
GENERAL REVIEW AND ENFORCEMENT POLICIES

**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 also provided for the assignment of a registration number to any person or any establishment registered in accordance with this section and provided for assignment of a drug listing number to each drug or class of drugs.

1. Purpose:

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): Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution.
- 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 207.3.
- b. **Drug Labeler Code** means the number established pursuant to section 510 of the act. The Labeler Code is used by sponsors on forms related to Drug Establishment

Registration and Drug Product Listing. The Labeler Code Number is assigned by the Product Information Management Branch, HFD-095, Division of Drug Labeling Compliance, Center for Drug Evaluation and Research.

- 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 Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, HFV-214, 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 Abbreviated NADAs) 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 207.20) who engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, including blood, blood products, and biologicals, are required to register each such establishment and to submit a list of every drug in commercial distribution, whether or not the output of such establishment or any particular drug so listed enters interstate commerce. (The terms, "manufacture, preparation, propagation, compounding, or processing" include repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.)

Distributors who are not otherwise required to register under Section 510 of the Act may submit drug listing information directly to the Food and Drug Administration in the absence of Certification from the distributor that they will submit information for their products (See 21 CFR, Section 207.20(b).)

Every foreign drug establishment shall comply with the drug listing requirements but is not

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:

The owner or operator of an establishment entering into the manufacture, preparation, propagation, compounding, processing, repackaging, or relabeling of a drug or drugs must register such establishment within 5 days after the beginning of such operations and submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment has not previously entered into such operation, as listed above, registration shall follow within five (5) days after the submission of a new drug application, new animal drug application, feed mill license, or an establishment license application in order to manufacture biological products. Owners and operators of all establishments so engaged must register annually within thirty (30) days of receipt of re-registration forms from the Food and Drug Administration (FDA).

b. Annual Registration Forms:

Annual registration forms shall be mailed to registered establishments by the FDA in each calendar year, according to a schedule based on the first letter of the name of the establishment's parent company, as stated in the firm's original registration form or, if no parent company name was stated on that form by the first letter of the establishments name. The schedule is as follows:

- (1) January - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter A or B.
- (2) February - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter C, D, or E.
- (3) March - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter F, G, or H.

- (4) April - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter I, J, K, L, or M.
- (5) May - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter N, O, P, Q, or R.
- (6) June - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter S or T.
- (7) July - To establishments whose parent company's name, or if no parent company name is given, whose firm name begins with the letter U, V, W, X, Y, or Z and numbers.

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

7. How to Register and List Drugs:

FDA Forms:

Form FD 2656 - Registration of Drug Establishment

Form FD 2657 - Drug Product Listing

Form FD 2658 - Registered Establishments' Report of Private Label Distributors.

These forms can be obtained by writing to:

Center for Drug Evaluation and Research
Product Information Management Branch, HFD-095
7520 Standish Place, Rm. 151, MPN I
Rockville, Maryland 20855.

The completed form(s) should be sent to:

Department of Health and Human Services

Food and Drug Administration
Center for Veterinary Medicine
Division of Epidemiology and Surveillance, HFV-214
7500 Standish Place
Rockville, Maryland 20855

The first registration and subsequent annual registration of an establishment will be on a Form FD 2656 and FD 2656E (Registration of Drug Establishment and Annual Registration of Drug Establishments.) Only one submission of Form FD 2656 is required, regardless of the number of product listing forms submitted.

Private label distributors voluntarily submitting drug listing information and foreign establishments will submit a Form FD 2656 completing only the upper portion of the form. Private label distributors will sign the certification section of the form. The original signed Form FD 2656 shall be submitted to the FDA and a signed copy shall be provided to the registered establishment.

8. Optional Distribution Data:

The first list of drugs and subsequent updates will be on Form FD 2657 (Drug Products Listing). Registered establishments, which are required to submit drug listing information in the absence of Certification from the distributor that they will list their products, will submit Form FD 2658 (Registered Establishments' Report of Private Label Distributors).

9. Information Required in Registration and Drug Listing:

- a. For Registration - Refer to Section 21 CFR 207.25(a).
 1. Name and street address of establishment including Zip Code.
 2. All trade names used by the establishment.
 3. Kind of ownership or operation.
 4. Name or owner or operator of such establishment (If a partnership - name each partner, if a corporation - name and title of each corporate officer and director and the name of the State of incorporation.)

- b. For Product Listing - Refer to 21 CFR 207.25(b).
- (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 on Form FD 2657.
 - (2) New Animal Drug Applications (NADA) number for each drug listed which is regarded by the registrant as subject to Section 505, 506, 507, or 512 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) Quantative listing of the active ingredient for each prescription or over-the-counter drug listed which is regarded by the registrant as not subject to Section 505, 506, 507, or 512 of the FFDCFA, or Section 351 of the Public Health Service Act.
 - (5) Registration number of every drug establishment within the parent company at which the listed drug is manufactured, prepared, propagated, compounded, or processed.
 - (6) National Drug Code (NDC) number for each drug listed. If no NDC Labeler Code has been assigned, the Product Code and Package Code will be included and a Labeler Code will be assigned as described in Section 207.35(b)(2)(i) of the Code of Federal Regulations.
- c. For Updating Drug Listing Information:
- (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 207.25(b) 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, and date of discontinuance.
- (3) Listing of all drugs for which a notice of discontinuance was submitted and for which commercial distribution has been resumed giving NDC number, established name, date of resumption of commercial distribution, and any other information required by Section 207.25(b) of the regulations not previously submitted.
- (4) Any material change in any information previously submitted. No report is required if no changes have occurred since the previously submitted list.

10. Voluntary Drug Listing Information:

- a. Quantity of drug distributed.
- b. Qualitative listing of the inactive ingredients for all listed drugs in the format prescribed in Form FD 2657 (Drug Product Listing).
- c. Quantitative listing of the active ingredients for all drugs listed which are subject to Section 505, 506, 507, or 512 of the Act.