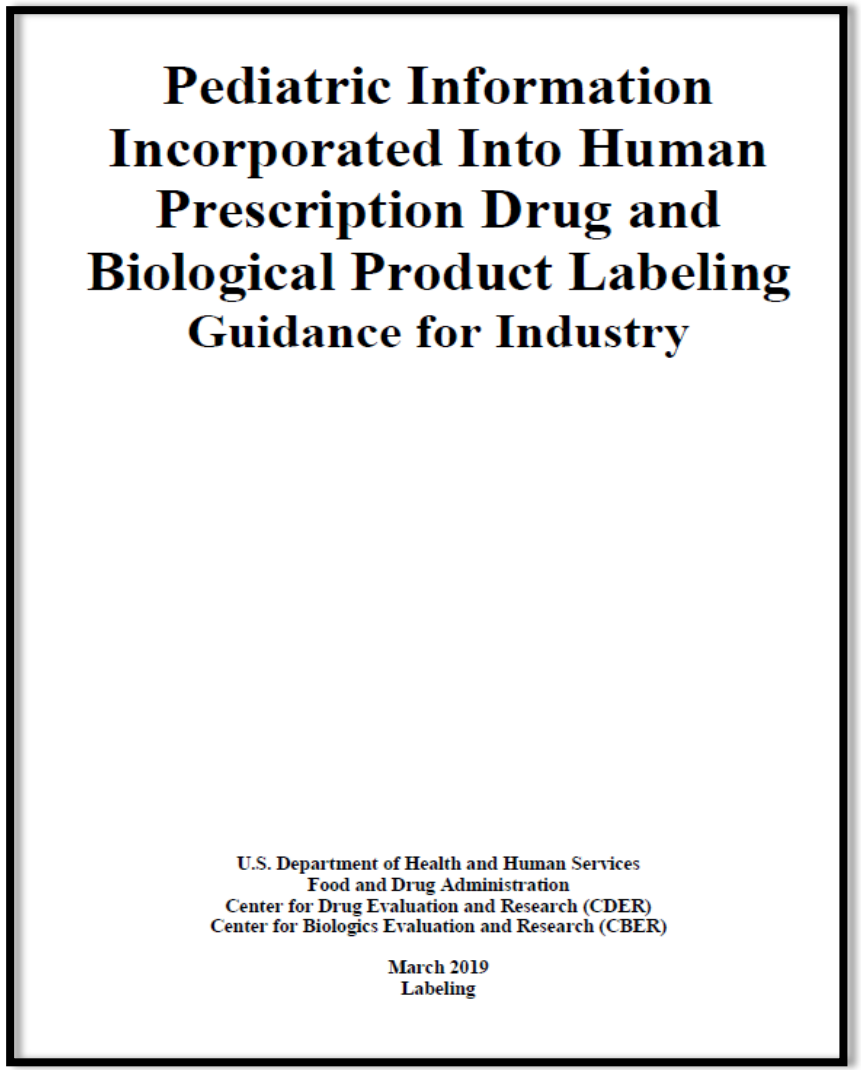
For questions regarding this draft document, contact (CDER) Iris Masucci at 301-796-2500 or (CBER) the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

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)

July 2018
Labeling

- Provides recommendations on the general principles to consider when drafting an indication and how to write, organize, and format the information in the INDICATIONS AND USAGE section
- Provides recommendations on what information to include in the indication and when limitations of use should be considered for the INDICATIONS AND USAGE section
- Recommends that the age groups that the drug is approved for are stated in the indication



- Provides recommendations on determining the appropriate placement and content of pediatric information in labeling as described in 21CFR 201.57(c)(9)(iv) based on 4 scenarios
- Provides recommendations for including juvenile animal toxicity data in the *Pediatric Use* subsection

Labeling Development Resources

PLR Requirements for Prescribing Information Website*

PLR Requirements for Prescribing Information

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On January 24, 2006, the U.S. Food and Drug Administration (FDA) issued final regulations governing the content and format of prescribing information (PI) for human drug and biological products. The rule is commonly referred to as the "**Physician Labeling Rule**" (PLR) because it addresses prescription drug labeling that is used by prescribers and other health care providers.

The goal of the PLR content and format requirements as described at 21 CFR 201.56 and 201.57 is to enhance the safe and effective use of prescription drug products by providing health care providers with clear and concise PI that is easier to access, read, and use. The PLR format also makes PI more accessible for use with electronic prescribing tools and other electronic information resources.

PI submitted with new drug applications (NDAs), biologic license applications (BLAs), and efficacy supplements must conform to the content and format regulations found at 21 CFR 201.56 and 201.57. The Labeling Development Team works with review divisions to ensure PI conforms with the PLR. This page includes links to the Final Rule, regulations, related guidance documents, and additional labeling resources.

On December 3, 2014, the FDA published the Pregnancy and Lactation Labeling Rule (PLLR). The goal of the PLLR is to enhance the safe and effective use of prescription drug products in pregnant women, lactating women, and females and males of reproductive potential.

PLR Final Rule and Labeling Requirements

- Physican Labeling Rule
- 21 CFR 201.56
- 21 CFR 201.57
- 21 CFR 201.80

Prescribing Information Guidances

- Implementing the PLR Content and Format Requirements
- Indications and Usage Section of Labeling (draft)
- Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway (draft)
- Dosage and Administration Section of Labeling
- Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling
- Adverse Reactions Section of Labeling
- Clinical Drug Interaction Studies - Study Design, Data Analysis, and Clinical Implications (draft)
- Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products-Content and Format (draft)
- Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling (draft)
- Clinical Pharmacology Section of Labeling
- Pharmacokinetics in Patients with Impaired Renal Function - Study Design, Data Analysis, and Impact on Dosing and Labeling (draft)
- Microbiology Data for Systemic Antibacterial Drugs - Development, Analysis, and Presentation
- Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs
- Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling
- Clinical Studies Section of Labeling
- Patient Counseling Information Section of Labeling

* https://www.fda.gov/drugs/laws-acts-and-rules/plr-requirements-prescribing-information

PLR Requirements for Prescribing Information Website Content

- PLR Final Rule and Labeling Requirements
- Labeling Guidances
- Labeling Presentations – Labeling Content
- Articles with Labeling Content
- Labeling Presentations – Labeling Review Process and Resources
- Sample Templates and Format Labeling Tools
- Product Quality-Related Resources for Prescribing Information
- ANDA Labeling Guidances
- Established Pharmacologic Class Resources
- Patient Labeling Resources
- Additional Labeling Resources

U.S. Department of Health and Human Services

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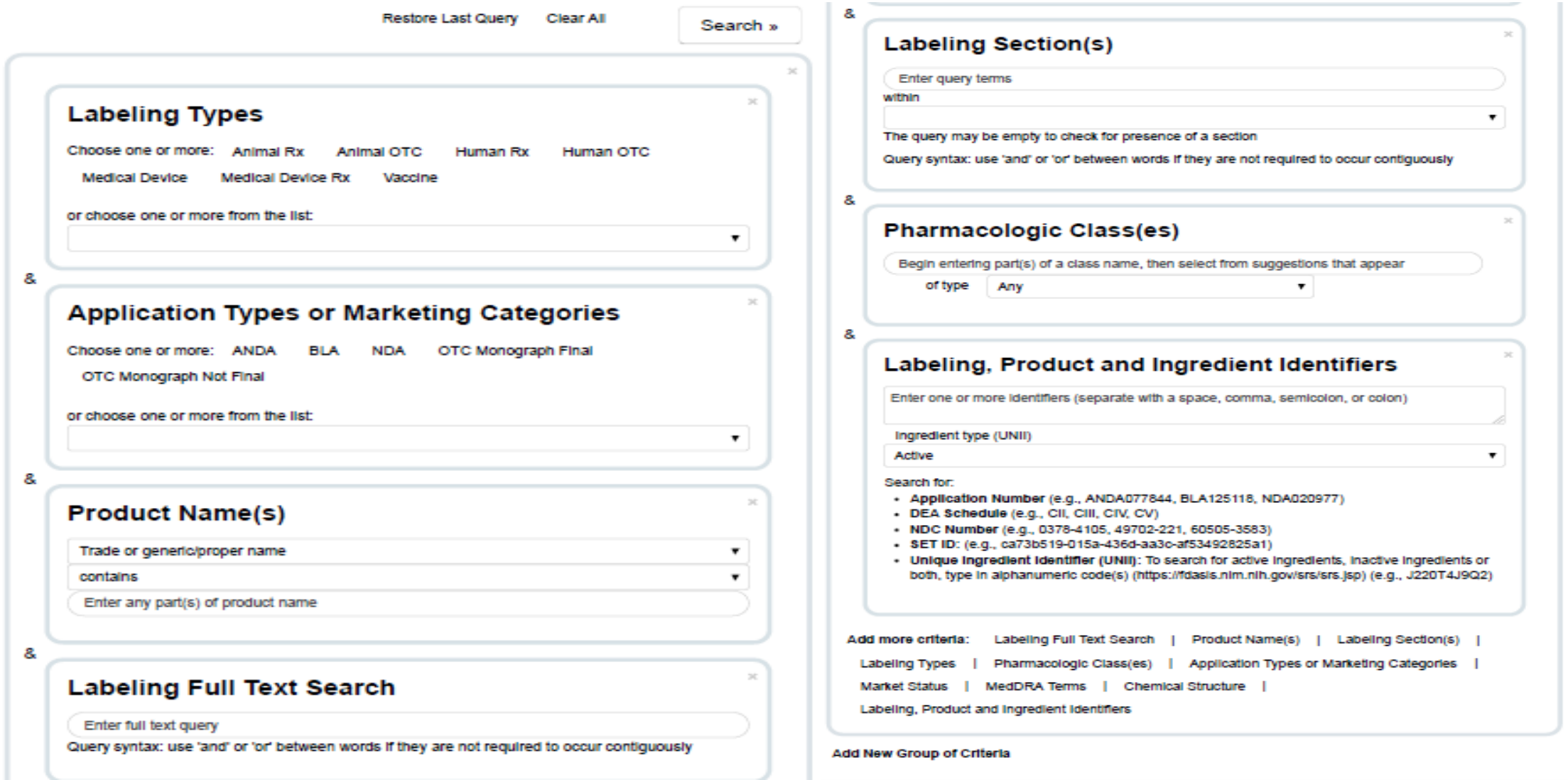
FDALabel*



*https://nctr-crs.fda.gov/fdalabel/ui/search; Disclaimer: Although the Structured Product Labeling (SPL) on FDALabel represents the most recent labeling that companies have submitted to FDA, the labeling has not been verified by FDA and may not be identical to the approved labeling of the labeling for currently distributed products.

Updating Labeling

Application Holder's Responsibilities

- Should review labeling at least annually for outdated information[1]
- Labeling must be updated when new information becomes available that causes labeling to become inaccurate, false, or misleading[2]
  - "a drug … shall be deemed to be misbranded .. (i)f its labeling is false or misleading in any particular"[3]

Labeling Update Opportunities

- Encourage updates in multiple labeling type submissions (e.g., PLR conversions, efficacy supplements)

[1] FDA Guidance: *Labeling for Human Prescription Drug and Biological Products — Implementing the Content and Format Requirements*; [2] 21 CFR 201.56(a)(2), [3] FD&C Act [section 352(a) of the U.S.C.]

Challenge Questions

Challenge Question #1

Which of the following is not a section of the prescribing information?

a. Full Prescribing Information
b. Contents
c. Index
d. Highlights

Challenge Question #2

Which of the following statements about the Prescribing Information is false?

a. Must not be misleading

b. Written for healthcare providers and patients for safe and effective use of prescription drugs and biological products

c. Must be updated when new information causes labeling to become inaccurate

d. Must be based whenever possible on human data

Want to Learn More About Labeling?

SBIA CDER Labeling Conference:

COMING SOON!

- December 4-5, 2019
- College Park MD
- Agenda/Registration (TBD): check SBIA website

www.fda.gov/CDERSBIA

www.fda.gov/CDERSBIA