

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