Subpart B—Labeling

§ 329.10 Labeling requirements for habit-forming drugs.

(a)(1) The name of a substance or derivative required to be borne on the label of a drug by section 502(d) of the act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of section 502(c).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502(d) of the act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement ''Warning—May be habit forming'', shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement ''Warning—May be habit forming'':

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, 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 (¼ 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 (½ 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 (¼ 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.

Subpart B—Administrative Procedures

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 Federal Food, Drug, and Cosmetic Act (the act) and subchapter C *et seq.* of this chapter, including the format and content requirements in § 201.66 of this chapter. An OTC drug product that is not in compliance with chapter V and subchapter C, including § 201.66 of this chapter, is subject to regulatory action. 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 OTC drug monograph established in this part.

(2) The ''Uses'' section of the label and labeling of the product shall contain the labeling describing the ''Indications'' that have been established in an applicable OTC drug monograph or alternative 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