

**CENTER FOR VETERINARY MEDICINE****PROGRAM POLICY AND PROCEDURES MANUAL**1240.3560

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**GENERAL REVIEW AND ENFORCEMENT POLICIES**

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**REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF  
DRUGS IN COMMERCIAL DISTRIBUTION**

The Drug Listing Act (DLA) of 1972 became effective on February 1, 1973. The DLA amended the Federal Food, Drug, and Cosmetic Act (FFDCA) as Section 510, and provided that every person who owns or operates any establishment engaged in the manufacture and processing of drugs (as described in section 510) shall register with the Secretary his/her name and place(s) of business. The DLA and the FDA Safety and Innovation Act (FDASIA) of 2012 also provides for the assignment of a registration number or a Unique Facility Identifier (UFI) to any person or any establishment registered in accordance with this section and provides for assignment of a drug listing number to each drug or class of drugs.

1. Purpose:  
The purpose is to provide general references and guidance to registration of producers of drugs and listings of drugs in commercial distribution.
2. Authorities:
  - a. Section 510 of the FFDCA.
  - b. Title 21, Part 207 of the Code of Federal Regulations (CFR): 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
  - c. Title 21, Section 510.600 of the Code of Federal Regulations, Names, Addresses, and Drug Labeler Codes of Sponsors of Approved Applications.
3. Definitions:
  - a. **Establishment** means a place of business under one management at one general physical location. The term is further defined in 21 CFR 207.1.

- b. **Drug Labeler Code** means the number established pursuant to section 510 of the act. The Labeler Code is used by sponsors on electronic forms related to Drug Establishment Registration and Drug Product Listing. The Labeler Code Number is assigned by the FDA.
- c. **NDC Code** means the National Drug Code number assigned as a listing number to each drug or class of drugs as described in section 510(e) of the Act.

#### 4. Responsibilities

- a. The Office of Surveillance and Compliance, Division of Surveillance, HFV-212, is responsible for procedures related to the responsibilities of the Center under section 510 of the Act.
- b. The Office of New Animal Drug Evaluation is responsible for providing information and advice to sponsors of approved new animal drug applications (NADAs) (including Conditional NADAs and Abbreviated NADAs) who may not be knowledgeable of the procedures for foreign and domestic drug establishments and drug listing requirements.
- c. The Office of Minor Use and Minor Species Animal Drug Development is responsible for providing information and advice to sponsors of legally marketed unapproved new animal drugs for minor species (indexed drugs) who may not be knowledgeable of the procedures for foreign and domestic drug establishments and drug listing requirements.

#### 5. Who Must Register and Submit a Drug List:

Owners or operators of all drug establishments not exempt under Section 510(g) of the Federal Food, Drug, and Cosmetic Act (Title 21 of the Code of Federal Regulations, Section 207.17) who engage in manufacturing, repacking, relabeling, or salvaging a drug or an animal feed bearing or containing a new animal drug. 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.

Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register. FDA will accept registration or listing information submitted by a private label distributor only if it is acting as an authorized agent of and submitting information that pertains to an establishment that manufactures, repacks, relabels, or salvages drugs.

Every foreign drug establishment whose drugs are imported or offered for import into the United States shall comply with the drug listing requirements and are required to register as an establishment. Failure to register in accordance with Section 510 of the Act is a violation of Section 301(p) of the FFD&C Act.

6. Time Frames for Registration and Drug Listing:

a. Registration:

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. 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.

b. Annual Registration:

Registrants who have registered a new establishment between January 1 and September 30 must review and update their information during the period October 1 and ending December 31 of the year of initial registration. Subsequent reviews and updates must occur annually, during the period beginning October 1 and ending December 31 of each calendar year. The updates must reflect all changes that have occurred since the last annual review and update. If no changes have occurred since the last registration, registrants must certify that no changes have occurred.

Owners and operators of all establishments so registered shall update their drug listing information each June and December.

7. Information Required in Registration and Drug Listing:

a. For Registration – Refer to 21 CFR 207.25 and 207.29.

- (1) 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.
- (2) Each establishment's name, physical address, and telephone number(s).
- (3) All name(s) of the establishment, including names under which the establishment conducts business or names by which the establishment is known.
- (4) Registration number of each establishment, if previously assigned by FDA.
- (5) A Unique Facility Identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act.
- (6) All business operations performed at each establishment
- (7) Name, mailing address, telephone number, and email address of the official contact for the establishment, as provided in 207.69(a).

- (8) With respect to foreign establishments subject to registration, the name, mailing address, telephone number, and email address must be provided for:
- i. The United States agent, as provided in 207.69(b).
  - ii. Each importer in the United states of drugs manufactured, repacked, relabeled, or salvaged at the establishment that is known to the establishment.
  - iii. Each person who imports or offer for import such drug to the United States.
- b. For Product Listing - Refer to 21 CFR 207.41 and 207.49.
- (1) List of drugs, including bulk drug substances and Type A Medicated Articles for use in the manufacture of animal feeds as well as finished dosage forms, by established name and by proprietary name which are being manufactured, prepared, propagated, compounded, or processed for commercial distribution and which have not been included in any list previously submitted.
  - (2) New Animal Drug Applications (NADA) or Minor Species Index File (MIF) number for each drug listed which is regarded by the registrant as subject to Section 512, 571, or 572 of the Act and a copy of all current labeling.
  - (3) A copy of the label and all current labeling except that only one representative carton label need be submitted where differences exist only in the quantity of contents statement.
  - (4) The name and quantity of each active pharmaceutical ingredient in the listed drug.
  - (5) The names, Unique Facility Identifiers (UFIs), and type of operations of every drug establishment at which the listed drug is manufactured.
  - (6) The appropriate National Drug Code (NDC) number for each drug listed that includes all package code variations. In the case of animal drugs, the appropriate NDC(s) submitted 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.
  - (7) Package type and volume information corresponding to the package code segment of the National Drug Code (NDC).
  - (8) The name of each inactive ingredient in the listed drug, along with any assertions of confidentiality associated with individual inactive ingredients.
  - (9) The dosage form.
  - (10) The drug type (e.g. human vs. animal, prescription vs. nonprescription).

- (11) In the case of an unfinished drug (an active pharmaceutical ingredient either alone or together with one or more other ingredients) the number assigned to the Drug Master File or Veterinary Master File, if any, that describes the manufacture of the drug.
  - (12) For each drug that is subject to the imprinting requirements of Section 206 including products that are exempted under 206.7(b), the drug's size, color, scoring, and code imprint (if any).
  - (13) The route or routes of administration of the drug.
  - (14) The schedule of the drug under Section 202 of the Controlled Substances Act, if applicable.
- c. For Updating Drug Listing Information – Refer to 21 CFR 207.57
- (1) Listing of all drugs introduced by the registrant for commercial distribution which have not been included in any previously submitted list. All of the information required by Section 207.49, 207.53, and 207.54 shall be provided for each such drug.
  - (2) Listing of all drugs formerly listed, for which commercial distribution has been discontinued giving NDC number, established name, if any, and proprietary name of product, date of discontinuance, and providing the expiration date of the last lot manufactured, repacked, relabeled, or salvaged.
  - (3) Submit the date that the firm resumed the manufacture, repacking, relabeling for commercial distribution of a drug previously discontinued, and provide any required listing information not previously submitted and any other information required by Section 207.49, 207.53, and 207.54 of the regulations not previously submitted.
  - (4) Any material change in any information previously submitted. For each listed drug, certify that no changes subject to reporting under 207.57(b)(1)(iv) have occurred if no such changes have occurred since the last review and update. Registrants are encouraged to submit listing information for every drug subject to listing under this part prior to commercial distribution and are encourage updating listing information at the time of any change affecting information previously submitted.