

Subpart D—Procedure for Foreign Drug Establishments

207.40 Establishment registration and drug listing requirements for foreign establishments.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

SOURCE: 45 FR 38043, June 6, 1980, unless otherwise noted.

Subpart A—General

§ 207.3 Definitions.

(a) The following definitions apply to this part:

(1) *Act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 et seq., as amended (21 U.S.C. 301–392)), except as otherwise provided.

(2) *Advertising* and *labeling* include the promotional material described in § 202.1(1) (1) and (2) respectively.

(3) *Any material change* includes but is not limited to any change in the name of the drug, any change in the identity or quantity of the active ingredient(s), any change in the identity or quantity of the inactive ingredient(s) where quantitative listing of all ingredients is required by § 207.31(a)(2), any significant change in the labeling of a prescription drug, and any significant change in the label or package insert of an over-the-counter drug. Changes that are not significant include changes in arrangement or printing or changes of an editorial nature.

(4) *Bulk drug substance* means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

(5) *Commercial distribution* means any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or animal feed bearing or containing an animal drug for non-investigational uses, but the term does not include internal or interplant transfer of a bulk drug substance between registered establishments within

the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term “commercial distribution” shall have the same meaning except that the term shall not include distribution of any drug that is neither imported nor offered for import into the United States.

(6) *Drug product salvaging* means the act of segregating drug products that may have been subjected to improper storage conditions, such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation, for the purpose of returning some or all of the products to the marketplace.

(7) *Establishment* means a place of business under one management at one general physical location. The term includes, among others, independent laboratories that engage in control activities for a registered drug establishment (e.g., *consulting* laboratories), manufacturers of medicated feeds and of vitamin products that are drugs in accordance with section 201(g) of the act, human blood donor centers, and animal facilities used for the production or control testing of licensed biologicals, and establishments engaged in drug product salvaging.

(8) *Manufacturing or processing* means the *manufacture, preparation, propagation, compounding, or processing of a drug or drugs* as used in section 510 of the act and is the making by chemical, physical, biological, or other procedures of any articles that meet the definition of drugs in section 201(g) of the act. The term includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The term also includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package to further the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(9) *Representative sampling of advertisements* means typical advertising material (excluding labeling as determined in § 202.1(1) (1) and (2)) that gives a balanced picture of the promotional claims used for the drug, e.g., if more

§ 207.7

than one medical journal advertisement is used but the promotional content is essentially identical, only one need be submitted.

(10) *Representative sampling of any other labeling* means typical labeling material (excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug, e.g., if more than one brochure is used but the promotional content is essentially identical, only one need be submitted.

(11) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

(b) The definitions and interpretations of terms in sections 201, 502(e), and 510 of the act apply to the use of terms in this part.

[45 FR 38043, June 6, 1980, as amended at 55 FR 11576, Mar. 29, 1990; 66 FR 59156, Nov. 27, 2001]

§ 207.7 Establishment registration and product listing for human blood and blood products and for medical devices.

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Center for Biologics Evaluation and Research (HFM-375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, on Form FDA-2830 (Blood Establishment Registration and Product Listing), in accordance with part 607 of this chapter. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

(b) [Reserved]

(c) Owners and operators of establishments engaged in manufacture or processing of medical devices shall register and list their products with the Center for Devices and Radiological Health, FDA, on Form FDA-2891 (Initial Registration of Device Establishments), FDA-2891a (Registration of Device Es-

21 CFR Ch. I (4-1-03 Edition)

tablishment), and FDA-2892 (Medical Device Listing), in accordance with part 807.

(d) Owners and operators of establishments engaged in the manufacture or processing at the same establishment of both drug products and medical devices shall (1) register with the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, FDA, and list their drug products in accordance with this part, and (2) register with the Center for Devices and Radiological Health and list their medical devices in accordance with part 807.

[45 FR 38043, June 6, 1980, as amended at 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 66 FR 59156, Nov. 27, 2001]

Subpart B—Exemptions

§ 207.10 Exemptions for establishments.

The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g)(1), (g)(2), and (g)(3) of the act, or because FDA has found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. The exemptions in paragraphs (a) and (b) of this section are limited to pharmacies, hospitals, clinics, and public health agencies located in any State as defined in section 201(a)(1) of the act.

(a) Pharmacies that operate under applicable local laws regulating dispensing of prescription drugs and that do not manufacture or process drugs for sale other than in the regular course of the practice of the profession of pharmacy, including dispensing and selling drugs at retail. The supplying of prescription drugs by these pharmacies to a practitioner licensed to administer these drugs for his or her use in the course of professional practice or to other pharmacies to meet temporary inventory shortages are not acts that require pharmacies to register.

(b) Hospitals, clinics, and public health agencies that maintain establishments in conformance with any applicable local laws regulating the practices of pharmacy or medicine and that regularly engage in dispensing prescription drugs, other than human