

and such drug contains one or more other active ingredients and is for parenteral use only.

CROSS REFERENCE: For the Spanish-language version of the required labeling statement, see §201.16(b) of this chapter.

[39 FR 11736, Mar. 29, 1974, as amended at 40 FR 13496, Mar. 27, 1975]

Subpart C—Exemptions

§329.20 Exemption of certain habit-forming drugs from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1)(A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502(d):

(a) The following exempt narcotic preparations:

(1) Pharmaceutical preparations containing not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(2) Pharmaceutical preparations containing not more than 16.2 milligrams ($\frac{1}{4}$ grain) morphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(3) Pharmaceutical preparations containing not more than 64.8 milligrams (1 grain) codeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(4) Pharmaceutical preparations containing not more than 32.4 milligrams ($\frac{1}{2}$ grain) dihydrocodeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(5) Pharmaceutical preparations containing not more than 16.2 milligrams ($\frac{1}{4}$ grain) ethylmorphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

Provided, That the preparations described in this paragraph contain one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the preparation valuable medicinal qualities other than those possessed by the narcotic drug alone.

(b) Drugs containing chlorobutanol, intended for external use only.

(c) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(d) Combination drugs listed in part 329 as exempted from section 511 of the act.

[39 FR 11736, Mar. 29, 1974, as amended at 55 FR 11581, Mar. 29, 1990]

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Subpart A—General Provisions

Sec.

330.1 General conditions for general recognition as safe, effective and not misbranded.

330.2 Pregnancy-nursing warning.

330.3 Imprinting of solid oral dosage form drug products.

330.5 Drug categories.

Subpart B—Administrative Procedures

330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

330.11 NDA deviations from applicable monograph.

330.12 Status of over-the-counter (OTC) drugs previously reviewed under the Drug Efficacy Study (DESI).

330.13 Conditions for marketing ingredients recommended for over-the-counter (OTC) use under the OTC drug review.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 39 FR 11741, Mar. 29, 1974, unless otherwise noted.

Subpart A—General Provisions

§330.1 General conditions for general recognition as safe, effective and not misbranded.

An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph. Any product which fails to conform to each of the conditions contained in this part and

in an applicable monograph is liable to regulatory action.

(a) The product is manufactured in compliance with current good manufacturing practices, as established by parts 210 and 211 of this chapter.

(b) The establishment(s) in which the drug product is manufactured is registered, and the drug product is listed, in compliance with part 207 of this chapter. It is requested but not required that the number assigned to the product pursuant to part 207 of this chapter appear on all drug labels and in all drug labeling. If this number is used, it shall be placed in the manner set forth in part 207 of this chapter.

(c)(1) The product is labeled in compliance with chapter V of the act and subchapter C *et seq.* of this chapter. For purposes of §201.61(b) of this chapter, the statement of identity of the product shall be the term or phrase used in the applicable monograph established in this part.

(2)(i) The label and labeling of the product contain in a prominent and conspicuous location the labeling describing the “Indications” that have been established in an applicable final monograph. At the option of the manufacturer, this labeling may be designated “APPROVED USES,” or be given a similar designation as permitted by this paragraph, each time it appears in the labeling, e.g., on the outer carton, inner bottle label, and on any package insert or display material. If the “APPROVED USES” or a similar designation is used, the labeling involved shall appear within a boxed area. Other applicable labeling established under this subchapter and subchapter C of this chapter may be included in the boxed area. If such other labeling is included, the boxed area shall be designated “APPROVED INFORMATION” rather than “APPROVED USES.” The “indications” information appearing in the boxed area shall be stated in the exact language of the monograph. Other information within the boxed area also shall be stated in exact language where exact language has been established and identified by quotation marks in an applicable monograph or by regulation (e.g., §201.63 of this chapter). A statement that the information in the box

was “published by the Food and Drug Administration” shall appear within the boxed area, or reasonably close by. In lieu of such statement, the designation of the boxed area may be modified to read: “FDA APPROVED USES” or “FDA APPROVED INFORMATION,” as appropriate, or “USES (or “INFORMATION”) APPROVED BY THE FOOD AND DRUG ADMINISTRATION,” or other similar wording.

(ii) At the option of the manufacturer, as an alternative to the requirements of paragraph (c)(2)(i) of this section, the label and labeling of the product may contain in a prominent and conspicuous location other truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. Such labeling shall not be boxed and shall not contain the statements provided in paragraph (c)(2)(i) of this section relating to “APPROVED USES,” or “APPROVED INFORMATION,” or contain a statement that the labeling has been published by the Food and Drug Administration.

(iii) At the option of the manufacturer, the label and labeling may meet the boxed-area requirements of paragraph (c)(2)(i) of this section and, in addition, other truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph may appear elsewhere in the labeling, that is, outside the boxed area, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(iv) At the option of the manufacturer, more than one of the alternatives described in paragraphs (c)(2)(i), (ii), and (iii) may be used in separate labeling, e.g., container label, outer carton, package insert, display material, for a particular OTC drug

product provided each labeling complies with all applicable statutory and regulatory labeling requirements in all respects.

(v) The term “prominent and conspicuous location” as used in paragraphs (c)(2) (i) and (ii) of this section means that the labeling within the boxed or nonboxed area shall be presented and displayed in such a manner as to render it likely to be read as understood by the ordinary individual under customary conditions at both time of purchase and use.

(vi) Regardless of the alternative selected by the manufacturer to describe indications, paragraphs (c)(2)(i), (ii), and (iii) of this section require other labeling established under this subchapter and subchapter C of this chapter to be stated in the exact language where exact language has been established and identified by quotation marks in an applicable monograph or by regulation (e.g., §201.63 of this chapter).

(d) The advertising for the product prescribes, recommends, or suggests its use only under the conditions stated in the labeling.

(e) The product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity. Color additives may be used only in accordance with section 721 of the act and subchapter A of this chapter.

(f) The product container and container components meet the requirements of §211.94 of this chapter.

(g) The labeling for all drugs contains the general warning: “Keep this and all drugs out of the reach of children.” The labeling of drugs used for oral administration shall also state: “In case of accidental overdose, seek professional assistance or contact a poison control center immediately.” The labeling for drugs administered rectally or used topically shall state: “In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.” The Food and Drug Administration will grant an exemption from these general

warnings where appropriate upon petition, which shall be maintained in a permanent file for public review by the Dockets Management Branch, Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

(h) Where no maximum daily dosage limit for an active ingredient is established in this part, it is used in a product at a level that does not exceed the amount reasonably required to achieve its intended effect.

(i) The following terms may be used interchangeably in any of the labeling established in parts 331 through 358 of this chapter:

- (1) “Ask” or “consult”.
- (2) “Assistance” or “help”.
- (3) “Clean” or “cleanse”.
- (4) “Continue” or “persist”.
- (5) “Continues” or “persists”.
- (6) “Doctor” or “physician”.
- (7) “Indication” or “use”.
- (8) “Indications” or “uses”.
- (9) “Lung” or “pulmonary”.

(j) It is recommended that the labeling of the product contain the quantitative amount of each active ingredient, expressed in terms of the dosage unit stated in the directions for use (e.g., tablet, teaspoonful).

[39 FR 11741, Mar. 29, 1974, as amended at 40 FR 11718, Mar. 13, 1975; 40 FR 13496, Mar. 27, 1975; 42 FR 15674, Mar. 22, 1977; 46 FR 8459, Jan. 27, 1981; 50 FR 8996, Mar. 6, 1985; 51 FR 16266, May 1, 1986; 55 FR 11581, Mar. 29, 1990; 59 FR 4000, Jan. 28, 1994; 59 FR 14365, Mar. 28, 1994]

§330.2 Pregnancy-nursing warning.

A pregnancy-nursing warning for OTC drugs is set forth under §201.63 of this chapter.

[47 FR 54758, Dec. 3, 1982]

§330.3 Imprinting of solid oral dosage form drug products.

A requirement to imprint an identification code on solid oral dosage form drug products is set forth under part 206 of this chapter.

[58 FR 47959, Sept. 13, 1993]

§330.5 Drug categories.

Monographs promulgated pursuant to the provisions of this part shall be established in this part 330 and following