(vii) Unique case identification number, which must be the same in the initial report and any subsequent followup report(s).

(c) *Electronic format for submissions.* (1) Each report required to be submitted to FDA under section 760 of the FD&C Act, accompanied by a copy of the label on or within the retail package of the drug and any other documentation (as ICSR attachments), must be in an electronic format that FDA can process, review, and archive. FDA will issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation, and organization of files).

(2) The responsible person may request, in writing, a temporary waiver of the requirements in paragraph (c)(1) of this section. These waivers will be granted on a limited basis for good cause shown. FDA will issue guidance on requesting a waiver of the requirements in paragraph (c)(1) of this section.

(d) *Patient privacy.* The responsible person should not include in reports under this section the names and addresses of individual patients; instead, the responsible person should assign a unique code for identification of the patient. The responsible person should include the name of the reporter from whom the information was received as part of the initial reporter information, even when the reporter is the patient. The names of patients, health care professionals, hospitals, and geographical identifiers in adverse drug event reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter.

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, 360fff–6, 371.

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

EDITORIAL NOTE: Nomenclature changes to part 330 appear at 69 FR 13717, Mar. 24, 2004.

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 introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. Any other labeling under this subchapter and subchapter C *et seq.* of this chapter shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation (e.g., § 201.63 of this chapter), except as provided in paragraphs (i) and (j) of this section.

(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 out of reach of children.'' [highlighted in bold type]. The labeling of drugs shall also state as follows: For drugs used by oral administration, ''In case of overdose, get medical help or contact a Poison Control Center right away''; for drugs used topically, rectally, or vaginally and not intended for oral ingestion, ''If swallowed, get medical help or contact a Poison Control Center right away''; and for drugs used topically and intended for oral use, ''If more than used for'' (insert intended use, e.g., pain) ''is accidentally swallowed, get medical help or contact a Poison Control Center right away.'' 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 Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(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 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 monograph or by regulation. The following terms shall not be used to change in any way the title, headings, and subheadings required under § 201.66(c)(1) through (c)(9) of this chapter:

(1) ''Abdominal'' or ''stomach'' (in context only).

(2) ''Administer'' or ''give''.

(3) ''Aggravate(s)'' or ''make(s) worse''.

(4) ''Application of this product'' or ''applying''.

(5) ''Are uncertain'' or ''do not know''.

(6) ''Ask'' or ''consult'' or ''contact''.

(7) ''Asking'' or ''consulting''.

(8) ''Assistance'' or ''help'' or ''aid''.

(9) ''Associated with'' or ''due to'' or ''caused by''.

(10) ''Avoid contact with eyes'' or ''do not get into eyes''.

(11) ''Avoid inhaling'' or ''do not inhale''.

(12) ''Before a doctor is consulted'' or ''without first consulting your doctor'' or ''consult your doctor before''.
(13) ''Beverages'' or ''drinks''.
(14) ''Clean'' or ''cleanse''.
(15) ''Consulting'' or ''advising''.
(16) ''Continue(s)'' or ''persist(s)'' or ''is persistent'' or ''do(es) not go away'' or ''last(s)''.
(17) ''Daily'' or ''every day''.
(18) ''Develop(s)'' or ''begin(s)'' or ''occur(s)''.
(19) ''Difficulty'' or ''trouble''.
(20) ''Difficulty in urination'' or ''trouble urinating''.
(21) ''Discard'' or ''throw away''.
(22) ''Discontinue'' or ''stop'' or ''quit''.
(23) ''Doctor'' or ''physician''.
(24) ''Drowsiness'' or ''the drowsiness effect''.
(25) ''Drowsiness may occur'' or ''you may get drowsy''.
(26) ''Enlargement of the'' or ''an enlarged''.
(27) ''Especially in children'' or especially children''.
(28) ''Exceed'' or ''use more than'' or ''go beyond''.
(29) ''Exceed recommended dosage'' or ''use more than directed''.
(30) ''Excessive'' or ''too much''.
(31) ''Excitability may occur'' or ''you may get excited''.
(32) ''Experience'' or ''feel''.
(33) ''For relief of'' or ''relieves''.
(34) ''For temporary reduction of'' or ''temporarily reduces''.
(35) ''For the temporary relief of'' or ''temporarily relieves''.
(36) ''For the treatment of'' or ''treats''.
(37) ''Frequently'' or ''often''.
(38) ''Give to'' or ''use in''.
(39) ''Immediately'' or ''right away'' or ''directly''.
(40) ''Immediately'' or ''as soon as''.
(41) ''Immediately following'' or ''right after''.
(42) ''Improve(s)'' or ''get(s) better'' or ''make(s) better''.
(43) ''Increased'' or ''more''.
(44) ''Increase your risk of'' or ''cause''.
(45) ''Indication(s)'' or ''Use(s)''.
(46) ''Inhalation'' or ''puff''.
(47) ''In persons who'' or ''if you'' or ''if the child''.
(48) ''Instill'' or ''put''.
(49) ''Is (are) accompanied by'' or ''you also have'' (in context only) or ''(optional: that) occur(s) with''.
(50) ''Longer'' or ''more''.
(51) ''Lung'' or ''pulmonary''.
(52) ''Medication(s)'' or ''medicine(s)'' or ''drug(s)''.
(53) ''Nervousness, dizziness, or sleeplessness occurs'' or ''you get nervous, dizzy, or sleepless''.
(54) ''Not to exceed'' or ''do not exceed'' or ''not more than''.
(55) ''Obtain(s)'' or ''get(s)''.
(56) ''Passages'' or ''passageways'' or ''tubes''.
(57) ''Perforation of'' or ''hole in''.
(58) ''Persistent'' or ''that does not go away'' or ''that continues'' or ''that lasts''.
(59) ''Per day'' or ''daily''.
(60) ''Presently'' or ''now''.
(61) ''Produce(s)'' or ''cause(s)''.
(62) ''Prompt(ly)'' or ''quick(ly)'' or ''right away''.
(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 subheadings 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''.
(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