

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

parts and shall cover the following designated categories:

- (a) Antacids.
- (b) Laxatives.
- (c) Antidiarrheal products.
- (d) Emetics.
- (e) Antiemetics.
- (f) Antiperspirants.
- (g) Sunburn prevention and treatment products.
- (h) Vitamin-mineral products.
- (i) Antimicrobial products.
- (j) Dandruff products.
- (k) Oral hygiene aids.
- (l) Hemorrhoidal products.
- (m) Hematinics.
- (n) Bronchodilator and antiasthmatic products.
- (o) Analgesics.
- (p) Sedatives and sleep aids.
- (q) Stimulants.
- (r) Antitussives.
- (s) Allergy treatment products.
- (t) Cold remedies.
- (u) Antirheumatic products.
- (v) Ophthalmic products.
- (w) Contraceptive products.
- (x) Miscellaneous dermatologic products.
- (y) Dentifrices and dental products such as analgesics, antiseptics, etc.
- (z) Miscellaneous (all other OTC drugs not falling within one of the above therapeutic 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.

For purposes of classifying over-the-counter (OTC) drugs as drugs generally recognized among qualified experts as safe and effective for use and as not misbranded drugs, the following regulations shall apply:

- (a) *Procedure for establishing OTC drug monographs*—(1) *Advisory review panels.* The Commissioner shall appoint advisory review panels of qualified experts to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise him on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effec-

tive and not misbranded. A single advisory review panel shall be established for each designated category of OTC drugs and every OTC drug category will be considered by a panel. The members of a panel shall be qualified experts (appointed by the Commissioner) and may include persons from lists submitted by organizations representing professional, consumer, and industry interests. The Commissioner shall designate the chairman of each panel. Summary minutes of all meetings shall be made.

(2) *Request for data and views.* The Commissioner will publish a notice in the FEDERAL REGISTER requesting interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of OTC drugs. Data and information submitted pursuant to a published notice, and falling within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j), shall be handled by the advisory review panel and the Food and Drug Administration as confidential until publication of a proposed monograph and the full report(s) of the panel. Thirty days thereafter such data and information shall be made publicly available and may be viewed at the office of the Dockets Management Branch of the Food and Drug Administration, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of one or more of those statutes. To be considered, eight copies of the data and/or views on any marketed drug within the class must be submitted, preferably bound, indexed, and on standard sized paper (approximately 8½ x 11 inches). When requested, abbreviated submissions should be sent. All submissions must be in the following format:

#### OTC DRUG REVIEW INFORMATION

- I. Label(s) and all labeling (preferably mounted and filed with the other data—facsimile labeling is acceptable in lieu of actual container labeling).
- II. A statement setting forth the quantities of active ingredients of the drug.
- III. Animal safety data.
  - A. Individual active components.
    - 1. Controlled studies.