Guidance for Industry

Labeling OTC Human Drug Products — Questions and Answers

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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OTC

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Contains Nonbinding Recommendations

Guidance for Industry[1] Labeling OTC Human Drug Products — Questions and Answers

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products who have questions about the standardized labeling content and format requirements set forth in 21 CFR 201.66. The examples in this guidance illustrate various format and content features of the labeling requirements and show how OTC drug monograph labeling information can be converted to the OTC Drug Facts labeling format. This guidance is one in a series of Food and Drug Administration (FDA) guidances intended to facilitate compliance with the labeling requirements in § 201.66.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

In the *Federal Register* of March 17, 1999 (64 FR 13254), the FDA published a final regulation (§ 201.66) establishing standardized content and format for the labeling of OTC drug products (Drug Facts labeling). The Drug Facts labeling for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use OTC drug products safely and effectively. The Drug Facts labeling regulation in § 201.66 covers all OTC drug and drug-

[1]This guidance has been prepared by the Office of Nonprescription Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

cosmetic products, whether marketed under a new drug application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or drug product not yet the subject of a final OTC drug monograph).[2]

The regulation is divided into two main parts: 1) content requirements in paragraph (c) (i.e., headings, subheadings, and the order in which certain information must be listed); and 2) format requirements in paragraph (d) (i.e., graphic specifications). This guidance primarily discusses questions received from manufacturers, packers, and distributors relating to these requirements, which are set forth in §§ 201.66(c) and (d), respectively.

III. CONTENT LABELING REQUIREMENTS

The following questions and answers address the OTC Drug Facts labeling requirements in § 201.66. Tables A and B in Appendix A list the specific section-by-section requirements in §§ 201.66(c) and (d) as well as the expectations for implementing the requirements in the regulation. These tables should be referred to for details on specific requirements.

Question 1: ***What labeling information do the regulations require for all OTC drug products?***

Answer 1: Section 201.66 requires that all OTC drug product labeling contain the following information about the drug product. This information must be organized according to the following headings and must be presented in the following order:

1. Title (**Drug Facts** or **Drug Facts** (continued))
2. Active ingredient(s)
3. Purpose(s)
4. Use(s)
5. Warning(s)
6. Directions
7. Other information
8. Inactive ingredients
9. Questions? or Questions or comments? (optional)

This information must appear on the outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper. (If the Drug Facts information appears on the outside container or wrapper of the retail package, its use on the immediate container is optional. See Appendix A.)

[2] The text of § 201.66 can be found at the Division of Dockets Management Web site located at http://www.fda.gov/cder/otc/label/label-fr-reg.htm.

Question 2: ***Why must the title* Drug Facts (continued) *appear on each subsequent panel in which the Drug Facts labeling appears?***

Answer 2: The title **Drug Facts** must appear on the first panel and the title **Drug Facts** (continued) must appear on each subsequent panel to ensure that the person reading the labeling can follow through to the end of the labeling (§ 201.66(c)(1)).

Question 3: ***What indications can be included in the* Use(s)*) section if the product is a drug-cosmetic product?***

Answer 3: For drug-cosmetic products, only the drug-related indications can be included in the **Use(s)** section.

Question 4: ***Is there a required order for listing subject-specific warnings?***

Answer 4: Section 201.66(c) requires that warnings in paragraph (c)(5) appear in the order listed.

Question 5: ***What information must appear under the Warnings subheading* Do not use*? Can I convert the text of existing warnings in final OTC drug monographs or approved applications to the bulleted statement format under this subheading?***

Answer 5: The **Do not use** subheading (§ 201.66(c)(5)(iii)) is reserved for: 1) drug products that should not be used unless a previous diagnosis has been made by a doctor; or 2) drug products that should not be used under any circumstances by certain consumers, regardless of whether a doctor or health care professional is consulted.

Manufacturers can convert existing formats to the Drug Facts labeling format. For example, the current warning "Do not use this product unless a diagnosis of asthma has been made by a doctor" can be placed under the subheading **Do not use** and shortened to read "unless a diagnosis of asthma has been made by a doctor" (i.e., "**Do not use** unless a diagnosis of asthma has been made by a doctor").

Question 6: ***How can I convert a lengthy warning under the subheading* Ask a doctor before use if you have *into the bulleted text format?***

Answer 6: Here is an example: The warning for oral and topical antitussives states: "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor." Under this subheading, this warning can be converted into bulleted statements as follows:

Ask a doctor before use if you have
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts as occurs with smoking, asthma, chronic bronchitis, or emphysema

Question 7: ***How can I convert the OTC antihistamine drug product warning "Do not take this product if you are taking sedatives or tranquilizers without first consulting your doctor" into bulleted text?***

Answer 7: This warning could appear as follows:

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

or

Ask a doctor or pharmacist before use if you are taking • sedatives
• tranquilizers

Question 8: ***What information must appear under the subheading* When using this product? *How can I convert text of existing required warnings to bulleted text format under this subheading?***

Answer 8: This subheading must be used for side effects that consumers may experience (§ 201.66(c)(5)(vi)). It identifies substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car) that should be avoided while using the drug product. This subheading also must include warnings for drugs in dispensers pressurized by gaseous propellants. Such information would appear in bulleted text format as follows:

- may cause drowsiness [or may appear as: • drowsiness may occur]
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect [or may appear as: • alcohol, sedatives, and tranquilizers may increase drowsiness]
- do not puncture or incinerate; contents under pressure.

Question 9: ***What information must appear under the subheading* Stop use and ask a doctor if?**

Answer 9: You must include under the **Stop use...** subheading any signs of toxicity or other reactions that would require a consumer to immediately stop using the drug product (§ 201.66(c)(5)(vii)). For example, the bulleted statement "you get nervous, dizzy, or sleepless" would appear in this section.

Question 10: ***Where must I put warnings required in an applicable OTC drug monograph, in other OTC drug regulations, or in an approved drug application that do not otherwise fit under the* Warnings *heading or subheadings?***

Answer 10: Such warnings must be placed in the Drug Facts **Warnings** section. For example, chlorofluorocarbons (CFC) warnings, required in certain approved drug applications, must be put in the **Warnings** section. The warning would appear as follows: "Contains CFC-[insert number] and CFC-[insert number], substances that harm public health and the environment by destroying ozone in the upper atmosphere" (§ 201.320).

Question 11: ***Where must pregnancy information and related warnings be placed?***

Answer 11: When applicable, these types of warnings also must be placed in the second-to-last subsection of the **Warnings** section. Warnings may include one or more of the following:

- The pregnancy/breast-feeding warning
- The third trimester warning for drug products containing aspirin or carbaspirin calcium
- The third trimester warning in approved drug applications for drug products containing ketoprofen, naproxen sodium, or ibuprofen (if not intended exclusively for use in children)

Question 12: ***Should all OTC drug product labeling include the* Keep out of reach of children *and the accidental overdose/ingestion warnings?***

Answer 12: In most cases, these warnings are required for OTC drug products and therefore must be included in the Drug Facts box. In a few special instances, the **Keep out of reach of children** warning may be omitted. (See lipstick with a sunscreen in § 352.52(f)(1)(vi).) The accidental overdose/ingestion warning also may be omitted in some instances, as specified in an applicable OTC drug monograph or approved drug application.

Question 13: ***Do I have to present information under* Directions *in a table format?***

Answer 13: Depending on the drug product, the directions can appear completely in a table, as a number of bulleted statements, or as a combination of a table and bulleted statements. For example, a table format must be used when dosage directions are provided for three or more age groups or populations (§ 201.66(d)(9)). Dosage directions provided for one or two age groups or populations can be presented using bulleted statements. However, a table format can be used for two age groups or populations if it helps make the presentation of the information clearer and easier to read.

Under this heading, information other than age groups should appear as bulleted statements. For example:

- shake well
- drink a full glass (8 oz) of liquid with each dose
- do not use more than directed

adults and children 12 years and older	2 tablets every 6 hours
children 6 – 12 years	1 tablet every 6 hours
children under 6 years	ask a doctor

Question 14: ***What information must be included under the heading* Other information?**

Answer 14: This section must include information that is not included under the other headings or subheadings, but is required or is made optional under an OTC drug monograph, other OTC drug regulation, approved drug application, statute, or OTC drug guidance.

If applicable, the first bulleted statement under this heading must include calcium, magnesium, potassium, and sodium to read as follows: "each (insert appropriate dosage unit) contains: [in bold type] (insert name(s) of ingredient(s) and quantity of each ingredient)" (§§ 201.70, 201.71, 201.72, and 201.64, respectively). See also § 201.66(c)(7)(i).

If applicable, phenylalanine/aspartame content shall appear as the next item as follows: "Phenylketonurics: Contains Phenylalanine (insert quantity) mg per (insert appropriate dosage unit)." This statement must be listed as the first bulleted statement under this heading or the second bulleted statement if Ca, Mg, K, or Na is (are) present. For example:

Other information

- **each tablet contains:** calcium 10 mg, magnesium 10 mg, and sodium 15 mg
- Phenylketonurics: Contains Phenylalanine 10 mg per tablet
- [insert storage conditions] if applicable
- [insert tamper-evident statement]

Question 15: ***Where must the tamper-evident statement appear in my OTC drug product labeling?***

Answer 15: The tamper-evident statement must be prominently placed on the drug product package to alert consumers about the drug product's tamper-evident features (21 CFR 211.132). The tamper-evident statement describes the tamper-evident feature of the drug product package and advises consumers that, if the feature is breached or missing when the drug product is purchased, tampering may have occurred. Tamper-evident packaging with an appropriate labeling statement will be more likely to protect consumers because the consumer will be in a better position to detect

tampering when he or she has knowledge that a tamper-evident feature has been incorporated into the drug product design. We allow flexibility in the placement of this statement on the package and do not require that it be included within the Drug Facts section. However, if included in this section, the statement must appear under the heading "**Other information**" (see § 201.66(c)(7)).

We also noted in the final rule preamble for the Drug Facts regulation that many drug products are now marketed with *peel back* or *fold out* labels affixed to the drug product package and that these labels could be used to accommodate all of the FDA required information in the Drug Facts section (64 FR 13254 at 13268; March 17, 1999). These types of labels were not in use at the time the tamper-evident requirements became effective. Recently, interested parties have inquired whether the tamper-evident statement may be included in a Drug Facts section that appears in such peel back or fold out labels. We believe that the goals of the tamper-evident statement would likely not be achieved if the statement only appears in a peel back or fold out label and is not clearly visible without peeling back or folding out the label.

It is important that the consumer view the tamper-evident statement before purchase and use of the drug product so that he or she will be better aware of the tamper-evident features and any signs of tampering. Once the consumer opens the tamper-evident package, the tamper-evident features have been breached. If the consumer has failed to examine these features before opening, then the consumer will likely not know if there were any signs of tampering. A tamper-evident statement inside a peel back or fold out label that is not visible on the outside of the package is unlikely to be viewed before breach of the tamper-evident feature. The consumer may not be aware to peel back or unfold this label to view the tamper-evident statement before opening the package. Thus, we recommend that the statement not appear within the Drug Facts box in a peel back or fold out label if the statement would not be clearly visible without peeling back or folding out the label. We recommend instead in these circumstances that the tamper-evident statement be outside the Drug Facts box in another part of the label where the statement is clearly visible without further manipulation of that label.

Question 16: ***Do I have to list the inactive ingredients in my OTC drug product labeling in alphabetical order?***

Answer 16: It depends.

For OTC drug products that are not also cosmetic products, the established name of each inactive ingredient must be listed in alphabetical order (§ 201.66(c)(8)). For example, the **Inactive ingredients** section would appear as follows:

> **Inactive ingredients** colloidal silicon dioxide, FD&C blue #1 lake, hydroxypropyl methylcellulose, lactose, magnesium stearate, polyethylene glycol, povidone, propylene glycol, titanium dioxide

For an OTC drug product that is a drug-cosmetic product, the inactive ingredients must be listed in descending order of predominance in the drug product formulation (§§ 201.66(c)(8) and 701.3(a)). For example, the **Inactive ingredients** section would appear as follows:

> **Inactive ingredients** water, sorbitan isostearate, sorbitol, triethanolamine, stearic acid, barium sulfate, benzyl alcohol, dimethicone, methylparaben, aloe extract, carbomer, disodium EDTA

Question 17: ***Do I have to include a* Questions? *section in the Drug Facts box or similar enclosure?***

Answer 17: No. Although this heading and subsequent information are not required, we encourage all manufacturers, packers, and distributors to include in this section a telephone number of a source to answer questions about the drug product or to receive reports of adverse events associated with the use of the drug product.

Although not permitted to appear in or otherwise interrupt the required Drug Facts labeling information, brand names or drug product attributes can appear in the telephone number and/or in the Web site address, if used. However, if the telephone number appears as letters of the brand name or drug product attribute, we recommend that the manufacturer also include the numerical representation of the telephone number in this section.

IV. FORMAT LABELING REQUIREMENTS[4]

Question 18: ***How must the content labeling requirements be presented within the Drug Facts box or similar enclosure?***

Answer 18: All features of the Drug Facts box or similar enclosure and the required content information must be presented according to graphic specifications, which are listed in Table B in Appendix A (see also §§ 201.66(c) and (d)).

Question 19: ***Can I use bold type for any information I consider needs greater prominence?***

Answer 19: We recommend that you avoid using bold type in the immediate area where existing regulations require specific text be in bold type.

Question 20: ***How should fractions be expressed within the Drug Facts box?***

Answer 20: Fractions (e.g., 1/2) can be expressed in mathematical notation or text format (i.e., one-half). The text must be in the same single, clear, easy-to-read type style and

[4] See Table B in Appendix A for specific format labeling requirements in § 201.66(d).

type size used for the other text included in the Drug Facts box. If expressed in mathematical notation, each component of the numerical notation must be no smaller than 6-point type.

Question 21: ***How should I arrange additional text related to a single bulleted statement?***

Answer 21: We recommend that additional text be formatted as indented sub-bulleted statements. For example:

Uses
- temporarily relieves pain and itching due to:
  - insect bites • minor skin irritations
- dries the oozing and weeping of:
  - poison ivy • poison oak • poison sumac

Question 22: ***Can I begin a bulleted statement on the same line as a heading or subheading?***

Answer 22: Yes. However, no bulleted statement or text can appear on the same line as the **Warnings** heading.

Question 23: ***Should bulleted statements be left justified when using the standard labeling format?***

Answer 23: Yes. The first bulleted statement on each horizontal line of text must be left justified, except if the bulleted statement appears on the same line of an appropriate heading or subheading (§ 201.66(d)(4)). Any bulleted statements that do not fit entirely on a multi-bulleted line should begin left justified on the following line. (Note: no bulleted statement or text can appear on the same line as the **Warnings** heading.) For example:

Ask a doctor before use if you have
- heart disease • glaucoma • high blood pressure
- thyroid disease • diabetes
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Question 24: ***Should bulleted statements be aligned with the bulleted statements on the previous line when using the modified labeling format?***

Answer 24: No. Using this format, bulleted statements do not need to be aligned and can continue to the next line of text (§ 201.66(d)(10)(iv)). For example:

Ask a doctor before use if you have • heart disease • glaucoma • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • a breathing problem such as emphysema or chronic bronchitis

Question 25: ***Where can I find guidance on the use of a column format as part of the new OTC drug labeling requirements?***

Answer 25: The guidance for industry *Labeling OTC Human Drug Products Using a Column Format* is available on the CDER Web site.[3] A written request for a copy can be sent to the Division of Drug Information, Center for Drug Evaluation and Research, FDA, 10903 New Hampshire Avenue, Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002.

Question 26: ***How can I obtain copies of other FDA labeling guidances relating to the new OTC drug labeling requirements?***

Answer 26: Copies of related guidances are available on the Internet,[4] or send a written request for single copies to the Division of Drug Information (see address above).

Question 27: ***How must I list ingredients under the heading*** **Active ingredient(s)*****?***

Answer 27: The ingredients must be listed in alphabetical order (§ 201.66(d)(6)).

Question 28: ***How should I list under the heading*** **Purpose(s)** ***ingredients with the same pharmacological action?***

Answer 28: When more than one active ingredient has the same purpose, the information can be presented in a manner that readily associates each active ingredient with its purpose (by using brackets, dot leaders, or other graphical features). For example:

Active ingredients	**Purpose**
Homosalate 6% }	
Oxybenzone 3% }	Sunscreen
Padimate O 2% }	

Question 29: ***How should I list inactive ingredients that may or may not be contained in my drug product?***

Answer 29: These ingredients should be listed in alphabetical order along with those ingredients that are contained in your drug product. We recommend that you place an asterisk next to those ingredients that, depending on the source, may or may not be contained

[3] See http://www.fda.gov/cder/guidance/index.htm.

[4] Ibid.

in the drug product (e.g., acacia*, dextrose*, sucrose, xanthum gum*). The asterisk should be referenced at the bottom or end of the inactive ingredient section in the Drug Facts box, with the notation "* contains one or more of these ingredients" (if more than one ingredient may or may not be in the drug product), or "* may contain this ingredient" (if only one ingredient may or may not be in the drug product), whichever is appropriate.

We recommend that for drug product labeling using the standard labeling format as described in §§ 201.66(d)(1) through (d)(9), the statement ("* contains one or more of these ingredients," or "* may contain this ingredient," whichever is appropriate) should be left justified at the end of the inactive ingredient section. The type size of these statements must be at least 6-point type. For drug product labeling that uses the modified format as described in § 201.66(d)(10), the asterisk statement could appear on the same line as the last listed inactive ingredient if separated from the last listed ingredient by at least two square ems.[5]

Listing too many alternative ingredients could be misleading and may cause consumer confusion. To avoid such confusion, manufacturers, packers, and distributors may wish to consider using a second set of labels for drug products with a lengthy list of different inactive ingredients.

Additionally, to provide consumers with the opportunity to learn if an ingredient is in the lot number of the drug product, we recommend that the optional information in § 201.66(c)(9) (**Questions?** or **Questions or comments?** followed by the telephone number of a source to answer questions about the drug product) be included in the labeling.

Manufacturers, packers, and distributors are also reminded to follow all applicable current good manufacturing practice regulations in 21 CFR part 211 for finished pharmaceuticals so that manufacturers maintain appropriate records showing which lot numbers of the drug product contain which inactive ingredients.

Question 30: ***Can I use a pictogram or graphical image such as the Universal Product Code (UPC) symbol within the Drug Facts box?***

Answer 30: No. The only pictogram that may be included within the Drug Facts information is a telephone or telephone receiver before the **Questions?** heading. Pictograms and graphical images such as the UPC symbol cannot appear in, or in any way interrupt, the information required in the Drug Facts labeling (§ 201.66(d)(7)). They can appear outside the Drug Facts box. The following examples illustrate how the UPC code can be placed in relation to the Drug Facts box.

[5] Two square ems are two squares of the size of the letter M. (See § 201.66(d)(4).)

Illustration 1.

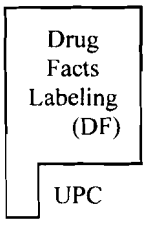
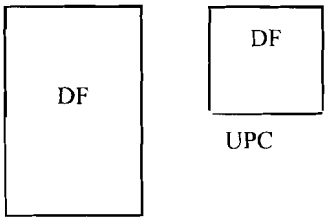


Illustration 2. (showing second panel)



Question 31: When can I use the modified labeling format?

Answer 31: When the required Drug Facts content information printed in the standardized format plus any other FDA required information for drug or drug-cosmetic products, other than information required to appear on the principal display panel, requires more than 60 percent of the total surface area available to bear labeling (§ 201.66(d)(10)).

Question 32: What is the difference between the standard and modified labeling formats?

Answer 32: Table 1 illustrates the differences between the two labeling formats.

Table 1. Standard Versus Modified Labeling Format

Labeling Element	**Standard Format**	**Modified Format**
Drug Facts box	Set off by barline	Barline may be omitted if color contrast used to set off from the rest of the labeling
Drug Facts	Larger than largest type size used in Drug Facts box or similar enclosure	Larger than largest type size used in the Drug Facts box or similar enclosure
Drug Facts (continued)	No smaller than 8-point type	No smaller than 7-point type
Headings	≥8-point type, or 2-point type > point size of text	≥7-point type, or 1-point type > point size of text
Subheadings	No smaller than 6-point type	No smaller than 6-point type
Bulleted text	No smaller than 6-point type	No smaller than 6-point type
Leading	Minimum 0.5-point type	Smaller than 0.5-point type can be used, provided the ascenders and descenders do not touch
Bullets	Minimum 5-point type Vertical alignment	Minimum 5-point type No alignment required

Question 33: What other labeling requirements may be applicable in addition to the standardized content and format requirements in § 201.66?

Answer 33: Additional labeling requirements in 21 CFR parts 201 and 211 that may be applicable are summarized in Table 2 as follows:

Table 2. Additional Labeling Requirements

Paragraph	Description of Paragraph
§ 201.1	Name and place of business of manufacturer, packer, or distributor
§ 201.17	Location of expiration date
§ 201.18	Control numbers
§ 201.60	Principal display panel
§ 201.61	Statement of identity • Established name of drug product • Statement of general pharmacological category(ies) or the principal intended actions • Bold type • Size related to the most prominent printed matter
§ 201.62	Declaration of net quantity of contents
§ 201.20	Declaration of the presence of FD&C Yellow No. 5 and/or FD&C Yellow No. 6
§ 211.132(c)	Tamper-evident labeling

Question 34: When must my product comply with the new OTC drug labeling requirements?

Answer 34: All OTC drug products must be in compliance with § 201.66 at this time, except for the following:

- The FDA has granted a stay of compliance for implementation of the Drug Facts regulation until further notice (67 FR 16304; April 5, 2002) for OTC drug products that contain no more than two doses of an OTC drug product and, because of their limited surface area available to bear labeling, qualify for the labeling modifications set forth in § 201.66(d)(10).

- The FDA has granted a stay of compliance for implementation of the Drug Facts regulation until further notice (69 FR 53801; September 3, 2004) for OTC sunscreen drug products. This stay also applies to OTC sunscreen drug-cosmetic products.

V. EXEMPTIONS AND DEFERRALS

Question 35: Are there any exemptions or deferrals to the Drug Facts labeling requirements?

Answer 35: Section 201.66(e) provides that the FDA on its own initiative or in response to written request from any manufacturer, packer, or distributor may exempt or defer, based on the particular circumstances presented, one or more specific requirements set forth in §§ 201.66(a) through (d), on the basis that the requirement is inapplicable, impracticable, or contrary to public health or safety. The FDA points out that exemption and deferral requests shall: 1) document why a particular requirement is inapplicable, impracticable, or is contrary to public health or safety;

and 2) include a representation of the proposed labeling, including any outserts, panel extensions, or other graphical or packaging techniques intended to be used with the drug product. The FDA reviews each exemption and deferral request submitted and, based on the data submitted, makes a determination whether to grant or deny such requests.

Manufacturers, packers, and distributors should contact the following relevant offices for questions on whether a particular FDA requirement applies to their drug or drug-cosmetic product:

- Office of Compliance (CDER) at
  http://www.fda.gov/cder/Offices/Compliance/default.htm

- Office of Nonprescription Products (CDER) at
  http://www.fda.gov/cder/Offices/OTC/default.htm

- Office of Cosmetics and Colors (CFSAN) at
  http://vm.cfsan.fda.gov/%7Edms/cos-toc.html

APPENDIX A: SUMMARY OF LABELING REQUIREMENTS

Table A. Labeling Content: §§ 201.66(c)(1) through (c)(9)

Paragraph	Description of Paragraph	Comments
(c)(1)	**Drug Facts**, **Drug Facts** (continued)	The title to be used is **Drug Facts** (on subsequent panels use **Drug Facts** (continued)).
(c)(2)	**Active ingredient(s)** (established name, strength/concentration)	For drug-cosmetic products, the drug ingredients are considered the active ingredients, and the cosmetic ingredients are considered the inactive ingredients. See §§ 201.66(b)(2), (b)(8), and (c)(8); and §§ 701.3(a) and (f).
(c)(3)	**Purpose(s)**	If there is no statement of identity or no applicable OTC drug monograph, the ingredient purpose is stated based on its general pharmacological category(ies), or the principal intended action(s) of the drug product.
(c)(4)	**Use(s)**	The use(s) are the specific indication(s) or approved use(s) for the drug product. For drug-cosmetic products, the use in the Drug Facts labeling is attributed only to the drug component. See § 201.66(c)(4).
(c)(5)	**Warning(s)**	Warning information appears in a specific order, under the heading **Warnings**, as applicable. Most warnings follow specific subheadings, as described in (c)(5)(i) through (c)(5)(x).
(c)(5)(i)	**For external/rectal/vaginal use only**	Appears in bold type. In some instances, the **external use only** warning can be omitted. For example, OTC lip protectant drug products that meet the criteria of § 201.66(d)(10) may omit this warning (§ 347.50(e)(1)(iii)).
(c)(5)(ii)	All applicable warnings	Appear with subheadings highlighted in bold type.
(c)(5)(ii)(A)	**Reye's syndrome warning**	When this warning is required, it is the first warning of the warnings listed in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) to appear in this location in the **Warnings** section.
(c)(5)(ii)(B)	Allergic reaction warnings	The subheading **Allergy alert** is used.
(c)(5)(ii)(C)	**Flammability warning**, with appropriate signal word	The appropriate flammability signal word in an approved drug application or OTC drug monograph is used.
(c)(5)(ii)(D)	Water soluble gum warning, **Choking**	The subheading **Choking** is used.
(c)(5)(ii)(E)	**Alcohol warning**	The subheading **Alcohol warning** is used.
(c)(5)(ii)(F)	**Sore throat warning**	The subheading **Sore throat warning** is used.
(c)(5)(ii)(G)	**Dosage warning**	The warnings in § 201.307(b)(2)(i) or (b)(2)(ii) for drug products containing sodium phosphates. The subheading **Dosage warning** is used to introduce this information.

continued

Table A, continued

Paragraph	Description of Paragraph	Comments
(c)(5)(iii)	**Do not use** followed by all contraindications	The subheading used for all absolute contraindications and involves different types of situations.
(c)(5)(iv)	**Ask a doctor before use if you have**	The subheading used for certain preexisting conditions or when experiencing certain symptoms.
(c)(5)(v)	**Ask a doctor or pharmacist before use if you are**	The subheading used for all drug-drug and drug-food interactions.
(c)(5)(vi)	**When using this product**	The subheading used for all side effects that the consumer may experience; identifies substances or activities that should be avoided while using the drug product.
(c)(5)(vii)	**Stop use and ask a doctor if**	The subheading used for any signs of toxicity or other adverse reactions that would necessitate immediately discontinuing use of the drug product.
(c)(5)(viii)	Any required warnings	The location used to include any other required warnings that do not fit within §§ 201.66(c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x).
(c)(5)(ix)	**The pregnancy/breast-feeding warning**	General warning and other related warnings.
(c)(5)(x)	**Keep out of reach of children**	General warning and accidental **overdose/ingestion** warning in § 330.1(g).
(c)(6)	**Directions**	Described in an applicable OTC drug monograph or approved drug application.
(c)(7)	**Other information** and additional information not included in (c)(2) – (c)(6), (c)(8), and (c)(9) of this section (e.g., storage conditions)	The subheading used for additional information that is not included under the other subheadings, but which is required or is made optional under an OTC drug monograph(s), other OTC drug regulation(s), approved drug application, statute, or OTC drug guidance.
(c)(7)(i)	certain ingredients (e.g., Na)	See §§ 201.64(b), 201.70(b), 201.71(b), and 201.72(b).
(c)(7)(ii)	Phenylalanine	See § 201.21(b).
(c)(7)(iii)	Additional information	For example: storage conditions, tamper-evident statement.
(c)(8)	**Inactive ingredients**	A list of each inactive ingredient, using its established name.
(c)(9)	**Questions?** (or **Questions or Comments?**)	Optional heading used to provide a telephone number of a source to answer questions about the drug product or to receive reports of adverse events associated with the use of the drug product.

Table B. Labeling Format: §§ 201.66(d)(1) through (d)(9)

Paragraph	Description of Paragraph
(d)(1)	Drug Facts: first letter of words uppercase
"	Headings, subheadings: first letter of first word uppercase
"	Left justification
(d)(2)	Drug Facts type size > largest type size used in Drug Facts labeling
"	Heading 8-pt, or 2-pt type sizes > text point size
"	≥ 6-pt type size for information in Drug Facts
"	Subheadings ≥ 6-pt type size
"	**Drug Facts** (continued): type size no smaller than 8-pt type
(d)(3)	Letters do not touch
"	≥ 0.5-pt leading (space between lines)
"	No more than 39 characters per inch
"	Bold italic headings and title
"	Bold subheading, except the phrase "(continued)"
"	Contrasting dark color for title and heading
(d)(4)	Bullet: solid circle or square 5-pt type, same shape and color, left justified or separated from heading or subheading by at least two square ems
"	Bullet on same lines: end of statement separated from bulleted statement by two ems
"	Bullet on same lines: additional bulleted statement does not continue on next line
"	Vertical alignment of bulleted statements
(d)(5)	Appear on more than one panel
"	Visual graphic signals continuation
(d)(6)	Left justification of information required by (c)(2)
"	Right justification of information required by (c)(3)
"	Alphabetical order of active ingredients
"	Information required by (c)(4), (c)(6) – (c)(9) may start on same line as required headings
"	None of the information required in (c)(5) shall appear on the same line as **Warnings**
(d)(7)	Graphical images should not interrupt the heading, subheading, and information. Hyphens should not be used except to punctuate compound words.
(d)(8)	Enclosed box using barline
"	Horizontal barline separates headings listed in (c)(2) – (c)(9)
"	Horizontal hairline precedes heading immediately after the title **Drug Facts**
"	Horizontal hairline immediately follows the title **Drug Facts** (continued)
"	Horizontal hairline extending within two spaces on either side of the Drug Facts box shall immediately follow the title and precede the subheadings set forth in (c)(5) (except (c)(5)(ii)(A) – (G))
(d)(9)	Directions in table format when dosage instructions are provided for three or more age groups or populations
"	Horizontal barline preceding the next heading may end the table