to provide for a new imprint is not required to bring its product into compliance with this section during the pendency of the agency's review. Once the review is complete, the drug product is subject to the requirements of the rule.

(c) A solid oral dosage form drug product that does not meet the requirement for imprinting in paragraph (a) of this section and is not exempt from the requirement may be considered adulterated and misbranded and may be an unapproved new drug.

(d) For purposes of this section, *code imprint* means any single letter or number or any combination of letters and numbers, including, e.g., words, company name, and National Drug Code, or a mark, symbol, logo, or monogram, or a combination of letters, numbers, and marks or symbols, assigned by a drug firm to a specific drug product.

[58 FR 47958, Sept. 13, 1993, as amended at 60 FR 19846, Apr. 21, 1995; 69 FR 18763, Apr. 8, 2004]

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

Subpart A—General

Sec.

Subpart B—Exemptions

Subpart C—Procedures for Domestic Drug Establishments

Subpart D—Procedure for Foreign Drug 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(l) (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 noninvestigational 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(l) (1) and (2)) that gives a balanced picture of the promotional claims used for the drug, e.g., if more 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 Establishment), and FDA–2892 (Medical