

§ 330.2

- (63) "Reduce" or "minimize".
- (64) "Referred to as" or "of".
- (65) "Sensation" or "feeling".
- (66) "Solution" or "liquid".
- (67) "Specifically" or "definitely".
- (68) "Take" or "use" or "give".
- (69) "Tend(s) to recur" or "reoccur(s)" or "return(s)" or "come(s) back".
- (70) "To avoid contamination" or "avoid contamination" or "do not contaminate".
- (71) "To help" or "helps".
- (72) "Unless directed by a doctor" or "except under the advice of a doctor" or "unless told to do so by a doctor".
- (73) "Use caution" or "be careful".
- (74) "Usually" or "generally" (in context only).
- (75) "You" ("Your") or "the child" ("the child's").
- (76) "You also have" or "occurs with".
- (77) "When practical" or "if possible".
- (78) "Whether" or "if".
- (79) "Worsen(s)" or "get(s) worse" or "make(s) worse".
- (j) The following connecting terms may be deleted from the labeling of OTC drug products, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable monograph or by regulation. The following terms shall not be used to change in any way the specific title, headings, and sub-headings required under § 201.66(c)(1) through (c)(9) of this chapter:
 - (1) "And".
 - (2) "As may occur with".
 - (3) "Associated" or "to be associated".
 - (4) "Consult a doctor".
 - (5) "Discontinue use".
 - (6) "Drug Interaction Precaution".
 - (7) "Due to".
 - (8) "Except under the advice and supervision of a physician".
 - (9) "If this occurs".
 - (10) "In case of".
 - (11) "Notice".
 - (12) "Or".
 - (13) "Occurring with".
 - (14) "Or as directed by a doctor".
 - (15) "Such as".
 - (16) "Such as occurs with".
 - (17) "Tends to".
 - (18) "This product".

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- (19) "Unless directed by a doctor".
- (20) "While taking this product" or "before taking this product".
- (21) "Within".

[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; 64 FR 13294, Mar. 17, 1999; 68 FR 24879, May 9, 2003]

§ 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 effective 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 or until the Commissioner places the panel's recommendations on public display at the office of the Division of Dockets Management. Thirty days thereafter such data and information shall be made publicly available and may be viewed at the office of the Division of Dockets Management 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 8½×11 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.

2. Partially controlled or uncontrolled studies.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

IV. Human safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.