chapter, supplemented its application 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—REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS, AND THE NATIONAL DRUG CODE

Subpart A—General

Sec.

Subpart B—Registration

Subpart C—National Drug Code

Subpart D—Listing

Subpart E—Electronic Format for Registration and Listing

Subpart F—Miscellaneous

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

SOURCE: 81 FR 60212, Aug. 31, 2016, unless otherwise noted.

Subpart A—General

§ 207.1 What definitions and interpretations of terms apply to this part?

The definitions and interpretations of terms in sections 201 and 510 of the Federal Food, Drug, and Cosmetic Act apply to the terms used in this part, if not otherwise defined in this section. The following definitions apply to this part:

Active pharmaceutical ingredient means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.

Bulk drug substance, as referenced in sections 503A(b)(1)(A) and 503B(a)(2) of the Federal Food, Drug, and Cosmetic Act, means the same as ''active pharmaceutical ingredient'' as defined in this section.

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 an animal feed bearing or containing an animal drug, except for investigational use under part 511 of this chapter. The term does not include internal or interplant transfer between registered establishments under common ownership and control, including a parent, subsidiary, or affiliate company. For foreign establishments that manufacture, repack, relabel, or salvage, or for foreign private label distributors, the term ''commercial distribution'' has the same meaning except the term does not include distribution of any drug that is neither imported nor offered for import into the United States.

Content of labeling means:

(1) For human prescription drugs that are subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act: The content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.

(2) For human prescription drugs that are not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act: The labeling equivalent to the content of the prescription drug labeling (as specified in §§ 201.56, 201.57, and 201.80 of this chapter), including all text, tables, and figures.

(3) For human over-the-counter (OTC) drugs: All text, tables, and figures including the drug facts labeling required by § 201.66 of this chapter.

(4) For animal drugs (including, but not limited to, drugs that are subject to section 512 of the Federal Food, Drug, and Cosmetic Act): The content of the labeling that accompanies the drug that is necessary to enable safe and proper administration of the drug (e.g., the labeling applicable to veterinary drugs specified in part 201 of this chapter), including all text, tables, and figures.

Domestic for purposes of registration and listing under this part, when used to modify the term ''registrant,'' ''manufacturer,'' ''repacker,'' ''relabeler,'' ''salvager,'' ''private label distributor,'' or ''establishment,'' refers to a registrant, manufacturer, repacker, relabeler, salvager, private label distributor, or establishment within any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Drug, for the purposes of registration and listing under this part, has the meaning given in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

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 Federal Food, Drug, and Cosmetic Act, human blood donor centers, and animal facilities used for the production or control testing of licensed biologicals, and establishments engaged in salvaging.

Establishment registration number means the number assigned to the establishment, as identified by FDA, after the establishment registration required in this part.

Finished drug product means a finished dosage form (e.g., tablet, capsule, or solution) that contains at least one

active pharmaceutical ingredient, generally, but not necessarily, in association with other ingredients in finished package form suitable for distribution to pharmacies, hospitals, or other sellers or dispensers of the drug product to patients or consumers.

Foreign for the purposes of registration and listing under this part:

(1) When used to modify the term ''manufacturer,'' ''repacker,'' ''relabeler,'' or ''salvager,'' refers to a manufacturer, repacker, relabeler, or salvager, who is located in a foreign country and who manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States.

(2) When used to modify the term ''establishment'' refers to an establishment that is located in a foreign country and is engaged in the manufacture, repackaging, relabeling, or salvaging of any drug, or any animal feed bearing or containing a new animal drug, that is imported or offered for import into the United States.

Importer means, for purposes of this part, a person in the United States that is an owner, consignee, or recipient, at the time of entry, of a foreign establishment's drug, or an animal feed bearing or containing a new animal drug, that is imported into the United States.

Manufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug or an animal feed bearing or containing a new animal drug. Manufacture includes the making by chemical, physical, biological, or other procedures or manipulations of a drug, or an animal feed bearing or containing a new animal drug, including control procedures applied to the final product or to any part of the process. Manufacture includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process, including, for example, analytical testing of drugs for another registered establishment's drug. For purposes of this part, and in order to clarify the responsibilities of the entities engaged in different operations, the term manufacture is defined and used separately from the terms relabel, repackage, and salvage, although the term ''manufacture, preparation, propagation, compounding, or processing,'' as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes relabeling, repackaging, and salvaging activities.

Manufacturer means a person who owns or operates an establishment that manufactures a drug or an animal feed bearing or containing a new animal drug. This term includes, but is not limited to, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug, or an animal feed bearing or containing a new animal drug, as defined in this paragraph. For purposes of this part, and in order to clarify the responsibilities of the entities engaged in different operations, the term manufacturer is defined and used separately from the terms relabeler, repacker, and salvager, although the term ''manufacture, preparation, propagation, compounding, or processing,'' as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. Repackers, relabelers, and salvagers are subject to the provisions of this part that are applicable to repackers, relabelers, and salvagers, but are not subject to the provisions of this part that are applicable to manufacturers. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic manufacturers and foreign manufacturers.

Material change means any change in any drug listing information, as required under §§ 207.49, 207.53, 207.54, 207.55, or 207.57 except changes in format of labeling, labeling changes of an editorial nature, or inclusion of a bar code or initial inclusion of an NDC on the label.

Outsourcing facility means a compounder that has elected to register with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act and that meets all of the conditions of section 503B.

Person who imports or offers for import means, for purposes of this part, the owner or exporter of a drug who consigns and ships a drug from a foreign

country to the United States. This includes persons who send a drug to the United States by international mail or other private delivery service, but it does not include carriers who merely transport the drug.

Private label distribution means commercial distribution of a drug under the label or trade name of a person who did not manufacture, repack, relabel, or salvage that drug.

Private label distributor means, with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed.

Registrant means any person that owns or operates an establishment that manufactures, repacks, relabels, or salvages a drug, and is not otherwise exempt from establishment registration requirements under section 510 of the Federal Food, Drug, and Cosmetic Act or this part.

Relabel means to change the existing label or labels on a drug or drug package, or change or alter the existing labeling for a drug or drug package, without repacking the drug or drug package. This term does not include the addition or modification of information affixed solely for purposes of delivery to a customer, customer identification, and/or inventory management.

Relabeler means a person who owns or operates an establishment that relabels a drug. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic relabelers and foreign relabelers.

Repack or repackage means the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug.

Repacker means a person who owns or operates an establishment that repacks a drug or drug package. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic repackers and foreign repackers.

Representative sampling of advertisements means typical advertising material (including the promotional material described in §202.1(l)(1) of this chapter, but excluding labeling as determined in §202.1(l)(2) of this chapter), that gives a balanced picture of the promotional claims used for the drug.

Representative sampling of any other labeling means typical labeling material (including the labeling material described in §202.1(l)(2) of this chapter, but excluding labels and package inserts) that gives a balanced picture of the promotional claims used for the drug.

Salvage means the act of segregating out those finished 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 the products to the marketplace and includes applying manufacturing controls such as those required by current good manufacturing practice in parts 210 and 211 of this chapter.

Salvager means a person who owns or operates an establishment that engages in salvaging. When not modified by ''domestic'' or ''foreign,'' the term includes both domestic and foreign salvagers.

Unfinished drug means an active pharmaceutical ingredient either alone or together with one or more other ingredients but does not include finished drug products.

[81 FR 60212, Aug. 31, 2016, as amended at 86 FR 17061, Apr. 1, 2021]

§ 207.3 Bulk drug substance.

Bulk drug substance, as referenced in sections 503A(b)(1)(A) and 503B(a)(2) of the Federal Food, Drug, and Cosmetic Act, previously defined in §207.3(a)(4), means the same as ''active pharmaceutical ingredient'' as defined in §207.1.

[81 FR 60212, Aug. 31, 2016, as amended at 86 FR 17061, Apr. 1, 2021]

§ 207.5 What is the purpose of this part?

Establishment registration information helps FDA identify who is manufacturing, repacking, relabeling, and