(d) The report in paragraph (a) of this section must include the following documentation:

(1) Documentation from the Foreign Seller specifying the manufacturer of each eligible prescription drug and the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller from that manufacturer;

(2) Documentation demonstrating that the eligible prescription drug was received by the Foreign Seller from the manufacturer and subsequently shipped by the Foreign Seller to the Importer;

(3) Documentation of the quantity of each lot of the eligible prescription drug(s) received by the Foreign Seller, demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the Foreign Seller; and

(4) Documentation demonstrating that the sampling and testing requirements described in section 804(d)(1)(J)(i)(III) of the Federal Food, Drug, and Cosmetic Act were met for each shipment of each eligible prescription drug.

(e) The report in paragraph (a) of this section must include certifications from the Importer for each shipment of each eligible prescription drug that the drug is approved for marketing in the United States and is not adulterated or misbranded and meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act. This certification must include:

(1) That there is an authorized SIP;

(2) That the imported drug is covered by the authorized SIP;

(3) That the drug is an eligible prescription drug as defined in this part;

(4) That the FDA-approved counterpart of the drug is currently commercially marketed in the United States;

(5) That the drug is approved for marketing in Canada; and

(6) That the drug is not adulterated or misbranded and meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act.

(f) The report in paragraph (a) of this section must include laboratory records, including complete data derived from all tests necessary to ensure that each eligible prescription drug is in compliance with established specifications and standards, and documentation demonstrating that the Statutory Testing was conducted at a 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

Subpart A—General Provisions

Sec.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

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 prohibe 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.