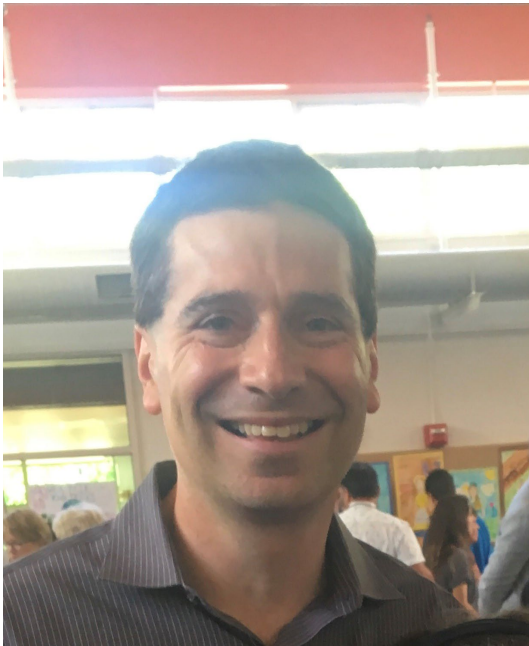# FDA Drug Topics: Frequently Asked Questions about Labeling for Prescription Medicines

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Food and Drug Administration

Disclaimer

FDA

➢ 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

➢ Explain the different types of labeling for prescription medicines for patients

➢ Review important information for labeling that is on the packaging of prescription medicines

➢ Discuss key features of the Prescribing Information for healthcare providers

➢ Describe how Prescribing Information is approved and updated

U.S. FOOD & DRUG
ADMINISTRATION

Regulatory Information / Laws, Acts, and Rules / FDA's Labeling Resources for Human Prescription Drugs / Frequently Asked Questions about Labeling for Prescription Medicines

Frequently Asked Questions about Labeling for Prescription Medicines

For Healthcare Professionals and Patients

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Frequently asked questions about labeling for prescription drugs (medicines) on this webpage are primarily directed to healthcare professionals (for example, doctors, nurse practitioners, physician assistants, pharmacists, nurses) and patients and their caregivers. For information about prescription drug labeling resources primarily directed to industry such as those for the Prescribing Information, FDA-approved patient labeling, carton and container labeling, biological product labeling, generic drug labeling, labeling databases, and product databases visit FDA's Labeling Resources for Prescription Drugs.

Labeling for prescription medicines is FDA's primary tool for communicating drug information to healthcare professionals, and patients and their caregivers. Labeling for prescription medicines includes:

- Prescribing Information (labeling for healthcare professionals),
- Carton and container labeling (cartons and containers are outside packaging that contain information about prescription medicines), and
- Labeling for patients or caregivers (e.g., Medication Guides, Patient Package Inserts, and Instructions for Use).

[1] See *https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/frequently-asked-questions-about-labeling-prescription-medicines*

Labeling for Prescription Medicines

Patient Labeling

FDA logo

FDA-Approved Patient Labeling

Medication Guides, Patient Package Inserts, and Instructions for Use

➢ Proposed by applicant
➢ Reviewed and approved by FDA
➢ Content is based on the Prescribing Information

Patient Labeling Not Approved by FDA

"Consumer medication information"

➢ Not submitted to FDA
➢ Not reviewed or approved by FDA

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.

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

FDA

Medication Guide[1] (FDA-Approved Patient Labeling)

[1] See the Medication Guide regulations [21 CFR 208] at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-208

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.
...

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

Patient Package Insert[1]
(FDA-Approved Patient Labeling)

[1] For oral contraceptives see regulations (21 CFR 310.501) at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-310/subpart-E/section-310.501

For estrogen-containing products see regulations (21 CFR 310.515) at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-310/subpart-E/section-310.515

Instructions for Use[1]
(FDA-Approved Patient Labeling)

FDA

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

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[1] See the guidance for industry: *Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products — Content and Format* (July 2022) available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/instructions-use-patient-labeling-human-prescription-drug-and-biological-products-content-and-format

Container Label

Outside package that contains information about the prescription medicine

- Recommended Dosage
- Product strength equivalency statement
- Reconstitution instructions
- Storage

Rx only   NDC 12345-6789-30

Mydrug
(drugozide) Injection

50 mg/10 mL

(5 mg/mL)

For continuous infusion after dilution
Single-dose vial – Discard unused portion.

10 mL single dose vial

Manufacturer name and logo

XXXX
XX/XX

1234567890120

[1] See guidance for industry: *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022) at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-considerations-container-labels-and-carton-labeling-design-minimize-medication-errors

Labeling for Healthcare Professionals (Prescribing Information) Must

FDA

➢ Contain a summary of essential scientific information needed for safe and effective use of the drug

➢ Be informative and accurate and neither promotional in tone nor false or misleading in any particular

➢ Be updated when new information becomes available that causes labeling to become inaccurate, false, or misleading

[1] See 21 CFR 201.56(a) at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.56

Prescribing Information

Highlights of Prescribing Information[1]

FDA

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 (nonproprietary 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/YYYY
Section Title, Subsection Title (x.x)   M/YYYY

-------------------------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/YYYY

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[1] See regulations [21 CFR 201.57(a)] at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.57#p-201.57(a) and guidance for industry: *Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements* (February 2013)

Established Pharmacologic Class in Highlights of Prescribing Information

FDA

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 (nonproprietary 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/YYYY
Section Title, Subsection Title (x.x)   M/YYYY

---------------------------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/YYYY

Guidance for industry and review staff: *Labeling for Human Prescription Drug and Biological Products – Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information* (October 2009); MAPP 7400.13 *Determining the Established Pharmacologic Class for Use in the Highlights of Prescribing Information*

Established Pharmacologic Class (EPC)[1]

An EPC is a term that:

- ➢ Refers to a group of active moieties that share scientifically valid properties and are clinically meaningful
- ➢ Is associated with an approved indication

Active Moiety Name	FDA EPC Phrase
Tobramycin	aminoglycoside antibacterial
Testosterone	androgen
Lisinopril	angiotensin converting enzyme inhibitor
Losartan	angiotensin II receptor blocker
Sotalol	antiarrhythmic

[1] See the EPC resources on https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources

Highlights: Adverse Reactions Reporting Contact Information[1]

FDA

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 (nonproprietary 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/YYYY
Section Title, Subsection Title (x.x)   M/YYYY

-----------------------------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/YYYY

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[1] 21 CFR 201.57(a)(11)(ii) and guidance for industry: *Labeling for Human Prescription Drug and Biological Products – Implementing the PLR Content and Format Requirements* (February 2013)

Table of Contents[1]

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: TITLE OF WARNING
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
   2.1 Subsection Title
   2.2 Subsection Title
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
   5.1 Subsection Title
   5.2 Subsection Title
6 ADVERSE REACTIONS
   6.1 Clinical Trials Experience
   6.2 Postmarketing Experience
7 DRUG INTERACTIONS
   7.1 Subsection Title
   7.2 Subsection Title
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
   8.6 Subpopulation X (e.g., Renal Impairment)

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
   12.5 Pharmacogenomics
   12.6 Immunogenicity
13 NONCLINICAL TOXICOLOGY
   13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
   13.2 Animal Toxicology and/or Pharmacology
14 CLINICAL STUDIES
   14.1 Subsection Title
   14.2 Subsection Title
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

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

[1] See regulations [21 CFR 201.57(b)] at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.57#p-201.57(b)

Full Prescribing Information Sections[1]

FDA

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

[1] See regulations [21 CFR 201.57(c)] at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.57#p-201.57(c)

Certain Sections That Focus on Usage

Indications and Usage (Section 1)[1]

FDA

Treatment, prevention, or diagnosis of a recognized disease or condition or manifestation of a recognized disease or condition (or a manifestation thereof)[2]

1 INDICATIONS AND USAGE

DRUG-X is indicated, in combination with methotrexate, for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an inadequate response to TNF inhibitor therapy

Dosage and Administration (Section 2)[1]

Include the following dosage information if applicable:

- ➢ Recommended starting dosage (dose and frequency), method of titration, dosage range, maximum dosage
- ➢ Dosage in specific populations (e.g., pediatrics, renal impairment)
- ➢ Dosage modifications due to drug interactions or adverse reactions
- ➢ Recommended concomitant therapy
- ➢ Discontinuation instructions

[1] 21 CFR 201.57(c)(3) and guidance for industry: *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* (March 2010)

Dosage and Administration (Section 2)[1]

Include important preparation and administration instructions such as:

- ➢ Route(s) of administration
- ➢ Reconstitution and/or dilution instructions
- ➢ Whether oral drug should be taken with or without food
- ➢ Specific injection site(s)
- ➢ Rate of administration of intravenous products

[1] 21 CFR 201.57(c)(3) and guidance for industry: *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* (March 2010)

Certain Sections That Focus on Safety

Contraindications Section[1]

Situations for which risk from use clearly outweighs any possible benefit

4 CONTRAINDICATIONS
DRUG-A is contraindicated in patients who are at increased risk of thromboembolic disease *[see Warnings and Precautions (5.x)].*

Concomitant use of DRUG-A with drug-b is contraindicated *[see Drug Interactions (7.x)].*

Boxed Warning[1]

FDA

WARNING: SERIOUS HYPERSENSITIVITY REACTIONS

Patients treated with DRUG-X have experienced serious hypersensitivity reactions, including anaphylaxis.

Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during DRUG-X administration. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue DRUG-X immediately, and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, consider using a desensitization procedure to DRUG-X _[see Warnings and Precautions (5.1)]._

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[1] 21 CFR 201.57(c)(1); guidance for industry: _Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format_ (October 2011).

Limitations of Use in the Indications and Usage (Section 1)[1]

FDA

Include if, reasonable concern or uncertainty about risk-benefit profile of the drug

1 INDICATIONS AND USAGE
DRUG-X is indicated to treat hypertension in adults.

Limitations of Use
The use of DRUG-X is not recommended for the treatment of hypertension in pediatric patients younger than 1 year of age because its direct activity on the renin-angiotensin system can adversely affect kidney development *[see Warnings and Precautions (5.x)].*

Drug Interactions (Section 7)[1]

FDA

➤ Include description of clinically significant drug interactions (DI)

➤ Include mechanism of clinically significant DI

➤ Include practical instructions for preventing or managing clinically significant DI

➤ Do not include negative DI unless drug does not have same interaction as other drugs in class

➤ Do not include details of pharmacokinetic studies

[1] 21 CFR 201.57(c)(8). If you want to learn more about drug interaction information in labeling, consider viewing an FDA webinar: https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/labeling-made-simple-how-what-and-where-drug-interactions-prescribing-information

How Supplied/Storage and Handling (Section 16)[1]

FDA

➢ Dosage form(s) and identifying characteristics

➢ Strength or potency in metric system (e.g., 10 mg)

➢ Units in which dosage form is ordinarily available for prescribing by practitioners (e.g., bottles of 100 tablets)

➢ National Drug Code (NDC) number(s)

➢ Special handling and storage conditions

[1] 21 CFR 202.57(c)(17) available at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-B/section-201.57#p-201.57(c)(17)

How Prescribing Information Are Approved

Step 1: Drug Company Submits Draft Prescribing Information (PI)

FDA

Drug company submits an application to approve a drug or a supplement to an approved drug (application/supplement includes draft PI)[1]

[1] If requested, FDA provides comments about drug companies' draft PI before application or supplement submission

Step 2: FDA Reviews Proposed Prescribing Information (PI)

➢ FDA reviews PI from the time of submission to the time of FDA action

➢ FDA review team is multi-disciplined (e.g., doctors with a specialty in the disease/condition being treated, clinical pharmacology staff, labeling specialists, product quality reviewers, pharmacology/toxicology staff, promotional content specialists, regulatory project managers, safety experts, statisticians)

➢ FDA review team helps ensure that the PI is accurate, meets regulatory requirements, provides a summary of the essential scientific information needed for the safe and effective use of the drug

Step 3: FDA and Drug Company Discuss Proposed Prescribing Information (PI)

➢ FDA review team frequency asks the drug company for additional data to support or to clarify statements in the proposed PI

➢ PI development typically involving several rounds of editing and discussions between FDA and the drug company to arrive at a final agreed-upon PI

➢ If the FDA and the drug company cannot agree on the information in the PI, the application will not be approved

Step 4: Prescribing Information (PI) Approval and Communication

FDA

> Upon approval of the application or supplement, PI are posted:

  - Drugs@FDA[1] (overwhelming majority)[2]
  - On CBER's webpage[3]

> Within 14 days of approval, the drug company submits Structured Product Labeling to FDA

> Subsequently, electronic labeling is posted to several webpages

CBER = Center for Biologics Evaluation and Research
[1] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
[2] The overwhelming majority of PI for drugs regulated under NDAs/BLAs are posted on Drugs@FDA; however, the PI for generic drugs are not typically posted on Drugs@FDA
[3] CBER approves vaccines, allergenic products, blood products, cellular and gene therapy products. See https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year

How Prescribing Information Are Updated

Principles of Updating Prescribing Information

- ➢ Ensure scientific accuracy

- ➢ Ensure meets statutory/regulatory requirements and is consistent with final guidance recommendations

- ➢ Ensure consistent message

- ➢ Improve organization/formatting

- ➢ Update terminology and remove/revise outdated, misleading, or clearly inapplicable information

- ➢ When updating, review and develop *entire* Prescribing Information

After Approval Prescribing Information (PI) Is Updated

➤ Drug company submits a supplement to their application:
- For required updates (e.g., safety information)
- To propose new indications, populations, dosages

➤ FDA may:
- Ask the drug company to submit a supplement to their application to update the PI
- Require the drug company to update their PI (new safety information)

Challenge Question #1

FDA

Which statement is correct?

a. Medication Guides are a type of labeling for healthcare providers

b. Consumer Medication Information is approved by the FDA

c. Instructions for Use is patient labeling for drugs with complicated preparation or administration instructions

d. Patient Package Inserts are generally required for all prescription drugs for outpatient use

e. Prescribing Information are directed to patients and caregivers

Challenge Question #2

What information is important to display on the packaging for drugs?

a. Brand name

b. Nonproprietary name (sometimes referred to as the generic drug name)

c. Dosage form

d. Strength

e. All the above

Challenge Question #3

Which section of the labeling would include preparation instructions (e.g., reconstitution of a lyophilized powder)?

a. Indications and Usage (section 2)

b. Dosage and Administration (section 2)

c. Warnings and Precautions (section 5)

d. Drug Interactions (section 7)

e. How Supplied/Storage and Handling (section 16)

Challenge Question #4

FDA

Which section of the labeling only contains situations or circumstances in which the drug must <u>not</u> be used (select the most appropriate section)?

a. Boxed Warning

b. Indications and Usage (section 1)

c. Dosage and Administration (section 2)

d. Contraindications (section 4)

e. Drug Interactions (section 7)

Challenge Question #5

FDA

Which of the following statements are true about the Prescribing Information:

a. The drug company determines the wording

b. FDA cannot require changes

c. Wording is an agreement between the drug company and FDA

d. Contains essential information directed to patients

e. The drug company only submits information to obtain new indications, uses, and other claims

References

➤ Frequently Asked Questions about Labeling for Prescription Medicines: https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/frequently-asked-questions-about-labeling-prescription-medicines

➤ The Ins and Outs of Prescription Drug Labeling: https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/fda-drug-topics-ins-and-outs-prescription-drug-labeling-march-23-2021

➤ FDA's Labeling Resources for Human Prescription Drugs: https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs

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