Small Business & Industry Assistance (SBIA) Webinar
April 20, 2023 (Day 2 of 2)

U.S. FOOD & DRUG ADMINISTRATION

Dosage and Administration Section of Labeling: Part 2 of 2

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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

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 and administration instructions for certain products
- Storage instructions for the prepared product

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DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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

Administration Instructions Included with the Recommended Dosage

Administration Instructions for Orally Administered Drugs

- Include specific instructions on how and when to administer the drug relative to the ingestion of food or food substances
- Include next to the recommended dosage

Example 1

2.1 Recommended Dosage and Administration

[[Include recommended dosage]] Take with or without food *[see Clinical Pharmacology (12.3)]*.

Administration Instructions With Recommended Dosage: Examples 2 and 3

Example 2

2.1 Recommended Dosage and Administration

[[Include recommended dosage]] Administer DRUG-X on an empty stomach, at least 2 hours prior to or 2 hours after food *[see Clinical Pharmacology (12.3)]*.

Example 3

2.1 Recommended Dosage and Administration

[[Include recommended dosage]] Take with a low-fat meal (e.g., meals with 400 calories, 25% fat or less) or on an empty stomach *[see Clinical Pharmacology (12.3)].*

Intravenous Administration Instructions

Include rate of administration and recommended infusion duration. For example:

2.x Recommended Dosage and Administration

The recommended starting intravenous infusion rate for DRUG-X is 1 mg/kg/hour over one hour and then administer as follows (total infusion time is five hours):

- Hour 1 to 2: 3 mg/kg/hour
- Hour 2 to 3: 5 mg/kg/hour
- Hours 3-5: 7 mg/kg/hour

Intravenous Bolus

Include the duration of the intravenous bolus:

2.x Recommended Dosage and Administration

...

The recommended dosage of DRUG-X is 1 mg every 8 hours by intravenous bolus injection (over two-minutes) for two days.

Intramuscular or Subcutaneous Administration (1 of 3)

State the recommended injection site(s) and the rotation, if needed:

2.x Recommended Dosage and Administration

… Administer DRUG-X as a subcutaneous injection in one of the following areas: (1) outer lateral aspect of the upper arm, (2) anterior upper thighs, (3) the upper back, or (4) at least 2 inches from the umbilicus in the abdominal region. Rotate the location of the injection every day.

Intramuscular or Subcutaneous Administration (2 of 3)

If more than one injection is needed to achieve a full dose, provide specific administration instructions:

2.x Recommended Dosage and Administration

The recommended DRUG-X dosage is 300 mg given subcutaneously (two 150 mg subcutaneous injections) every three months into *[[include locations]]*.

Administer the second of the two subcutaneous injections at least two inches from the site of the first subcutaneous injection.

Intramuscular or Subcutaneous Administration (3 of 3)

If the injection depth is important for administration or the injection duration is lengthy (e.g., two minutes or longer), include the recommended injection depth or the recommended duration of the injection, respectively.

2.x Recommended Dosage and Administration
The recommended dosage of DRUG-X is 1,000 mg every two weeks. Administer DRUG-X subcutaneously over approximately 8 minutes.

Administration Instructions: Modified-Release Dosage Forms

- If there are data that demonstrate a risk associated with manipulating the drug, include the following (or similar) statement:

  2.1 Recommended Dosage and Administration
  … Swallow tablets whole. Do not split, crush, or chew the extended-release tablets *[see Clinical Pharmacology (12.3)].*

- If there are no data to inform the risk associated with manipulating the drug but there is concern that modification may alter the drug's safety or effectiveness generally include rationale:

  2.1 Recommended Dosage and Administration
  … Swallow tablets whole. Avoid splitting, crushing, or chewing the extended-release tablets because doing so may compromise the extended-release characteristics, effectiveness, or safety of DRUG-X.

Chewable Tablets Dosage Form:[1]

Include the following (or similar) statement to inform the health care practitioner that chewable tablets must always be chewed or crushed:

2.1 Recommended Dosage and Administration

The recommended DRUG-X dosage is 50 mg once daily. Chew or crush DRUG-X completely before swallowing. Do not swallow the chewable tablets whole [*see Clinical Pharmacology (12.3)].*

[1] Chewable tablets are an oral dosage form that **must** always be chewed and must not be swallowed whole (if it may be chewed, then the dosage form is "tablets"). See the draft guidance for industry *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) (when final, this guidance will represent FDA's current thinking on this topic) and see the guidance for industry *Quality Attribute Considerations for Chewable Tablets* (August 2018).

Tablets for Oral Suspension and Tablets for Oral Solution Dosage Forms[1]

Include a statement noting that these dosage forms should be dispersed in liquid and, if applicable, can also be swallowed whole or chewed:

2.1 Recommended Dosage and Administration

The recommended DRUG-X dosage is 50 mg once daily. These tablets for oral solution may be dispersed in water or fruit juice; swallowed whole; or chewed.

[1] The format "[DRUG] Tablets for Oral Suspension" or "[DRUG] Tablets for Oral Solution" will be used for tablets intended to be dispersed in a liquid before administration. This title will be used even if the tablet may also be chewed or swallowed whole. There will also be a labeling statement indicating all methods of administration. See USP Nomenclature Guidelines, available at https://www.usp.org/sites/default/files/usp/document/uspnomenclature-guidelines.pdf.

System Dosage Forms[1]

Provide the rate of release and the total duration of the drug release, and instructions for application, rotation, and removal, when applicable:

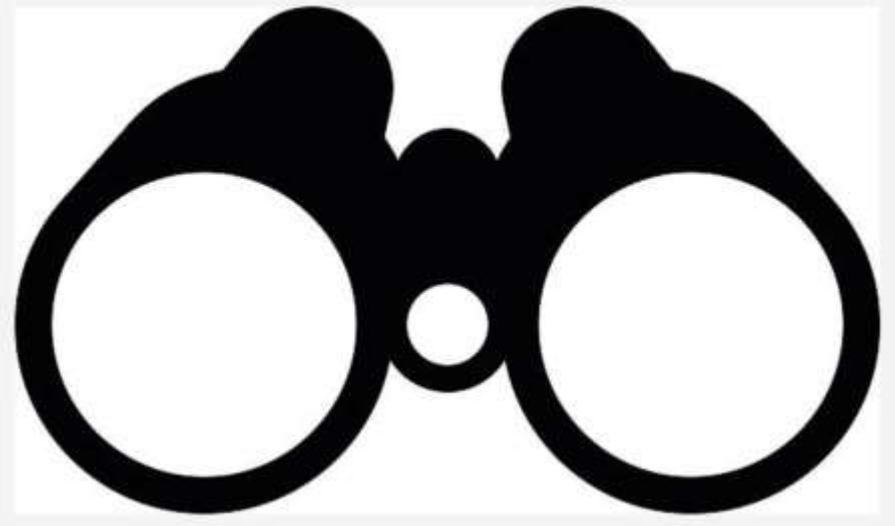
2.1 Recommended Dosage and Administration

The recommended daily dosage of DRUG-X is 5 mg. Administer as follows:

1. Apply one DRUG-X transdermal system (delivers 5 mg of drugoxide over 24 hours) to dry, intact skin below the neck and above the waist for 24 hours
2. Remove the transdermal system after 24 hours
3. Apply another transdermal system for 24 hours to a different location in the same area
4. Repeat steps 1-3

[1] A system dosage form is a drug-containing delivery system that controls the release rate of the drug from the system by diffusion kinetics, active transport, or other means. See the draft guidance for industry *Transdermal and Topical Delivery Systems – Product Development and Quality Considerations* (November 2019) (when final, this guidance will represent the FDA's current thinking on this topic)

Recommended Monitoring for Effectiveness



Monitoring for Effectiveness: Therapeutic Drug Monitoring[1] Include:

- Efficacious or toxic concentration ranges of the drug or metabolites (if established and clinically significant)
- Recommended frequency of monitoring
- Dosage modifications based on concentration levels

[1] Therapeutic drug monitoring is used for some drugs as part of the dosing regimen to achieve or maintain effectiveness or to reduce the risk of adverse reactions (e.g., cyclosporine, digoxin, gentamicin, lithium, phenytoin, tacrolimus, valproic acid, vancomycin)

Therapeutic Drug Monitoring Example

2.x Recommended Therapeutic Drug Monitoring

Obtain plasma trough concentrations of drugoxide after kidney transplant surgery and titrate the DRUG-X dosage to maintain drugoxide concentrations *[see Clinical Pharmacology (12.3)]* within the following therapeutic drug concentration windows:

- Post-surgery to Month 1: 15 ng/mL to 20 ng/mL
- Month 1 to 2: 10 ng/mL to 15 ng/mL
- Month 2 to 6: 7.5 ng/mL to 10 ng/mL
- After Month 6: 5 ng/mL to 10 ng/mL

Therapeutic Drug Monitoring Example

2.x Recommended Therapeutic Drug Monitoring

Monitor serum drugoxide (7 to 10 hours after the morning dose) 4 weeks after initiating DRUG-X, and periodically thereafter. Based on the following serum drugoxide measurements, determine if DRUG-X should be continued or discontinued:

- 300 - 1080 ng/dL: continue dosage
- < 300 ng/dL: increase daily dosage by x mg
- > 1080 ng/dL: decrease daily dosage by x mg

Other Therapy Used Prior to Subject Drug Use and Concomitant Therapy

Other Therapy Used Before Subject Drug Use

Include important dosage- and administration-related information about other drugs before initiating subject drug

2.1 Recommended Premedication

Prior to DRUG-X administration, premedicate to reduce the risk of cytokine release syndrome and hypersensitivity reactions *[see Warnings and Precautions (5.1, 5.2)]:*

- Dexamethasone 20 mg intravenously (or similar corticosteroid) at least one hour prior to DRUG-X infusion
- Diphenhydramine 50 mg intravenously (or similar antihistamine) at least 30 minutes prior to DRUG-X infusion

Required Concomitant Therapy

If the subject drug is indicated for use only in conjunction with concomitant therapy, the D&A section should identify the concomitant therapy

1 INDICATIONS AND USAGE
DRUG-X is indicated, in combination with drug-a and drug-b, for the treatment of adults with Disease-A.

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosage and Administration
The recommended dosage of DRUG-X, in combination with drug-a and drug-b, is 10 mg given intravenously once weekly …

Dosage Modifications

Recommended Dosage vs. Dosage Modifications

Recommended dosage in specific populations

Dosage modifications due to adverse reactions or drug interactions

Dosage Modifications

Dosage modifications include dosage reduction, dosage interruption, or permanent discontinuation

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 Drug Interactions

Dosage Modifications Intended to Reduce the Risk of Adverse Reactions

Dosage Modifications Intended to Reduce the Risk of Adverse Reactions

2.x Dosage Modifications for Adverse Reactions

See Table 1 for DRUG-X dosage modifications for adverse reactions.

Table 1: DRUG-X Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity[1]	Dosage Modification
Pneumonitis	Grade 2	Reduce to 10 mg every other week
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2 or 3	Withhold; resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.
	Grade 4	Permanently discontinue

[1] Based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

Dosage Modifications Intended to Reduce the Risk of Adverse Reactions

2.x Dosage Modifications for Hypersensitivity Reactions
For a *[see Warnings and Precautions (5.1)]*:

- *Severe* hypersensitivity reaction (e.g., anaphylaxis), immediately discontinue DRUG-X administration
- *Mild to moderate* hypersensitivity reaction, slow the infusion rate and/or reduce the DRUG-X dosage to 1 mg/kg given intravenously

5.x Hypersensitivity Reactions
Hypersensitivity reactions, including anaphylaxis, have been reported in 3 (5%) of DRUG-X-treated patients in Trials 1, 2, and 3 *[see Clinical Studies (14)] …*

Tests, Procedures, and/or Evaluations Needed Before or During Treatment

D&A Section	Include in Other Sections of Labeling (e.g., W&P Section)
Required or necessary before drug initiation	Needed during treatment with the drug but do not modify the dosage or administration
If it can result in modification of dosage or administration	

Dosage Modifications for Drug Interactions

Dosage Modifications for Drug Interactions (DI) in D&A Section

- Include when there is sufficient information to support specific recommendations to modify the dosage or administration of subject drug to reduce the risk of a DI
- Include recommendations for use of the subject drug for the remaining subgroups in the drug interacting class (e.g., strong CYP3A inhibitors) even if there are no specific dosage or administration recommendation

If There Are Dosage Modifications for …

- One drug, drug class, or food consider including a specific subsection title:

  2.x Dosage Modifications for CYP3A Inhibitors

- Two or more drugs, drug classes, or foods, consider including the dosage modifications in one subsection with appropriate headings:

  2.x Dosage Modifications for Drug Interactions

  CYP3A Inducers

  …

  P-glycoprotein Inhibitors

  …

Drug Interaction Information in Labeling

2.x Dosage Modifications for CYP3A Inhibitors

Avoid concomitant use of DRUG-X with strong CYP3A inhibitors. Reduce the DRUG-X dosage to 100 mg once daily when used concomitantly with moderate CYP3A inhibitors *[see Drug Interactions (7.x)].*

7.x Effects of Other Drugs on DRUG-X

Table 1 describes drug interactions where concomitant use of another drug affects DRUG-X.

Strong and Moderate CYP3A Inhibitors	
Prevention or Management	Strong CYP3A Inhibitors: Avoid concomitant use.
	Moderate CYP3A Inhibitors: Reduce the DRUG-X dosage *[see Dosage and Administration (2.4)]*.
Clinical Effect(s)	Drugozide-x is a CYP3A substrate. Strong or moderate CYP3A inhibitors increase drugozide-x exposure *[see Clinical Pharmacology (12.3)]*, which may increase the risk of DRUG-X adverse reactions.

Recommendations For Drug Discontinuation When There Are Withdrawal Risks

Recommendations For Drug Discontinuation When There Are Withdrawal Risks[1]

2 DOSAGE AND ADMINISTRATION

…

2.x Discontinuation of DRUG-X

… When discontinuing DRUG-X, decrease the daily oral dosage by 5 mg once weekly until discontinued *[see Drug Abuse and Dependence (9.3)].*

9 DRUG ABUSE AND DEPENDENCE

…

9.3 Dependence

… If DRUG-X is abruptly discontinued in a physically dependent patient, a withdrawal syndrome may occur, characterized by chills, restlessness, lacrimation, rhinorrhea, perspiration, myalgia, and mydriasis … *[see Dosage and Administration (2.x)].*

[1] Withdrawal reactions may also be including in a warning

Preparation Instructions

Preparation Instructions

- Must contain specific directions for preparation of the drug[1] before administration, if needed
- Should identify compatible diluents and provide volume of diluent needed for reconstitution

2.x Preparation Instructions

Reconstitute DRUG-X in the following manner:

a. …

b. Reconstitute each vial with 2.5 mL of Sterile Water for Injection by directing the diluent flow to the inside wall of the vial to avoid foaming.

c. Gently roll and tilt vial(s) to reconstitute DRUG-X and avoid foaming.

[1] 21 CFR 201.57(c)(3)(iv).

Identifying the Diluents

- When identifying compatible diluent(s) for reconstitution or dilution use the established name and strength of diluent
- If there is a USP monograph for the diluent, use the USP monograph title. For example, use:
  - “0.9% Sodium Chloride Injection” instead of “normal saline” or “saline”.
  - “5% Dextrose Injection” instead of “dextrose in sterile water”
  - “0.9% Sodium Chloride Irrigation” instead of “Sterile isotonic sodium chloride 9 mg/mL solution”

Preparation Instructions

Include the strength of the final dosage form in terms of mg of active ingredient per mL

If a Drug Requires	Identify Volume
Only reconstitution before administration	Reconstituted solution to be withdrawn and administered
Only dilution before administration	Diluted solution to be withdrawn and administered
Both reconstitution and dilution before administration	Reconstituted solution to be withdrawn (for dilution) and diluted solution to be withdrawn and administered

Preparation of a Product Stored in the Refrigerator or Freezer (1 of 2)

If applicable, discuss the time needed to allow a refrigerated or frozen product (supplied or prepared) to warm to room temperature before use:

2.x Preparation Instructions

Remove the DRUG-X vial from the refrigerator and allow the vial to sit for 30 to 40 minutes at room temperature 20ºC to 25ºC (68ºF to 77ºF) before use. Do not use an external heat source to heat the product because heat may damage the product.

Preparation of a Product Stored in the Refrigerator or Freezer (2 of 2)

If a refrigerated reconstituted or diluted product is removed from the refrigerator, include recommendations on the length of time the reconstituted or diluted product can be kept at room temperature before use and appropriate discard instructions:

2.x Preparation Instructions
After removal of the DRUG-X reconstituted solution from the refrigerator, use the reconstituted solution within 2 hours or discard.

Preparation and Administration Instructions for Certain Products

Preparation and Administration Instructions: Parenteral Products[1]

- If specific container(s) or device(s) are needed for preparation or administration, include this information
- If the container(s) or device(s) will not be approved under the application, describe the types of container(s) or device(s) in general terms rather than identifying a specific manufacturer's product
- If there are data that provide important incompatibility information about the use of the drug with specific containers or devices, include information on which containers or devices are incompatible with the drug.

[1] Parenteral is a general route of administration that is characterized by injection through the skin or other external boundary tissue or implantation within the body. Specific parenteral routes include intra-arterial, intra-articular, intracisternal, intramuscular, intraocular, intrathecal, intravenous, intraventricular, and subcutaneous. See USP General Chapter <1151> *Pharmaceutical Dosage Forms.*

Preparation/Administration of Solid Oral Dosage Forms With Qualified Liquids or Soft Foods

If a liquid or soft food is qualified as a vehicle to be used for the administration of a solid oral dosage form, include directions for using the recommended liquid or soft food vehicle to administer the drug:

2.x Preparation and Administration Instructions

Swallow DRUG-X whole. However, for patients who have difficulty swallowing capsules:

- Carefully open the capsule and sprinkle the entire contents of the capsule onto room temperature applesauce - between a teaspoonful (5 mL) and a tablespoonful (15 mL).
- Stir the mixture for 10 seconds.
- Consume the entire mixture within 30 minutes of mixing. Do not save the mixture for later use.

Preparation and Administration of Oral Dosage Forms Via Enteral Tubes

- If there are adequate data that support the use of an oral dosage form via enteral tube, include information on the preparation and administration of the oral dosage form via the enteral tube
- Include (as applicable):
  - Characteristics of the recommended enteral tube
  - Drug and enteral tube preparation instructions
  - Recommended administration instructions
  - Instructions on maintenance of the enteral tube following administration.

Preparation and Administration of Oral Dosage Forms Via Enteral Tubes[1]

To administer DRUG-X tablets (all strengths) via nasogastric tube (ngt) (French size 8 or larger) follow these steps *[see Clinical Pharmacology (12.3)]:*

- Place one tablet in a catheter-tip syringe and draw up 20 mL of distilled water.
- Shake gently to allow for a quick dispersal.
- After the tablet has dispersed, swirl the catheter-tip syringe gently to keep the microgranules from settling, and immediately inject the mixture through the ngt into the stomach. Do not save the water and microgranule mixture for later use.
- Refill the catheter-tip syringe with approximately 10 mL of distilled water, shake gently, and flush the ngt.
- Refill the catheter-tip syringe again with 10 mL of distilled water, swirl gently, and administer.

[1] See the draft guidance for industry *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations* (June 2021). When final, this guidance will represent the FDA's current thinking on this topic.

Storage Instructions for the Prepared Product

Storage Instructions for the Prepared Product vs. Supplied Product

- The HOW SUPPLIED/STORAGE AND HANDLING section must include, as appropriate, storage conditions of the supplied drug[1] (e.g., unopened package).
- The D&A section “must contain specific direction on … preparation .. of the dosage form”[2] and should not include storage of the supplied drug

[1] 21 CFR 201.57(c)(17)(iv).
[2] 21 CFR 201.57(c)(3)(iv).

Storage Instructions for the Reconstituted or Diluted Product (1 of 2)

- Include the storage conditions needed to maintain the stability and the administration conditions of the reconstituted product and/or the diluted product, when important
- Include the duration for which the reconstituted or diluted product can be safely used under these storage conditions, and an appropriate discard statement

Storage Instructions for the Reconstituted or Diluted Product (2 of 2)

2.x Storage Instructions for the Reconstituted Product

If the DRUG-X reconstituted solution is not used immediately, store at controlled room temperature at 20ºC to 25ºC (68ºF to 77ºF) for up to 6 hours or refrigerate at 2ºC to 8ºC (36ºF to 46ºF) for no more than 24 hours. Discard the unused DRUG-X reconstituted solution after 6 hours if stored at controlled room temperature or after 24 hours if refrigerated.

Challenge Questions

Challenge Question #1

What information about adverse reactions (AR) should be included in the D&A section:

A. Detailed description of the clinically significant ARs
B. All steps to take to prevent, mitigate, monitor for, or manage AR
C. Dosage reduction intended to reduce the risk of ARs
D. Nothing. AR information should not be included in labeling
E. AR data from the clinical trials

Challenge Question #2

What information about drug interactions (DI) must/should be included in the D&A section:

A. Description of the clinically significant DI with digoxin
B. Dosage modifications due to CYP3A4 inhibitors
C. Clinical implications of the clinically significant DI
D. Nothing. DI information should not be included in labeling
E. A and B

Challenge Question #3

Which answer is **not** correct?

A. Include dilution instructions in D&A section
B. Include reconstitution instructions in the D&A section
C. Include dilution instructions in the HOW SUPPLIED/STORAGE AND HANDLING section
D. Include storage information about supplied product in the HOW SUPPLIED/STORAGE AND HANDLING section

Closing Thoughts

When you are submitting labeling (e.g., new labeling, or modifying existing labeling), please ensure the D&A section contains the dosage- and administration-related information needed for safe and effective use of a drug

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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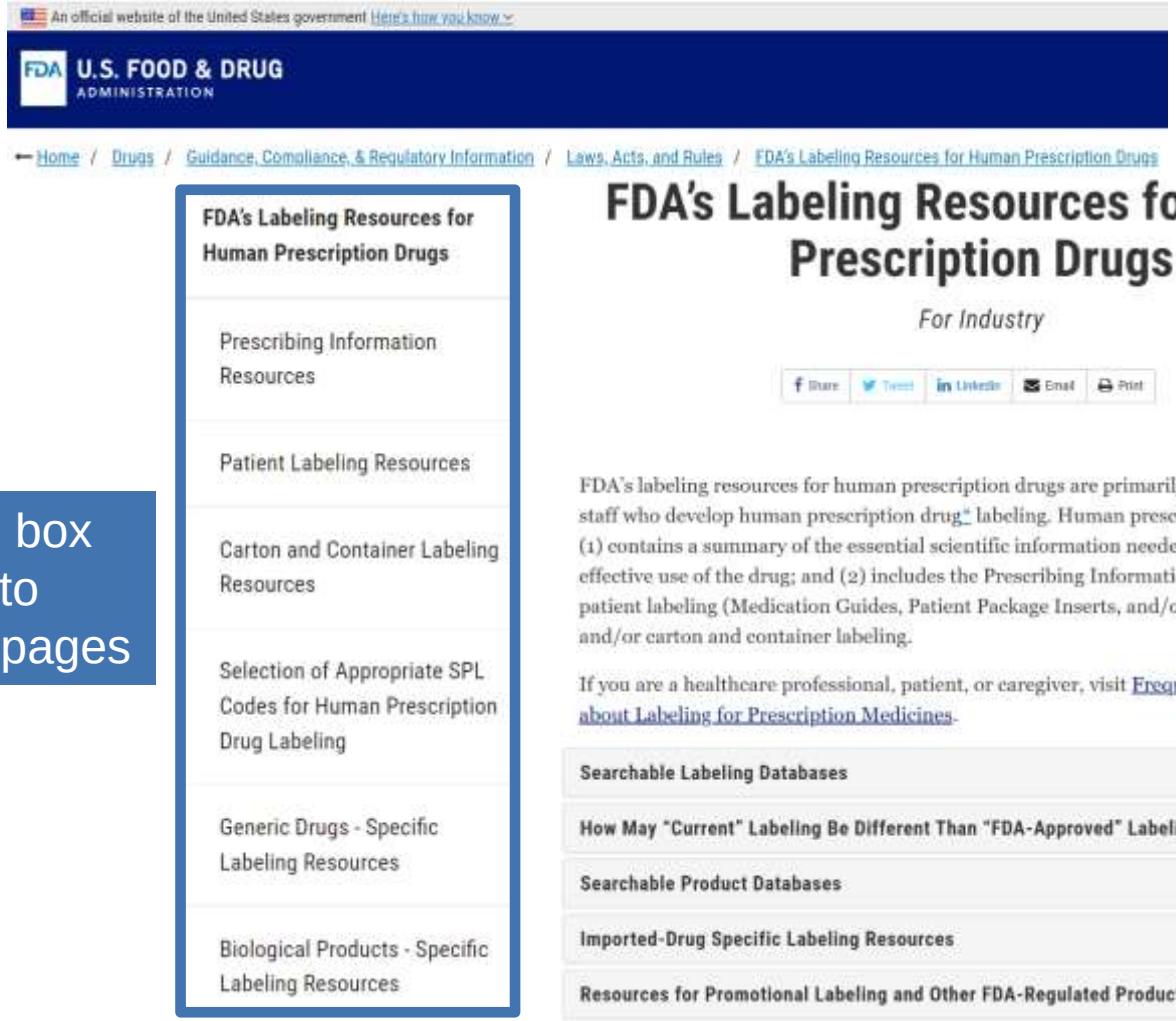
Extra Slides



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.