Small Business & Industry Assistance (SBIA) Webinar
April 19, 2023 (Day 1 of 2)

U.S. FOOD & DRUG ADMINISTRATION

Dosage and Administration Section of Labeling: Part 1 of 2

Eric Brodsky, M.D.
Associate Director, Labeling Policy Team
Office of New Drug Policy, Office of New Drugs
Center for Drug Evaluation and Research, U.S. FDA

Disclaimer

- The views and opinions expressed in this presentation represent those of the presenter, and do not necessarily represent an official FDA position.

- The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.

Learning Objectives for Day 1: Describe/Discuss

- General principles
- Recommended organization and format
- Critical dosage- and administration-related information
- Recommended dosage information
- Recommended dosage in specific populations
- Recommended dosage for fixed-combination drug products and co-packaged products

What Is the "Most Useful" Section?

In a qualitative study, 70 physicians were interviewed about their preferences for and understanding of specific PI content:[1] They were asked which section(s) of the PI were most useful to their practice:

- DOSAGE AND ADMINISTRATION (76%)
- DRUG INTERACTIONS (57%)
- INDICATIONS AND USAGE (56%)
- CONTRAINDICATIONS (56%)
- ADVERSE REACTIONS (53%)

PI = Prescribing Information

[1] Sullivan, H.W., Squire, C., Aikin, K.J., Tzeng, J., Ferriola-Bruckenstein, K., Brodsky, E., Trentacosti, A.M., & Johnson, M. *Physicians' use of and preferences for FDA-approved prescribing information.* Research in Social and Administrative Pharmacy. Available at https://www.sciencedirect.com/science/article/pii/S1551741121002862?via%3Dihub

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

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

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be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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

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

January 2023
Labeling
Revision 1

[1] Available under the **"2 Dosage and Administration"** heading on the *Prescribing Information Resources* webpage (see https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources). May submit comments to https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dosage-and-administration-section-labeling-human-prescription-drug-and-biological-products-content.

Purpose of Dosage and Administration (D&A) Section of Labeling Draft Guidance

- To assist applicants in developing the format and content of the D&A section of labeling[1]
- To ensure that this section contains the dosage- and administration-related information needed for safe and effective use of a drug[2]

[1] As described in 21 CFR 201.57(c)(3)
[2] For purposes of this presentation the term *drug* refers to human prescription drug and biological products

Principles of Developing the D&A Section

Principles of Developing the D&A Section (1 of 2)

- Use the term *dose* or *dosage* when appropriate[1]
- Present information in a clear, concise manner
- Use active voice and command language:

  State “Administer 50 mg orally once daily” or
  “The recommended dosage is 50 mg orally once daily”
  instead of “~~DRUG-X treatment should be administered at a dose of 50 mg once daily~~”

[1] *Dose* refers to a specific amount of drug taken at one time vs. *dosage* refers to a specific amount of drug administered at a specific frequency (and over a certain duration, if applicable)

Principles of Developing the D&A Section (2 of 2)

- Must be updated when new information becomes available that causes the labeling to be inaccurate, false, or misleading[1]
- Dosing regimens must not be implied or suggested in other sections of the labeling if not included in this section[2]

[1] 21 CFR 201.56(a)(2).
[2] 21 CFR 201.57(c)(3)(ii) and 21 CFR 201.57(c)(15)(i).

Avoid the Following in the D&A Section (1 of 3)

- Information not directly related to dosage, preparation, or administration or storage of a prepared product[1]
- Term “usual dosage” or “usual dose” (for PLR labeling)
- Term “interchangeable”
- Efficacy data

[1] There are a few exceptions. For example, if the recommended dosage in patients with mild and moderate renal impairment is different than the recommended dosage in patients with normal kidney function, the D&A draft guidance recommends including a recommendation that the use of the drug is not recommended in patients with severe renal impairment, as appropriate.

Avoid the Following in the D&A Section (2 of 3)

- Descriptions of dosing regimens from trials
  - Avoid: “In controlled trials of DRUG-X in Disease-Y, dosages in the range of 1 mg to 10 mg once daily were administered”
- USP descriptor next to the subject drug
- How supplied information (e.g., package-type terms, identifying characteristics of the dosage form)
  - Avoid: “DRUG-X is supplied in single-dose vials without preservatives”
- British Imperial System measurements

Avoid the Following in the D&A Section (3 of 3)

- Avoid abbreviations or symbols that could create the potential for medication errors (e.g., avoid *QD*, instead use the term *once daily*)

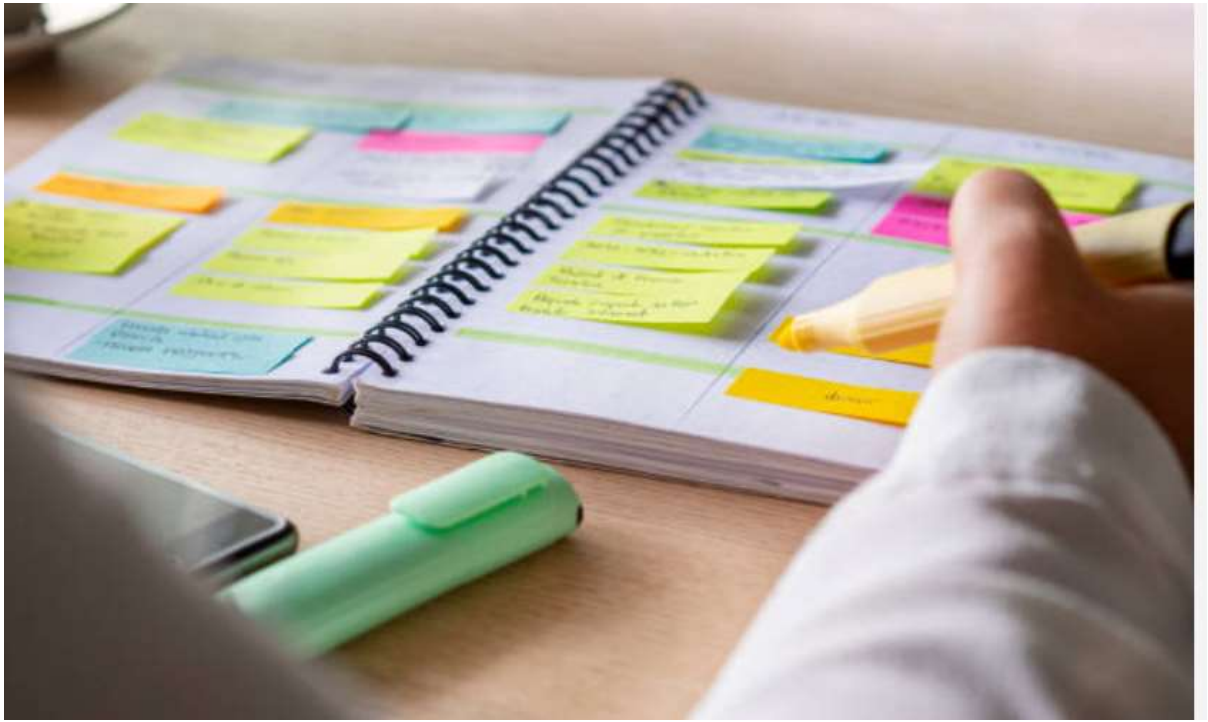
Refer to ISMP's list of error-prone symbols, abbreviations, and dose designation[1]

- However, certain commonly used symbols (e.g., /, >, <, ≥, ≤) may sometimes be preferable[1]
  - May state: ALT > 3 times ULN to ≤ 5 times ULN instead of "~~ALT greater than 3 times ULN to less than or equal to ALT 5 times ULN~~"
  - May state 5 mg/kg/day instead of "~~5 mg per kg per day~~"

[1] See Institute for Safe Medication Practices (ISMP's) list at https://www.ismp.org/recommendations/error-prone-abbreviations-list.

[2] Certain symbols may be preferrable when there is minimal risk of medication errors and where the replacement of symbols by lengthier, spelled-out words would make the presented information more difficult to understand.

Organization and Format



Order of Information in D&A Section

Sequence of dosage- and administration-related information should be based on its relative clinical importance:

1) Dosage overview subsection (very complicated dosage- and administration-related information) - uncommon
2) Critical information for safe and effective use of the drug
3) Fundamental dosage- and administration-related information
4) Other information about dosage, preparation, administration, and storage of the prepared product

Subsections in D&A Section: Example #1

2 DOSAGE AND ADMINISTRATION

- 2.1 Recommended Premedication
- 2.2 Recommended Dosage for Disease A
- 2.3 Recommended Dosage for Disease B
- 2.4 Recommended Dosage in Patients With Renal Impairment
- 2.5 Dosage Modifications for Drug Interactions
- 2.6 Preparation and Administration Instructions
- 2.7 Storage of the Diluted Product

Subsections in D&A Section: Example #2

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Evaluation and Testing Before Initiating DRUG-X
2.2 Important Administration Instructions
2.3 Recommended Dosage in Adults
2.4 Recommended Dosage in Pediatric Patients 12 Years of Age and Older
2.5 Recommended Dosage in Patients With Renal Impairment
2.6 Dosage Modifications for Adverse Reactions
2.7 Dosage Modification for CYP3A Inhibitors

Subsections in the D&A Section

- Present the recommended dosage information in a single subsection if the recommended dosage for a drug is the same across multiple approved indications or subpopulations
- Place all information under numbered subsections instead of inserting information between the D&A section heading and first subsection heading

2 DOSAGE AND ADMINISTRATION

~~Administer DRUG-X once daily with or without food.~~

2.1 Recommended Dosage

…

Avoid Same Subsection Titles in I&U[1] and D&A Subsections

Before	After
1 INDICATIONS AND USAGE	1 INDICATIONS AND USAGE
1.1 Condition-A	1.1 Condition-A
1.2 Condition-B	1.2 Condition-B
2 DOSAGE AND ADMINISTRATION	2 DOSAGE AND ADMINISTRATION
2.1 Condition-A	2.1 Recommended Dosage for Condition-A
2.2 Condition-B	2.2 Recommended Dosage for Condition-B

[1] I&U = INDICATIONS AND USAGE

Tables and Figures

- For complex dosage- or administration-related information, recommend using tables, figures, bulleted lists, or algorithms
- Text preceding the table or figure should briefly mention or identify the content in the table or figure:

  "See Table Y for the recommended dosage in pediatric patients aged 12 years and older with renal impairment"

Table: Example

2.1 Recommended Dosage and Administration

The recommended starting dose of DRUG-X is 0.05 mg/kg by intravenous infusion. Subsequently titrate the dose over 16 weeks to the recommended maintenance dosage (2 mg/kg by intravenous infusion every two weeks) – see Table 1.

Table 1: Recommended DRUG-X Titration Schedule[1]

First dose (Day 1/Week 0)	0.05 mg/kg
Second dose (Week 2)	0.1 mg/kg
Third dose (Week 4)	0.5 mg/kg
Fourth dose (Week 6)	0.5 mg/kg
Fifth dose (Week 8)	0.7 mg/kg
Sixth dose (Week 10)	0.7 mg/kg
Seventh dose (Week 12)	1 mg/kg
Eighth dose (Week 14)	1 mg/kg
Ninth dose (Week 16)	2 mg/kg

[1] By intravenous infusion

Formula: Example

2.1 Recommended Dosage in Adults and Pediatric Patients

The recommended weight-based dosage of DRUG-X is as follows:

- ≤ 30 kg, the dosage is based on actual body weight in kg
- > 30 kg, the dosage is based on adjusted body weight in kg. Calculate the adjusted body weight based on the following formula:

  Adjusted body weight (in kg) = (actual height in meters)^2 × 30

Dosage Overview Subsection Example

2 DOSAGE AND ADMINISTRATION

2.1 Dosage and Administration Overview

Administration of two doses of DRUG-X and additional water for dilution is required for a complete preparation for colonoscopy. The recommended dosage is:

- **Adults:** Two 300 mL doses of strength-a *[see Dosage and Administration (2.3)]*
- **Pediatric patients 12 years of age and older:** Two 150 mL doses of strength-b *[see Dosage and Administration (2.4)]*

Critical Dosage- or Administration-Related Information

Critical Dosage- or Administration-Related Information[1] (1 of 2)

- Medication errors have occurred and resulted in serious adverse reactions (ARs)
- Dosage form needs to be diluted before administration (administration of undiluted drug may result in toxicity)
- Inappropriate substitution of one drug for another drug may lead to clinically significant ARs or loss of effectiveness
- Infusion rates that exceed the maximum recommended infusion rate have resulted in clinically significant ARs

[1] Dosage- and administration-related information that is critical to the safe and effective use of the drug (e.g., lack of knowledge of the information or nonadherence to a recommendation could have serious consequences for patients)

Critical Dosage- or Administration-Related Information[1] (2 of 2)

- Drug must be administered in a specific health care setting or by a specific user
- Evaluations, tests, procedures, or evaluations are required or necessary. For example:

2.x Recommended Evaluation and Testing Before Initiating DRUG-X

Before initiating DRUG-X, evaluate for active tuberculosis and test for latent tuberculosis [*see Warnings and Precautions (5.1)].*

[1] Dosage- and administration-related information that is critical to the safe and effective use of the drug (e.g., lack of knowledge of the information or nonadherence to a recommendation could have serious consequences for patients)

Testing Prior to Drug Initiation: Example

2.1 Important Recommendations Prior to DRUG-X Initiation
Before initiating DRUG-X:

- Obtain baseline alanine aminotransferase and aspartate aminotransferase levels within 1 month prior to treatment initiation *[see Warnings and Precautions (5.3)]*.
- Verify pregnancy status in females of reproductive potential *[see Warnings and Precautions (5.4) and Use in Specific Populations (8.1, 8.3)]*

5.3 Elevated Transaminases Levels

…

5.4 Embryo-Fetal Toxicity

…

Fundamental Dosage- or Administration-Related Information

Fundamental Dosage- or Administration-Related Information

- Recommended dosage includes, as appropriate:
  - Dosage range
  - Recommended starting or loading dose or dosage
  - Recommended titration schedule
  - Maximum recommended dosage and maximum recommended duration
  - For weight-based or BSA-based dosing based on ideal or adjusted body weight, method for calculating the dose
  - Therapeutic drug monitoring information
- Administration instructions included with recommended dosage (e.g., route(s) of administration)

BSA = body surface area

Recommended Starting or Loading Dose or Dosage

2 DOSAGE AND ADMINISTRATION

2.x Recommended Dosage and Administration

The recommended dosage of DRUG-X is as follows:

- Day 1: Administer a single 50 mg dose by intravenous infusion over 30 minutes (loading dose)
- Day 2: Administer the first 50 mg subcutaneous dose
- Day 9 and thereafter: Administer 50 mg every week subcutaneously

Recommended Titration Schedule

If the dosage of a drug is titrated include the recommended titration schedule including dosage increments and frequency and timing of increments

2.x Recommended Dosage and Administration

Administer DRUG-X as a continuous intravenous infusion over 48 hours as follows (dosage is based on ideal body weight):

- Initiate at 50 mcg/kg/hour
- 0 to 4 hours: 50 mcg/kg/hour
- 4 to 8 hours: 100 mcg/kg/hour
- 8 to 12 hours: 150 mcg/kg/hour
- 12 to 48 hours: 200 mcg/kg/hour

[1] Increased incrementally to achieve effectiveness while reducing the risk of adverse reactions

Maximum Recommended Duration

When there are reasonable concerns about safety of the drug with longer-term use.

2.x Recommended Dosage and Administration

The recommended dosage of DRUG-X is 10 mg orally once daily with or without food. The maximum recommended duration of use is 12 months *[see Warnings and Precautions (5.x)].*

5.x Bone Loss

DRUG-X causes a dosage-dependent decrease in bone mineral density that is greater with increasing duration of use that may not be reversible on discontinuation … *[see Dosage and Administration (2.x)].*

Recommended Dosage in Specific Populations

Recommended Dosage vs. Dosage Modifications

Recommended dosage in specific populations

Dosage modifications due to adverse reactions or drug interactions

Recommended Dosage in Pediatric Patients[1]

- The recommended dosage in pediatric patients for all approved pediatric indications must be included in the D&A section
- If the recommended dosage is different between adults and pediatric patients, or among pediatric subpopulations, the D&A section must identify the recommended dosages for each of the pediatric subpopulations (e.g., by pediatric age group, by weight or body surface area)

[1] 21 CFR 201.57(c)(3)(i)(C) and (H) and 21 CFR 201.57(c)(9)(iv)(B), (C), and (D).

Example: Avoid Unclear Pediatric Use Information in Labeling

1 INDICATIONS AND USAGE

DRUG-X is indicated for the treatment of patients with Disease-A.

2 DOSAGE AND ADMINISTRATION

The recommended oral dosage of DRUG-X is 10 mg once daily.

8 USE IN SPECIFIC POPULATIONS

…

8.4 Pediatric Use

The safety and effectiveness of DRUG-X for Indication-A have been established in pediatric patients 12 years of age and older … The safety and effectiveness of DRUG-X in pediatric patients less than 12 years of age has not been established.

Improved Clarity of Pediatric Use Information in Labeling

1 INDICATIONS AND USAGE

DRUG-X is indicated for the treatment of patients 12 years of age and older with Disease-A.

2 DOSAGE AND ADMINISTRATION

The recommended oral dosage of DRUG-X is:

- 10 mg once daily in adults
- 5 mg once daily in pediatric patients 12 years of age and older

8.4 Pediatric Use

The safety and effectiveness of DRUG-X for Indication-A have been established in pediatric patients 12 years of age and older …

Recommended Dosage in Geriatric Patients

- If the recommended dosage is different between geriatric patients and adults younger than 65 years of age, the D&A section must include the recommended dosage in geriatric patients[1]
- The D&A section must include the recommended dosage in geriatric patients for all approved geriatric-specific indications[2]

[1] 21 CFR 201.57(c)(3)(i)(C) and (H) and 21 CFR 201.57(c)(9)(v)(B)(3).
[2] 21 CFR 201.57(c)(9)(v)(A).

Example: Recommended Dosage in Geriatric Patients

2.1 Recommended Dosage in Adults Less Than 65 Years of Age

The recommended oral dosage range of DRUG-X in adults less than 65 years of age for:

- Disease-A is 4 to 8 mg twice daily.
- Disease-B is 2 to 4 mg twice daily

2.2 Recommended Dosage in Geriatric Patients

The recommended oral dosage range of DRUG-X in patients 65 years of age or older for *[see Use in Specific Populations (8.5)]:*

- Disease-A is 1 to 2 mg twice daily.
- Disease-B is 0.5 to 1 mg twice daily

Recommended Dosage in Patients with Renal Impairment

- If the dosage in patients with renal impairment is different from the recommended dosage in patients with normal kidney function, must include the dosage in the applicable renal impairment subpopulation(s)[1]
- If there are dosage differences for at least one of the renal impairment subpopulations compared with patients with normal renal function, recommendations for use of the drug should generally be provided for all the renal impairment subpopulations

[1] 21 CFR 201.57(c)(3)(i)(C) and (H)

Recommended Dosage in Patients with Renal Impairment: Example

2.x Recommended Dosage in Patients With Renal Impairment

The recommended dosage of DRUG-X in patients with renal impairment with a stable estimated GFR is described in Table 1 *[see Use in Specific Populations (8.6) and Clinical Pharmacology (12.3)]*. Administer each intravenous infusion over 3 hours.

Table 1. Recommended DRUG-X Dosage in Patients With Renal Impairment

Estimated GFR*	Dose	Frequency
50–89 mL/minute	2 grams	Every 8 hours
25–49 mL/minute	1.5 grams	Every 8 hours
15–24 mL/minute	1.5 grams	Every 12 hours
<15 mL/minute or receiving intermittent hemodialysis**	1 gram	Every 12 hours

* If the estimated GFR (eGFR) for an adult patient is calculated using an equation standardized to a body surface area value of 1.73 m^2 (reported in units of mL/minute/1.73 m^2), then multiply the standardized eGFR value by the patient's body surface area and divide by 1.73 to obtain the eGFR in units of mL/minute. Finally, use the eGFR in units of mL/minute to determine the recommended dose and frequency.

** For adult patients with kidney failure receiving intermittent hemodialysis, administer DRUG-X after dialysis.

Recommended Dosage in Patients with Renal Impairment: Example

2.x Recommended Dosage in Pediatric Patients With Renal Impairment

The recommended dosage of DRUG-X in pediatric patients with renal impairment with a stable estimated GFR is described in Table 2 *[see Use in Specific Populations (8.4, 8.6) and Clinical Pharmacology (12.3)]*.

Table 2. Recommended DRUG-X Dosage in Pediatric Patients With Renal Impairment

Estimated GFR*	Dosage**
60–89 mL/minute/1.73 m^2	30 mg/kg orally once daily
30–59 mL/minute/1.73 m^2	20 mg/kg orally once daily
15–29 mL/minute/1.73 m^2	10 mg/kg orally once daily
<15 mL/minute/1.73 m^2 or receiving peritoneal dialysis or hemodialysis	Use is not recommended

* Estimate GFR using an equation validated for use in the appropriate pediatric age range

** Dosage based on actual body weight.

Recommended Dosage in Patients with Hepatic Impairment (1 of 2)

- If the dosage in patients with hepatic impairment (caused by chronic liver disease) is different from the recommended dosage in patients with normal hepatic function, must include the dosage in the applicable hepatic impairment subpopulation(s)[1]
- If there are dosage differences for at least one of the hepatic impairment subpopulations compared with patients with normal hepatic function, recommendations for use of the drug should generally be provided for all the hepatic impairment subpopulations

[1] 21 CFR 201.57(c)(3)(i)(C) and (H)

Recommended Dosage in Patients with Hepatic Impairment (2 of 2)

If the dosage in patients with hepatic impairment is included, identify the method used for classifying hepatic function (e.g., the Child-Pugh Classification)

Recommended Dosage in Patients with Hepatic Impairment: Example

2.1 Recommended Dosage

The recommended oral dosage of DRUG-X is 50 mg once daily …

…

2.x Recommended Dosage in Patients with Hepatic Impairment

Avoid use of DRUG-X in patients with severe hepatic impairment (Child-Pugh C) *[see Use in Specific Populations (8.6)].* The recommended oral dosage of DRUG-X in patients with:

- Moderate hepatic impairment (Child-Pugh B) is 25 mg once daily
- Mild hepatic impairment (Child-Pugh A) is 50 mg once daily

Recommended Dosage in Other Specific Populations[1]

- Males vs. females
- Patients defined by certain genetic characteristics (such as patients who are CYP2D6 poor metabolizers vs. those who are CYP2C19 normal metabolizers)
- Postpartum patients
- Pregnant patients vs. patients who are not pregnant
- Racial or ethnic subgroups

[1] Not an exhaustive list

Recommended Dosage for Fixed-Combination Drug Products and for Co-Packaged Products

Recommended Dosage for Fixed-Combination Drug Products[1]

Should identify the recommended dosage of each drug or biologic component

~~**2.x Recommended Dosage**~~

~~The recommended dosage of DRUG-X is one tablet orally once daily.~~

2.x Recommended Dosage

The recommended dosage of DRUG-X is one tablet (containing 500 mg of active-ingredient-a, 250 mg of active-ingredient-b, and 100 mg of active-ingredient-c) orally once daily.

[1] A fixed-combination drug product (FCDP) is one in which two or more active ingredients are combined at a fixed dosage in a single dosage form

FCDP Recommended Dosage Examples

Example 1

2.1 Recommended Dosage

Administer DRUG-X (50 mg of active-ingredient-a and 10 mg of active-ingredient-b) intravenously every 6 weeks …

Example 2

2.1 Recommended Dosage

The recommended initial dosage of drugoxide for oral suspension is 1 packet (4 grams of active-ingredient-a and 2 grams of active ingredient-b) daily for the first 4 weeks …

FCDP = fixed-combination drug product

Recommended Dosage for Co-packaged Products[1]

- Should identify the recommended dosage for each drug that is co-packaged
- May include some identifying characteristics of a drug if necessary to facilitate safe use

2.x Recommended Dosage

DRUG-X is a co-packaged product containing active-ingredient-a tablets and active-ingredient-b tablets. The recommended oral dosage of DRUG-X is the following:

- In the morning, take 100 mg of active-ingredient-a (one square blue tablet) and 50 mg of active-ingredient-b (one round yellow tablet)
- In the evening, take 100 mg of active-ingredient-a (one square blue tablet)

[1] A co-packaged drug product is a product that contains two or more separate drugs (e.g., two drugs, two biologics, one drug and one biologic) in their final dosage forms that are intended to be used together for a common or related therapeutic purpose and that are contained in a single package or unit

Challenge Questions

Challenge Question #1: What Information Should be Retained Or Removed?

2.X Administration Instructions Regarding Infusion Reactions Including Anaphylaxis

Adverse reactions during DRUG-X administration included flu-like symptoms, dyspnea, hypotension, fever, chills, gastrointestinal symptoms, and skin rashes. Approximately 15% of DRUG-X-treated patients in Trials 1 and 2 experienced an infusion reaction compared with 5% of placebo-treated patients *[see Adverse Reactions (6.1)].* In these trials, 3% of DRUG-X-treated patients developed anaphylaxis. Prior to DRUG-X infusion, administer antihistamines, acetaminophen, and/or corticosteroids *[see Warnings and Precautions 5.x)].*

Challenge Question #2: What Information Should be Retained Or Removed?

2.x Recommended Dosage

While a relationship between dosage and effect has not been established, patients were dosed in a range of 50-200 mg/day in the clinical trials demonstrating the effectiveness of DRUG-X for the treatment of disease-Y.

Challenge Question #3

What information generally must/should be included in the D&A section of Physician Labeling Rule labeling?

A. A statement that the drug is supplied in single-dose vials
B. Information about the dosages studied in the phase 3 clinical trial(s)
C. Usual dosage
D. Route(s) of administration
E. A statement that use is in advisable in patients with mild, moderate, and severe renal impairment

Challenge Question #4

When providing the recommended dosage in patients with renal impairment in the D&A section:

A. Only include the recommended dosage in the renal impairment subpopulations that have a different recommended dosage than patients with normal kidney function

B. Phrase “dosage adjustment in patients with renal impairment” is preferred over “recommended dosage in patients with renal impairment”

C. If a drug can be administered in patients who receive hemodialysis, provide the timing of administering the drug in relationship to hemodialysis

Learning Objectives for Day 2: Describe/Discuss (1 of 2)

- Administration instructions included with the recommended dosage
- Recommended monitoring for effectiveness
- Other therapy used before subject drug use and concomitant therapy
- Dosage modifications due to adverse reactions and drug interactions

Learning Objectives for Day 2: Discuss/Describe (2 of 2)

- Recommendations for drug discontinuation when there are withdrawal risks
- Preparation instructions
- Preparation and administration instructions for certain products
- Storage instructions for the prepared product

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Eric Brodsky
Associate Director, Labeling Policy Team
Office of New Drug Policy, Office of New Drugs
CDER | US FDA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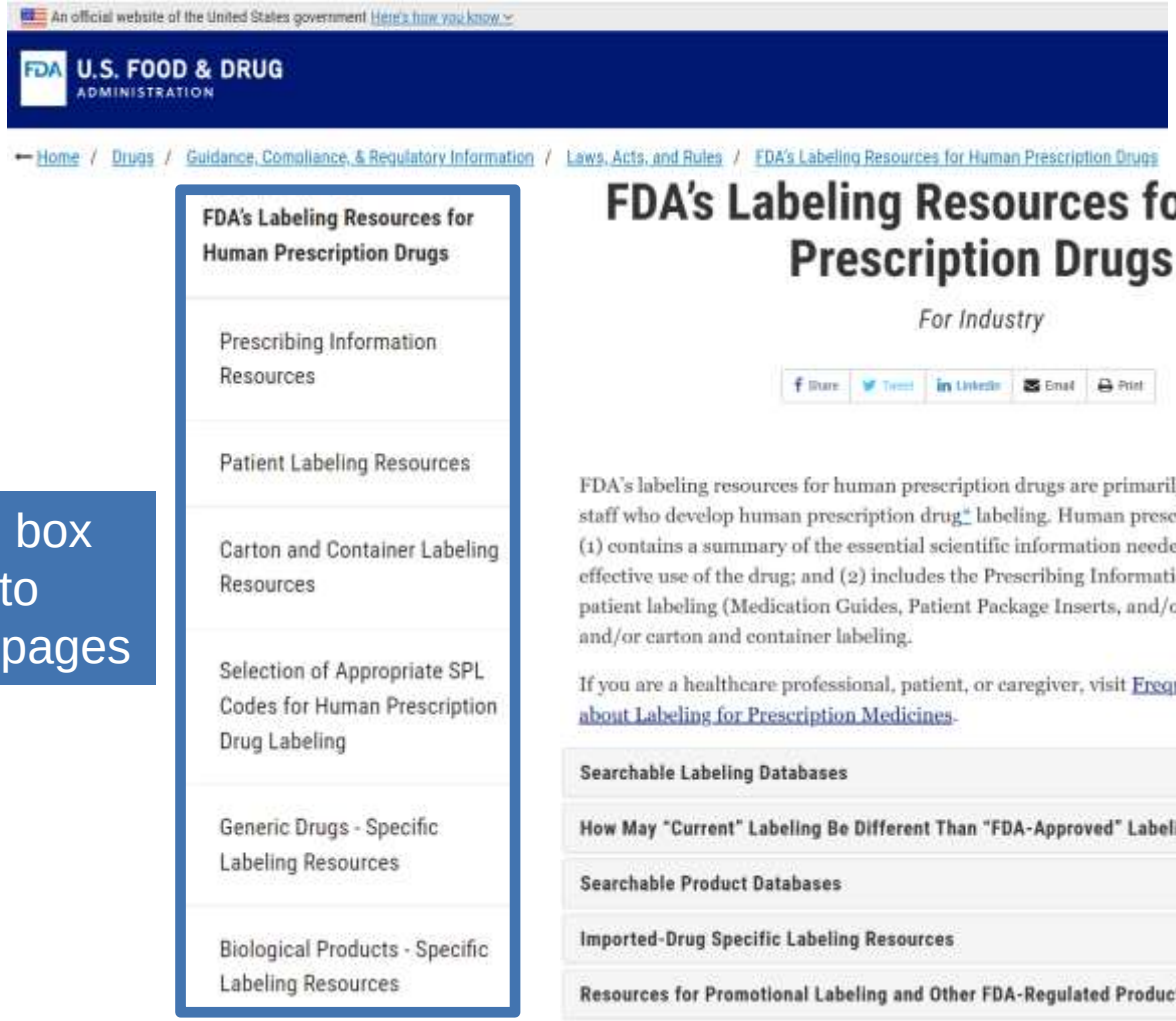
Extra Slides



Left-sided box with links to other webpages

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

FDA's Labeling Resources for Human Prescription Drugs

[1] See the bottom of the FDA's Labeling Resources for Human Prescription Drugs webpage (see https://www.fda.gov/drugs/laws-acts-and-rules/fdas-labeling-resources-human-prescription-drugs)

Prescribing Information Resources

For Industry

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Who is the Audience for This Webpage?

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

What is the Prescribing Information?

When Should Prescribing Information Be Updated?

Prescribing Information Resources webpage available at
https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources

Prescribing Information Resources

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Prescribing Information

- Highlights of Prescribing Information
- Boxed Warning
- 1 Indications and Usage
- 2 Dosage and Administration
- 3 Dosage Forms and Strengths
- 4 Contraindictions
- 5 Warnings and Precautions
- 6 Adverse Reactions
- 7 Drug Interactions

https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources

Prescription Drug Labeling Guidances Published in the Last Year

(February 2022 to January 2023)

Recently Published Labeling Guidances[1] (1 of 3)

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

[1] Published between February 2022 to January 2023

Recently Published Labeling Guidances[1] (2 of 3)

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

[1] Published between February 2022 to January 2023

Recently Published Labeling Guidances[1] (3 of 3)

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

[1] Published between February 2022 to January 2023

Future Draft Labeling Guidances and Future Finalization of Draft Labeling Guidances

Notable Labeling Draft Guidances on CDER's Guidance Agenda[1]

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

[1] See CDER guidance agenda (July 2022) at https://www.fda.gov/media/134778/download

Notable Labeling Draft Guidances We Are Working to Finalize[1]

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

[1] We are actively considering the comments to this draft guidances and will work to finalize this guidance as appropriate.