made in writing to the appropriate review division in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266 or the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002. If FDA denies the request, the holder of the approved application will have 1 year after the date of an agency denial to imprint the drug product.

(ii) Exemption requests for products that have not yet received approval shall be made in writing to the appropriate review division in CDER or CBER.

(2) Any product not subject to premarket approval is exempt from the requirement of §206.10 if, based on the product's size, shape, texture, or other physical characteristics, the manufacturer or distributor of the product is prepared to demonstrate that imprinting the dosage form is technologically infeasible or impossible.

(c) For drugs that are administered solely in controlled health care settings and not provided to patients for self-administration, sponsors may submit requests for exemptions from the requirements of this rule. Controlled settings include physicians' offices and other health care facilities. Exemption requests should be submitted in writing to the appropriate review division in CDER or CBER.

[58 FR 47958, Sept. 13, 1993, as amended at 70 FR 14981, Mar. 24, 2005; 74 FR 13112, Mar. 26, 2009; 80 FR 18091, Apr. 3, 2015]

§206.10 Code imprint required.

(a) Unless exempted under §206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. Identification of the drug product requires identification of its active ingredients and its dosage strength. Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself. Homeopathic drug products are required only to bear an imprint that identifies the manufacturer and their homeopathic nature.

(b) A holder of an approved application who has, under §314.70 (b) of this 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

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 salvaging drugs and where those operations are performed. Drug listing information gives FDA a current inventory of drugs manufactured, repacked, relabeled, or salvaged for commercial distribution. Both types of information facilitate implementation and enforcement of the Federal Food, Drug, and Cosmetic Act and are used for many important public health purposes.

§ 207.9 Who does this part cover?

(a) Except as provided in paragraph (b) of this section, this part applies to:

(1) Domestic manufacturers, domestic repackers, domestic relabelers and domestic salvagers, not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or §207.13, regardless of whether their drugs enter interstate commerce;

(2) Foreign manufacturers, foreign repackers, foreign relabelers and foreign salvagers, not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or §207.13;

(3) Private label distributors, because they must have labeler codes;

(4) Establishments engaged in the manufacture, repacking, relabeling, or salvaging of human drugs regulated under a biologics license application (BLA). These establishments are subject to the requirements of this part unless they are required to register and list such drugs as human blood or blood products under part 607 of this chapter and do not engage in activities that would otherwise require them to register and list under this part.

(5) Establishments engaged in the manufacture (as defined in §1271.3(e) of this chapter) of human cells, tissues, and cellular and tissue-based products (HCT/Ps) (as defined in §1271.3(d) of this chapter) that, under §1271.20 of this chapter, are also drugs regulated under section 351 of the Public Health Service Act or section 505 of the Federal Food,

Drug, and Cosmetic Act. These establishments must register and list those HCT/Ps following the procedures described in this part.

(b) This part does not apply to owners and operators of establishments that collect or process human whole blood and blood products unless the establishment also manufactures, repacks, or relabels other drugs. For purposes of this paragraph (b), human whole blood and blood products do not include plasma derivatives such as albumin, Immune Globulin, Factor VIII and Factor IX, and recombinant versions of plasma derivatives or animal derived plasma derivatives, or bulk product substances such as fractionation intermediates or pastes. Establishments that collect or process human whole blood and blood products as well as establishments involved in testing of human whole blood and blood products must register and list under part 607 of this chapter. Manufacturers of licensed devices and manufacturers of licensed biological products used in a licensed device must register and list under part 607 of this chapter.

(c) This part does not apply to establishments that solely manufacture, prepare, propagate, compound, assemble, or process medical devices. Registration and listing regulations for such establishments are codified in part 807 of this chapter.

§ 207.13 Who is exempt from the registration and listing requirements?

Except as provided in § 207.13(l), the following classes of persons are exempt from registration and drug listing in accordance with section 510(g) of the Federal Food, Drug, and Cosmetic Act or because FDA has determined, under section 510(g)(5) of the Federal Food, Drug, and Cosmetic Act, that their registration is not necessary for the protection of the public health. This exemption is limited to establishment registration and drug listing requirements and does not relieve a person from other statutory or regulatory obligations.

(a)(1) Pharmacies that:

(i) Operate in conformance with all applicable local laws regulating the practice of pharmacy and medicine, including all applicable local laws regulating the dispensing of prescription drugs;

(ii) Regularly engage in dispensing prescription drugs upon a valid prescription by practitioners licensed by law to administer these drugs to patients under their professional care; and

(iii) Do not manufacture, repack, relabel, or salvage drugs other than in the regular course of their business of dispensing or selling drugs at retail.

(2) The exemption in this paragraph (a) is limited to pharmacies located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Hospitals, clinics, other health care entities, and public health agencies that:

(i) Operate establishments in conformance with all applicable local laws regulating the practice of pharmacy and medicine, including all applicable local laws regulating the dispensing of prescription drugs;

(ii) Regularly engage in dispensing prescription drugs, other than human whole blood or blood products, upon a valid order or prescription by practitioners licensed by law to administer these drugs to patients under their professional care; and

(iii) Do not manufacture, repack, relabel, or salvage drugs other than in the regular course of their practice of pharmacy, including dispensing.

(2) The exemption in this paragraph (b) is limited to hospitals, clinics, other health care entities, and public health agencies located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(c) Individuals or establishments under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment to become components of a biological product are exempt from registration and listing under this part unless FDA determines that drug establishment registration and listing is necessary for the protection of the public health.

(d) Practitioners who are licensed by law to prescribe or administer drugs

and who manufacture, repack, relabel, or salvage drugs solely for use in their professional practice.

(e) Manufacturers, repackers, relabelers, or salvagers who manufacture, repack, relabel, or salvage drugs solely for use in research, teaching, or chemical analysis and not for sale.

(f) Manufacturers, repackers, and relabelers of harmless inactive ingredients such as excipients, colorings, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs.

(g) Manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds, except for persons who manufacture, repack, relabel, or salvage Type B or Type C medicated feeds starting from Category II, Type A medicated articles for which a medicated feed mill license approved under part 515 of this chapter is required. This exemption also does not apply to persons that would otherwise be required to register (such as manufacturers, repackers, relabelers, or salvagers of certain free-choice feeds, as defined in §510.455 of this chapter, or certain liquid feeds, as defined in §558.5 of this chapter, where the specifications and/or formulas are not published and a medicated feed mill license is required). All manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds are exempt from listing.

(h) Any manufacturer, repacker, relabeler, or salvager of a virus, serum, toxin, or analogous product intended for the treatment of domestic animals who holds an unsuspended and unrevoked license issued by the Secretary of Agriculture under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832 (21 U.S.C. 151 *et seq.*)), provided that this exemption from registration applies only to the manufacturer, repacker, relabeler, or salvager of that animal virus, serum, toxin, or analogous product.

(i) Carriers, in their receipt, carriage, holding, or delivery of drugs in the usual course of business as carriers.

(j) Foreign establishments whose drugs are imported or offered for import into the United States must comply with the establishment registration and listing requirements of this part unless exempt under this section or unless:

(1) Their drugs enter a foreign trade zone and are re-exported without having entered U.S. commerce, or

(2) Their drugs are imported in conformance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act.

(k) Entities that are registered with FDA as outsourcing facilities and that compound drugs in conformance with section 503B of the Federal Food, Drug, and Cosmetic Act.

(l) The exemptions provided in paragraphs (a) through (k) of this section do not apply to such persons if they:

(1) Manufacture (as defined in §207.1), repack, relabel, or salvage compounded positron emission tomography drugs as defined in section 201(ii) of the Federal Food, Drug, and Cosmetic Act;

(2) Manufacture (as defined in §600.3(u) of this chapter) a human biological product subject to licensing under section 351 of the Public Health Service Act; or

(3) Engage in activities that would otherwise require them to register under this part.

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

Subpart B—Registration

§207.17 Who must register?

(a) Unless exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or this part, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug, or an animal feed bearing or containing a new animal drug, and each foreign establishment that 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. When operations are conducted at more than one establishment and common ownership and control among all the establishments exists, the parent, subsidiary, or affiliate company may submit registration information for all establishments.

(b) Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to

register under this part. FDA will accept registration or listing information submitted by a private label distributor only if it is acting as an authorized agent for and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

§ 207.21 When must initial registration information be provided?

(a) Registrants must register each domestic establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug at such establishment.

(b) Registrants must register each foreign establishment before a drug or an animal feed bearing or containing a new animal drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States.

§ 207.25 What information is required for registration?

Registrants must provide the following information:

(a) Name of the owner or operator of each establishment; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation;

(b) Each establishment's name, physical address, and telephone number(s);

(c) All name(s) of the establishment, including names under which the establishment conducts business or names by which the establishment is known;

(d) Registration number of each establishment, if previously assigned by FDA;

(e) A Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act.

(f) All types of operations performed at each establishment;

(g) Name, mailing address, telephone number, and email address of the official contact for the establishment, as provided in § 207.69(a); and

(h) Additionally, with respect to foreign establishments subject to registration, the name, mailing address, telephone number, and email address must be provided for:

(1) The United States agent, as provided in § 207.69(b);

(2) Each importer in the United States of drugs manufactured, repacked, relabeled, or salvaged at the establishment that is known to the establishment; and

(3) Each person who imports or offers for import such drug to the United States.

§ 207.29 What are the requirements for reviewing and updating registration information?

(a) *Expedited updates.* Registrants must update their registration information no later than 30 calendar days after:

(1) Closing or selling an establishment;

(2) Changing an establishment's name or physical address; or

(3) Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent. A registrant, official contact, or United States agent may notify FDA about a change of information for the designated official contact or United States agent, but only a registrant is permitted to designate a new official contact or United States agent.

(b) *Annual review and update of registration information.* Registrants must review and update all registration information required under § 207.25 for each establishment.

(1) The first review and update must occur during the period beginning on October 1 and ending December 31 of the year of initial registration, if the initial registration occurs prior to October 1. Subsequent reviews and updates must occur annually, during the period beginning on October 1 and ending December 31 of each calendar year.

(2) The updates must reflect all changes that have occurred since the last annual review and update.

(3) If no changes have occurred since the last registration, registrants must certify that no changes have occurred.

Subpart C—National Drug Code

§ 207.33 What is the National Drug Code (NDC), how is it assigned, and what are its requirements?

(a) *What is the NDC for a drug and what products must have unique NDCs*? The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of this part must have a unique NDC to identify its labeler, product, and package size and type.

(b) *What is the format of an NDC*? (1) Except as described in paragraph (b)(4) of this section, the NDC must consist of 10 or 11 digits, divided into three segments as follows:

(i) The first segment of the NDC is the labeler code and consists of 4, 5, or 6 digits. The labeler code is assigned by FDA.

(ii) The second segment of the NDC is the product code and consists of 3 or 4 digits, as specified in paragraphs (b)(2) and (3) of this section.

(iii) The third segment of the NDC is the package code and consists of 1 or 2 digits as specified in paragraphs (b)(2) and (3) of this section. The package code identifies the package size and type of the drug and differentiates between different quantitative and qualitative attributes of the product packaging.

(2) The following combinations of labeler code, product code and package code character lengths are permissible:

(i) If a labeler code is either 5 or 6 digits in length, it may be combined with:

(A) A product code consisting of 4 digits and a package code consisting of 1 digit for a total NDC length of 10 or 11 digits (5–4–1 or 6–4–1), or

(B) A product code consisting of 3 digits and a package code consisting of 2 digits for a total NDC length of 10 or 11 digits (5–3–2 or 6–3–2).

(ii) If a labeler code is 4 digits in length, it may be combined only with a product code consisting of 4 digits and a package code consisting of 2 digits for a total NDC length of 10 digits (4–4–2).

(3) A registrant or private label distributor with a given labeler code must use only one Product-Package Code configuration (e.g., a 3-digit product code combined with a 2-digit package code or a 4-digit product code combined with a 1-digit package code). This single configuration must be used in all NDCs that include the given labeler code that are reserved in accordance with § 207.33(d)(3) or listed in accordance with § 207.49 or § 207.53.

(4) An alternatively formatted NDC that is approved for use by the relevant Center Director may be used for the following HCT/Ps if they are minimally manipulated: Hematopoietic stem/progenitor cells derived from peripheral and cord blood, and lymphocytes collected from peripheral blood.

(c) *Who must obtain an NDC labeler code and how is the code assigned and updated*? (1) Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under this part must apply for an NDC labeler code, by providing the following information:

(i) The name, physical address, email address, and other contact information FDA may request, of the person for whom the NDC labeler code is requested;

(ii) The type(s) of activities (e.g., manufacture or repacking) in which the person requesting the NDC labeler code engages with respect to human drugs; and

(iii) The type(s) of drug(s) (human, animal, or both, and prescription, nonprescription, or both) to which the NDC labeler code will be applied.

(2) Each person who is assigned an NDC labeler code must update the information submitted under paragraph (c)(1)of this section within 30 calendar days after any change to that information.

(d) *How is an NDC proposed for assignment by FDA, when is an NDC assigned by FDA, and how can a proposed NDC be reserved*? (1) An NDC is proposed for assignment by FDA when it is submitted for the first time with listing information in accordance with § 207.49 or § 207.53, as applicable.

(i) Each manufacturer, repacker, or relabeler must propose for assignment by FDA an NDC that includes its own labeler code for each package size and

type of drug that it manufactures, repacks, or relabels for commercial distribution.

(ii) In addition, if a drug is distributed under the trade name or label of a private label distributor, the manufacturer, repacker, or relabeler must also propose for assignment by FDA an NDC that includes the labeler code of the private label distributor under whose trade name or label the drug is distributed, for each package size and type so distributed.

(2) If a proposed NDC conforms to the requirements of this section and is not reserved for a different drug or was not previously assigned to a different drug, FDA will assign the NDC to a drug when it receives listing information required for that drug under § 207.49 or § 207.53.

(3) A manufacturer, repacker, relabeler, or private label distributor may voluntarily reserve a proposed NDC for a drug, before the drug is listed, by submitting the following information:

(i) A proposed NDC that conforms to the requirements of this section;

(ii) The established name of the active ingredient(s) and the strength of each active ingredient in the drug; and

(iii) In the case of a finished drug product, the dosage form, and route of administration.

(4) If the required information is submitted and the proposed NDC is properly formatted and not already assigned or reserved, FDA will reserve the proposed NDC for a period of 2 years from the date of submission. If the drug for which the proposed NDC is reserved is not listed in accordance with § 207.49 or § 207.53 during such 2-year period, the reservation of the proposed NDC will lapse. FDA may also cancel the reservation of a proposed NDC at any time on the request of the person whose labeler code is included in the proposed NDC.

(e) *How must the information be submitted to us*? The information described in paragraphs (c) and (d) of this section must be submitted electronically unless FDA grants a waiver under § 207.65.

§ 207.35 What changes require a new NDC?

(a) Once an NDC has been assigned by FDA, the registrant must propose a new and unique NDC for a drug when there is a change, after the drug is initially marketed, to any of the information identified in paragraphs (b) and (c) of this section. A new NDC must be proposed to FDA for assignment through an updated listing in accordance with § 207.57.

(b) The proposed new NDC must include a new product code when there is a change to any of the following information:

(1) The drug's established name or proprietary name, if any;

(2) Any active pharmaceutical ingredient or the strength of any active pharmaceutical ingredient;

(3) The dosage form;

(4) A change in the drug's status, between prescription and nonprescription, or for animal drugs, between prescription, nonprescription, or veterinary feed directive (VFD) status;

(5) A change in the drug's intended use between human and animal; or

(6) The drug's distinguishing characteristics such as size, shape, color, code imprint, flavor, and scoring (if any).

(c) When there is a change only to the package size or type, including the immediate unit-of-use container, if any, the proposed new NDC must include only a new package code and retain the existing product code unless all available package codes have already been combined with the existing product code in NDCs assigned by FDA.

§ 207.37 What restrictions pertain to the use of the NDC?

(a) A product may be deemed to be misbranded if an NDC is used:

(1) To represent a different drug than the drug for which the NDC has been assigned, as described in § 207.33;

(2) To denote or imply FDA approval of a drug; or

(3) On products that are not subject to parts 207, 607 of this chapter, or 1271 of this chapter, such as dietary supplements and medical devices.

(b) If marketing is resumed for a discontinued drug, and no changes have been made to the drug that would require a new NDC under § 207.35, the

drug must have the same NDC that was assigned to it as described in § 207.33, before marketing was discontinued.

Subpart D—Listing

§ 207.41 Who must list drugs and what drugs must they list?

(a) Each registrant must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution. Each domestic registrant must list each such drug regardless of whether the drug enters interstate commerce. When operations are conducted at more than one establishment, and common ownership and control exists among all the establishments, the parent, subsidiary, or affiliate company may submit listing information for any drug manufactured, repacked, relabeled, or salvaged at any such establishment. A drug manufactured, repacked, or relabeled for private label distribution must be listed in accordance with paragraph (c) of this section.

(b) Registrants must provide listing information for each drug in accordance with the listing requirements described in §§ 207.49, 207.53, and 207.54 that correspond to the activity or activities they engage in for that drug.

(c)(1) For both animal and human drugs, each registrant must list each drug it manufactures, repacks, or relabels for commercial distribution under the trade name or label of a private label distributor using an NDC that includes such private label distributor's labeler code.

(2) Additionally, in the case of human drugs, each registrant must list each human drug it manufactures, repacks, or relabels using an NDC that includes the registrant's own labeler code, regardless of whether the drug is commercially distributed under the registrant's own label or trade name or under the label or trade name of a private label distributor.

§ 207.45 When, after initial registration of an establishment, must drug listing information be submitted?

For each drug being manufactured, repacked, relabeled, or salvaged for commercial distribution at an establishment at the time of initial registration, drug listing information must be submitted no later than 3 calendar days after the initial registration of the establishment.

§ 207.49 What listing information must a registrant submit for a drug it manufactures?

(a) Each registrant must provide the following listing information for each drug it manufactures for commercial distribution.

(1) The appropriate NDC(s), as described in § 207.33, that include all package code variations. In the case of human drugs, the appropriate NDC(s) submitted under this paragraph include the registrant's labeler code. In the case of animal drugs, the appropriate NDC(s) submitted under this paragraph include the registrant's labeler code, except that when the drug is manufactured for commercial distribution under the trade name or label of a private label distributor, the appropriate NDC(s) for animal drugs include the private label distributor's labeler code;

(2) Package type and volume information corresponding to the package code segment of the NDC;

(3) The listed drug's established name and proprietary name, if any;

(4) The name and quantity of each active pharmaceutical ingredient in the listed drug;

(5) The name of each inactive ingredient in the listed drug, along with any assertions of confidentiality associated with individual inactive ingredients;

(6) The dosage form;

(7) The drug's approved U.S. application number, if any;

(8) The drug type (e.g., as applicable, finished vs. unfinished, human vs. animal, prescription vs. nonprescription);

(9) In the case of an unfinished drug, the number assigned to the Drug Master File or Veterinary Master File, if any, that describes the manufacture of the drug;

(10) For each drug that is subject to the imprinting requirements of part 206 of this chapter including products that are exempted under § 206.7(b), the drug's size, shape, color, scoring, and code imprint (if any);

(11) The route or routes of administration of the drug;

(12) For each drug bearing an NDC:

(i) The name and Unique Facility Identifier of the establishment where the registrant who lists the drug manufactures it and the type of operation performed on the drug at that establishment, and

(ii) The name and Unique Facility Identifier of every other establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment. This includes all establishments involved in the production of each unfinished drug received by the registrant for use in the production of the drug being listed. The names, Unique Facility Identifiers, and type of operations for establishments involved in production of each unfinished drug received by the registrant for use in the production of the drug being listed may be provided by including the properly assigned and listed NDC for such unfinished drug.

(13) The schedule of the drug under section 202 of the Controlled Substances Act, if applicable;

(14) Advertisements:

(i) A representative sampling of advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(ii) If FDA requests it, for good cause, a copy of all advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, including those advertisements described in § 202.1(*l*)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after FDA's request.

(15) For drugs bearing the NDC(s) reported under paragraph (a)(1) of this section, except those drugs manufactured exclusively for private label distribution and not distributed under the registrant's own name and label, provide the following labeling, as applicable:

(i) *Human prescription drugs.* All current labeling except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in § 207.1.

(ii) *Human nonprescription drugs.* (A) For each human nonprescription drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in § 207.1.

(B) For each human nonprescription drug not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), the package insert (if any), and a representative sampling of any other labeling. This labeling submission must include the content of labeling as defined in section § 207.1.

(iii) *Animal drugs.* (A) For each animal drug that is subject to section 512 of the Federal Food, Drug, and Cosmetic Act, which includes, but is not limited to, new animal drugs that have been approved, conditionally approved, or indexed under sections 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), including the content of labeling as defined in § 207.1;

(B) For all other animal drugs, a copy of the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), the package insert, the content of labeling as defined in § 207.1, and a representative sampling of any other labeling;

(iv) *All other listed drugs.* For all other listed drugs, including unfinished drugs, the label (if any), except that only one representative label need be submitted where differences exist only in the quantity of contents statement.

(16) Listing submissions described in § 207.41(c)(2) for human drugs manufactured for private label distribution must include all information specified in § 207.49(a)(2) through (14) and:

(i) The appropriate NDC(s) (as described in § 207.33) that include the private label distributor's labeler code and all package code variations;

(ii) The name, mailing address, telephone number, and email address of the private label distributor; and

(iii) For drugs bearing the NDC(s) reported under paragraph (a)(16)(i) of this section, labeling as described in paragraph (a)(15) of this section that accompanies the private label distributor's product.

(b) Additionally, each registrant is requested, but not required, to provide the following information for each human drug it manufactures for commercial distribution:

(1) The drug's over-the-counter monograph reference, if any; and

(2) The date on which the drug was or will be introduced into commercial distribution.

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

§ 207.53 What listing information must a registrant submit for a drug that it repacks or relabels?

Each registrant must provide the following listing information for each drug it repacks or relabels:

(a) *NDC.* The appropriate NDC(s), as described in § 207.33, that include the registrant's labeler code and all package code variations;

(b) *Source NDC.* The NDC assigned to each finished drug received by the registrant for repacking or relabeling, with the exception of medical gases. Each such NDC must be associated with the corresponding NDC(s) for repacked or relabeled drugs, reported under paragraph (a) of this section.

(c) *Name and Unique Facility Identifier.* For each drug identified by an NDC reported under paragraph (a) of this section, the name and Unique Facility Identifier of every establishment where repacking or relabeling is performed for the drug and the type of operation (repacking vs. relabeling) performed at each such establishment.

(d) *Labeling.* For each drug identified by an NDC reported under paragraph (a) of this section, except those human drugs repacked or relabeled exclusively for private label distribution and not distributed under the registrant's own name and label, provide the following:

(1) *Human prescription drugs.* All current labeling for the repacked or relabeled drug except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in section § 207.1.

(2) *Human nonprescription drugs.* (i) For each human nonprescription drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code. This labeling submission must include the content of labeling, as defined in § 207.1.

(ii) For each human nonprescription drug not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement or the bar code), the package insert (if any), and a representative sampling of any other labeling. This labeling submission must include the content of labeling as defined in § 207.1.

(3) *Animal drugs.* (i) For each animal drug that is subject to section 512 of the Federal Food, Drug, and Cosmetic Act, which includes but is not limited to, new animal drugs that have been approved, conditionally approved, or indexed under sections 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), including the content of labeling as defined in § 207.1;

(ii) For all other animal drugs, a copy of the current label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement), the package insert, the content of labeling as defined in § 207.1, and a representative sampling of any other labeling;

(4) *All other*. For all other listed drugs, including unfinished drugs, the label (if any), except that only one representative label need be submitted where differences exist only in the quantity of contents statement.

(e) *Advertisements*. (1) A representative sampling of advertisements for a human prescription drug that is not subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

(2) If we request it for good cause, a copy of all advertisements for a particular drug described in paragraph (e)(1) of this section, including advertisements described in § 202.1(l)(1) of this chapter. Such advertisements must be submitted within 30 calendar days after our request.

(f) *Private label distributor products*. A listing submission for a human drug distributed by a private label distributor described in § 207.41(c)(2) must include information specified in § 207.53(b) through (e) as applicable and:

(1) The appropriate NDC(s) (as described in § 207.33) that include the private label distributor's labeler code and all package code variations;

(2) The name, mailing address, telephone number, and email address of the private label distributor; and

(3) For drugs bearing the NDC(s) reported under paragraph (f)(1) of this section, labeling as described in paragraphs (d)(1) through (4) of this section, as applicable, that accompanies the private label distributor's product.

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

§ 207.54 What listing information must a registrant submit for a drug that it salvages?

A registrant who also relabels or repacks a drug that it salvages must list the drug it relabels or repacks in accordance with § 207.53 rather than in accordance with this section. A registrant who performs only salvaging with respect to a drug must provide the following listing information for that drug.

(a) The NDC assigned to the drug immediately before the drug is received by the registrant for salvaging;

(b) The lot number and expiration date of the salvaged drug product; and

(c) The name and Unique Facility Identifier for each establishment where the registrant salvages the drug.

§ 207.55 What additional drug listing information may FDA require?

For a particular listed drug, upon our request, the registrant must briefly state the basis for its belief that the drug is not subject to section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

§ 207.57 What information must registrants submit when updating listing information and when?

Registrants must review and update listing information at a minimum, as follows:

(a) Registrants must provide listing information at the time of annual establishment registration for any drug manufactured, repacked, relabeled, or salvaged by them for commercial distribution that has not been listed previously.

(b) Registrants must review and update their drug listing information each June and December. When doing so, registrants must:

(1)(i) Provide listing information, in accordance with §§ 207.49, 207.53, and 207.54, for any drug manufactured, repacked, relabeled, or salvaged by them for commercial distribution that has not been previously listed;

(ii) Submit the date that they discontinued the manufacture, repacking, relabeling or salvaging for commercial distribution of a listed drug and provide the expiration date of the last lot manufactured, repacked, relabeled, or salvaged;

(iii) Submit the date that they resumed the manufacture, repacking, or relabeling for commercial distribution of a drug previously discontinued, and

provide any required listing information not previously submitted; and

(iv) Submit any material changes in any information previously submitted pursuant to §§ 207.49, 207.53, 207.54, or other relevant sections of this part; or

(2) For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single ''no changes'' certification during the annual registration update under § 207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.

(c) Registrants are encouraged to submit listing information for every drug subject to listing under this part prior to commercial distribution and are encouraged to update listing information at the time of any change affecting information previously submitted.

Subpart E—Electronic Format for Registration and Listing

§ 207.61 How is registration and listing information provided to FDA?

(a) *Electronic format.* (1) Except as provided in § 207.65, all information submitted under this part must be transmitted to FDA in electronic format by using our electronic drug registration and listing system, in a form that we can process, review, and archive. We may periodically issue guidance on how to provide registration and listing information in electronic format (specifying for example method of transmission, media, file formats, preparation, and organization of files).

(2) Information provided in electronic format must comply with part 11 of this chapter, except as follows:

(i) Advertisements and labeling, including the content of labeling, required under this part are exempt from the requirements in § 11.10(a), (c) through (h), and (k) of this chapter and the corresponding requirements in § 11.30 of this chapter.

(ii) All other information submitted under this part is exempt from the requirements in § 11.10(b), (c), and (e) of this chapter and the corresponding requirements in § 11.30 of this chapter.

(b) *English language.* Drug establishment registration and drug listing information must be provided in the English language. The content of labeling must be provided at a minimum in the English language. Where § 201.15(c) of this chapter permits product labeling solely in a foreign language, the content of labeling must be submitted in that language along with an accurate English translation.

§ 207.65 How can a waiver of the electronic submission requirement be obtained?

(a) All information submitted under this part must be transmitted to FDA electronically in accordance with § 207.61(a) unless FDA has granted a request for waiver of this requirement prior to the date on which submission of such information is due. Submission of a request for waiver does not excuse timely compliance with the registration and listing requirements. FDA will grant a waiver request if FDA determines that the use of electronic means for submission of registration and listing information is not reasonable for the registrant making the waiver request.

(b) Waiver requests under this section must be submitted in writing and must include the specific reasons why electronic submission is not reasonable for the registrant and a U.S. telephone number and mailing address where FDA can contact the registrant. All waiver requests must be sent to: SPL Coordinator, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993.

(c) If FDA grants the waiver request, FDA may limit its duration and will specify terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable.

Subpart F—Miscellaneous

§ 207.69 What are the requirements for an official contact and a United States agent?

(a) *Official contact.* Registrants subject to the registration requirements of this part must designate an official contact for each establishment. The official contact is responsible for:

(1) Ensuring the accuracy of registration and listing information; and

(2) Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications.

(b) *United States agent.* Registrants of foreign establishments subject to this part must designate a single United States agent. The United States agent must reside or maintain a place of business in the United States and may not be a mailbox, answering machine or service, or other place where a person acting as the United States agent is not physically present. The United States agent is responsible for:

(1) Reviewing, disseminating, routing, and responding to all communications from FDA including emergency communications;

(2) Responding to questions concerning those drugs that are imported or offered for import to the United States;

(3) Assisting FDA in scheduling inspections; and

(4) If FDA is unable to contact a foreign registrant directly or expeditiously, FDA may provide the information and/or documents to the United States agent. FDA's providing information and/or documents to the United States agent is equivalent to providing the same information and/or documents to the foreign registrant.

§ 207.77 What legal status is conferred by registration and listing?

(a) Registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment, nor does it mean that a product may be legally marketed. Any representation that creates an impression of official approval or that a drug is approved or is legally marketable because of registration or listing is misleading and constitutes misbranding.

(b) FDA's acceptance of registration and listing information, inclusion of a drug in our database of drugs, or assignment of an NDC does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed. Any representation that creates the impression that a drug is approved or is legally marketable because it appears in our database of drugs, has been assigned or displays an NDC, or the establishment has been assigned an establishment registration number or Unique Facility Identifier is misleading and constitutes misbranding. Failure to comply with § 207.37 may also constitute misbranding.

(c) Neither registration nor listing constitutes a determination by FDA that a product is a drug as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. Registration or listing may, however, be evidence that a facility intends to or does manufacture, repack, relabel, distribute, or salvage drugs or that a product is intended to be a drug.

§ 207.81 What registration and listing information will FDA make available for public disclosure?

(a) Except as provided in paragraphs (b) and (c) of this section, the following information will be available for public disclosure, upon request or at FDA's discretion:

(1) All establishment registration information, and

(2) After a drug is marketed, information obtained under § 207.33, § 207.49, § 207.53, § 207.54, or § 207.57.

(b) Unless such information is publicly available or FDA finds that confidentiality would be inconsistent with protection of the public health, FDA will not make publicly available:

(1) Any information submitted under § 207.55 as the basis upon which it has been determined that a particular drug is not subject to section 505 or 512 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act,

(2) The names of any inactive ingredients submitted under § 207.49(a)(4) for

which the registrant makes a valid assertion of confidentiality under §20.61 of this chapter or other provision of law, or

(3) Drug listing information obtained under §207.33(d)(3), §207.49(a)(9) and (12), §207.53(b) and (c), or §207.54(a) or (c).

(c) FDA may determine, in limited circumstances and on a case-by-case basis, that it would be consistent with the protection of the public health and the Freedom of Information Act to exempt from public disclosure specific information identified in paragraph (a) of this section.

PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

Subpart A—General Provisions

Subpart B—General Requirements for a Medication Guide

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 371, 374; 42 U.S.C. 262.

SOURCE: 63 FR 66396, Dec. 1, 1998, unless otherwise noted.

Subpart A—General Provisions

§208.1 Scope and purpose.

(a) This part sets forth requirements for patient labeling for human prescription drug products, including biological products, that the Food and Drug Administration (FDA) determines pose a serious and significant public health concern requiring distribution of FDA-approved patient information. It applies primarily to human prescription drug products used on an outpatient basis without direct supervision by a health professional. This part shall apply to new prescriptions and refill prescriptions.

(b) The purpose of patient labeling for human prescription drug products required under this part is to provide information when the FDA determines in writing that it is necessary to patients' safe and effective use of drug products.

(c) Patient labeling will be required if the FDA determines that one or more of the following circumstances exists:

(1) The drug product is one for which patient labeling could help prevent serious adverse effects.

(2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients' decision to use, or to continue to use, the product.

(3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.

§208.3 Definitions.

For the purposes of this part, the following definitions shall apply:

(a) *Authorized dispenser* means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products on prescription in the course of professional practice.

(b) *Dispense to patients* means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c) *Distribute* means the act of delivering, other than by dispensing, a drug product to any person.

(d) *Distributor* means a person who distributes a drug product.

(e) *Drug product* means a finished dosage form, e.g., tablet, capsule, or solution, that contains an active drug ingredient, generally, but not necessarily, in association with inactive ingredients. For purposes of this part, drug product also means biological product within the meaning of section 351(a) of the Public Health Service Act.