

§ 251.20

qualifying laboratory, unless the manufacturer conducted the testing and submitted this information directly to FDA.

(g) The report in paragraph (a) of this section must include data, information, and analysis on the SIP's cost savings to the American consumer for the drugs imported under the SIP.

(h) A SIP Sponsor must submit a report to FDA within 10 calendar days, in electronic format via the ESG or to an alternative transmission point identified by FDA, regarding any applicable criminal conviction, violation of law, or disciplinary action as described in § 251.3(e)(2) and (3).

§ 251.20 Severability.

The provisions of this part are not separate and are not severable from one another. If any provision is stayed or determined to be invalid or unenforceable, the remaining provisions shall not continue in effect.

§ 251.21 Consequences for violations.

(a) An article that is imported or offered for import into the United States in violation of section 804 of the Federal Food, Drug, and Cosmetic Act or this part is subject to refusal under section 801 of the Federal Food, Drug, and Cosmetic Act.

(b) The importation of a prescription drug in violation of section 804 of the Federal Food, Drug, and Cosmetic Act; the falsification of any record required to be maintained or provided to FDA under section 804; or any other violation of this part is a prohibited act under section 301(aa) of the Federal Food, Drug, and Cosmetic Act.

PART 290—CONTROLLED DRUGS

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AUTHORITY: 21 U.S.C. 352, 353, 355, 371.

SOURCE: 40 FR 14040, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 290.1 Controlled substances.

Any drug that is a controlled substance listed in schedule II, III, IV, or V of the Federal Controlled Substances Act or implementing regulations must be dispensed by prescription only as required by section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act unless specifically exempted in § 290.2.

[67 FR 4906, Feb. 1, 2002]

§ 290.2 Exemption from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to a compound, mixture, or preparation containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams that also includes one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by codeine alone.

[67 FR 4907, Feb. 1, 2002]

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a “controlled substance” in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.” This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are “blind.”

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, § 290.5, promulgated under section 503(b) of the Federal Food, Drug, and

Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." The Spanish version of this is: "Precaucion: La ley Federal prohíbe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada."

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term *emergency situation* means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

Subpart A—General Provisions

Sec.

299.3 Definitions and interpretations.

299.4 Established names for drugs.

299.5 Drugs; compendial name.

AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

SOURCE: 40 FR 14041, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 299.3 Definitions and interpretations.

(a) As used in this part 299, *act* means the Federal Food, Drug, and Cosmetic Act, sections 201-902, 52 Stat. 1040 (21 U.S.C. 321-392), with all amendments thereto.

(b) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part 299.

(c) The term *official name* means, with respect to a drug or ingredient thereof, the name designated in this part 299 under section 508 of the act as the official name.

§ 299.4 Established names for drugs.

(a) Section 508 of the Federal Food, Drug, and Cosmetic Act (added by the Kefauver-Harris Drug Amendments of 1962; Pub. L. 87-781) authorizes the Commissioner of Food and Drugs to designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Section 502(e) of the act (as amended by said Drug Amendments) prescribes that the labeling of a drug must bear its established name, if there is one, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula) and, if the drug is fabricated from two or more ingredients, the established name of each active ingredient.

(b) The term *established name* is defined in section 502(e)(3) of the act as (1) an official name designated pursuant to section 508 of the act; (2) if no such official name has been designated for the drug and the drug is an article recognized in an official compendium, then the official title thereof in such compendium; and (3) if neither paragraphs (b) (1) or (2) of this section applies, then the common or usual name of the drug.

(c) The Food and Drug Administration recognizes the skill and experience of the U.S. Adopted Names Council (USAN) in deriving names for drugs. The U.S. Adopted Names Council is a private organization sponsored by the American Medical Association, the United States Pharmacopeia, and the