over 5 percent alcohol and labeled for use by adults and children 12 years of age and over, the labeling shall contain the following statement in the directions section: ''Consult a physician for use in children under 12 years of age.''

(g) For any OTC drug product intended for oral ingestion containing over 0.5 percent alcohol and labeled for use by children ages 6 to under 12 years of age, the labeling shall contain the following statement in the directions section: ''Consult a physician for use in children under 6 years of age.''

(h) When the direction regarding age in paragraph (e) or (f) of this section differs from an age-limiting direction contained in any OTC drug monograph in this chapter, the direction containing the more stringent age limitation shall be used.

PART 329—NONPRESCRIPTION HUMAN DRUG PRODUCTS SUBJECT TO SECTION 760 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 379aa.

SOURCE: 79 FR 33089, June 10, 2014, unless otherwise noted.

§ 329.100 Postmarketing reporting of adverse drug events under section 760 of the Federal Food, Drug, and Cosmetic Act.

(a) *Reporting requirements.* Reports of serious adverse events required by section 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) must include the information specified in this section, as applicable. Except as provided in paragraph (c)(2) of this section, these reports must be submitted to the Agency in electronic format as described in paragraph (c)(1) of this section.

(b) *Contents of reports.* For purposes of reporting serious adverse events under section 760 of the FD&C Act, an individual case safety report (ICSR) constitutes the MedWatch form required to be submitted by section 760(d) of the FD&C Act. ICSRs include the following information:

(1) *Patient information.*

(i) Patient identification code;

(ii) Patient age at the time of adverse drug experience, or date of birth;

(iii) Patient gender; and

(iv) Patient weight.

(2) *Adverse event.*

(i) Outcome attributed to adverse drug event;

(ii) Date of adverse drug event;

(iii) Date of ICSR submission;

(iv) Description of adverse drug event (including a concise medical narrative);

(v) Adverse drug event term(s);

(vi) Description of relevant tests, including dates and laboratory data; and

(vii) Other relevant patient history, including preexisting medical conditions.

(3) *Suspect medical product(s).*

(i) Name;

(ii) Dose, frequency, and route of administration used;

(iii) Therapy dates;

(iv) Diagnosis for use (indication);

(v) Whether the product is a combination product as defined in § 3.2(e) of this chapter;

(vi) Whether the product is a prescription or nonprescription product;

(vii) Whether adverse drug event abated after drug use stopped or dose reduced;

(viii) Whether adverse drug event reappeared after reintroduction of drug;

(ix) Lot number;

(x) Expiration date;

(xi) National Drug Code (NDC) number; and

(xii) Concomitant medical products and therapy dates.

(4) *Initial reporter information.*

(i) Name, address, and telephone number;

(ii) Whether the initial reporter is a health care professional; and

(iii) Occupation, if a health care professional.

(5) *Responsible person (as defined in section 760(b) of the FD&C Act) information.*

(i) Name and contact office address;

(ii) Telephone number;

(iii) Report source, such as spontaneous;

(iv) Date the report was received by responsible person;

(v) Whether the ICSR is a 15-day report;

(vi) Whether the ICSR is an initial report or followup report; and

(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