

interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in § 330.1(j) of this chapter may be deleted from the labeling of OTC drug products when the labeling is revised to comply with this section, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in § 330.1(i) and (j) of this chapter shall not be used to change in any way the specific title, headings, and subheadings required under paragraphs (c)(1) through (c)(9) of this section.

(g) *Regulatory action.* An OTC drug product that is not in compliance with the format and content requirements in this section is subject to regulatory action.

[64 FR 13286, Mar. 17, 1999, as amended at 65 FR 8, Jan. 3, 2000; 65 FR 48904, Aug. 10, 2000; 69 FR 13733, Mar. 24, 2004; 72 FR 71785, Dec. 19, 2007; 73 FR 403, Jan. 3, 2008; 74 FR 19407, Apr. 29, 2009; 76 FR 44487, July 26, 2011]

§ 201.67 Labeling requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU).

(a) *Scope.* This section sets forth labeling requirements for a nonprescription drug product with an ACNU.

(b) *Definition.* The following definition applies to this section:

(1) *Additional condition for nonprescription use (ACNU)* means one or more FDA-approved conditions that an applicant of a nonprescription drug product must implement to ensure consumers' appropriate self-selection or appropriate actual use, or both, of the nonprescription drug product without the supervision of a practitioner licensed by law to administer such drug, if the applicant demonstrates and FDA determines that labeling alone is insufficient to ensure appropriate self-selection or appropriate actual use, or both.

(2) [Reserved]

(c) *General labeling requirements.* (1) A nonprescription drug product with an ACNU must comply with applicable labeling requirements for nonprescrip-

tion drug products under this part, including the format and content requirements for nonprescription drug product labeling under § 201.66 and the statements specified in § 201.130(a) and (b).

(2) A nonprescription drug product with an ACNU may also be approved with additional labeling that supplements the format and content requirements for nonprescription drug product labeling under § 201.66.

(d) *Format requirements for the required statement about the ACNU.* The statement about the ACNU specified in § 201.130(b)(1) must meet all format requirements as follows:

(1) The statement about the ACNU must appear on the principal display panel (see § 201.60) and the immediate container surface that the consumer is most likely to view when seeking information about the drug product. If the immediate container is a bottle, the statement about the ACNU must appear on the surface that the consumer is most likely to consider the front of the bottle. If the immediate container is a blister card (including a card that contains more than one blister unit), the statement about the ACNU must appear on the blister card surface that the consumer would most likely view when removing the drug product from the blister card. If the blister card contains more than one blister unit (*e.g.*, perforated blister card where individual blister units can be separated from one another), the statement about the ACNU does not need to be included on each blister unit of a blister card. However, the statement about the ACNU must remain intact and be readable on the blister card when the drug product is removed from each blister unit.

(2) The statement about the ACNU must appear in boldface and black type.

(3) The statement about the ACNU must appear in a yellow background banner. No other information or statements may be included within the yellow background banner.

(4) The statement about the ACNU must be in one of the following font sizes, whichever is greater:

(i) At least 25 percent as large as the font size of the largest printed words

on the principal display panel and immediate container; or

(ii) At least 12-point font (1 point = 0.0138 inches).

(5) An applicant may request an exception to the minimum font size requirement specified in paragraph (d)(4) of this section for containers where its size would render compliance with this requirement impractical. FDA may allow such an exception upon request by an applicant if FDA determines an exception is warranted.

(e) *Misbranding.* A nonprescription drug product with an ACNU is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) if—

(1) It does not comply with the labeling requirements specified in paragraphs (c) and (d) of this section and § 201.130(a) through (c); or

(2) The ACNU is not implemented by the applicant in accordance with the following, as approved by FDA in the application:

(i) The key elements of the ACNU under § 314.56(c)(1)(iv) of this chapter for NDAs or § 314.56(c)(2)(ii) of this chapter for ANDAs; or

(ii) The operationalization of the ACNU under § 314.56(c)(1)(vii) of this chapter for NDAs or § 314.56(c)(2)(iii) of this chapter for ANDAs.

[89 FR 105329, Dec. 26, 2024]

EFFECTIVE DATE NOTE: At 89 FR 105329, Dec. 26, 2024, § 201.67 was added, effective Jan. 27, 2025. At 90 FR 8173, Jan. 27, 2025, the effective date was delayed until Mar. 21, 2025. At 90 FR 13553, Mar. 25, 2025, the effective date was further delayed until May 27, 2025.

§ 201.70 Calcium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the calcium content per dosage unit (e.g., tablet, teaspoonful) if the calcium content of a single maximum recommended dose of the product (which may be one or more dosage units) is 20 milligrams or more. OTC drug products intended for oral ingestion include gum and lozenge dosage forms, but do not include dentifrices, mouthwashes, or mouth rinses.

(b) The calcium content shall be expressed in milligrams or grams per dosage unit and shall include the total amount of calcium regardless of the

source, i.e., from both active and inactive ingredients. If the dosage unit contains less than 1 gram of calcium, milligrams should be used. The calcium content per dosage unit shall be rounded-off to the nearest 5 milligrams (or nearest tenth of a gram if over 1 gram). The calcium content per dosage unit shall follow the heading “Other information” as stated in § 201.66(c)(7).

(c) The labeling of OTC drug products intended for oral ingestion shall contain the following statement under the heading “Warning” (or “Warnings” if it appears with additional warning statements) if the amount of calcium present in the labeled maximum daily dose of the product is more than 3.2 grams: “Ask a doctor before use if you have [in bold type] [bullet]¹ kidney stones [bullet] a calcium-restricted diet”. The warnings in §§ 201.64(c), 201.70(c), 201.71(c), and 201.72(c) may be combined, if applicable, provided the ingredients are listed in alphabetical order, e.g., a calcium or sodium restricted diet.

(d) Any product subject to this paragraph that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after the following dates is misbranded under sections 201(n) and 502(a) and (f) of the Federal Food, Drug, and Cosmetic Act.

(1) As of the date of approval of the application for any single entity and combination products subject to drug marketing applications approved on or after April 23, 2004.

(2) September 24, 2005, for all OTC drug products subject to any OTC drug monograph, not yet the subject of any OTC drug monograph, or subject to drug marketing applications approved before April 23, 2004.

[69 FR 13733, Mar. 24, 2004]

§ 201.71 Magnesium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the magnesium content per dosage unit (e.g., tablet, teaspoonful) if the magnesium content of a single maximum recommended

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.