

(f) Persons who manufacture Type B or Type C medicated feed using Category I, Type A medicated articles; Category I, Type B medicated feeds; and/or Category II, Type B medicated feeds, as defined in §558.3 of this chapter, as drug sources.

(g) Any manufacturer of a virus, serum, toxin, or analogous product intended for 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 manufacture or processing of that animal virus, serum, toxin, or analogous product.

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

[45 FR 38043, June 6, 1980, as amended at 51 FR 7389, Mar. 3, 1986]

Subpart C—Procedures for Domestic Drug Establishments

§ 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or subpart D of this part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs are required to register and to submit a list of every drug in commercial distribution (except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Such owners or operators are required to register and to submit a list of every drug in commercial distribution (except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments), whether or not the output of such establishment or any particular drug so listed enters interstate commerce, except that drug

listing is not required at this time for the manufacturing, preparation, propagation, compounding, or processing of an animal feed (including a Type B and Type C medicated feed) bearing or containing an animal drug, nor is drug listing required for establishments engaged in drug product salvaging. No owner or operator may register an establishment, if any part of the establishment is registered by any other owner or operator.

(b) Owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. A distributor who submits drug listing information shall include the registration number of the drug establishment that manufactured, prepared, propagated, compounded, or processed each drug listed. All distributors who submit drug listing information to FDA assume full responsibility for compliance with all of the requirements of this part. Each such distributor at the time of submitting or updating drug listing information as required under §207.30 shall certify to the registered establishment that the submission has been made by providing a signed copy of Form FDA-2656 (Registration of Drug Establishment) to the registered establishment that manufactures or processes the drug. Each such distributor shall submit the original of Form FDA-2656 showing this certification to FDA, and shall accompany the certification with a list showing the National Drug Code number that the distributor has assigned to each drug product. If a distributor does not elect to submit drug listing information directly to FDA and to obtain a Labeler Code, the registered establishment shall submit the drug listing information. Distributors or registered establishments shall use Form FDA-2658 (Registered Establishments' Report of Private Label Distributors) to submit drug listing information or to request a Labeler Code, or both.

(c) Before beginning manufacture or processing of a drug subject to one of the following applications, an owner or

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operator of an establishment is required to register before the agency approves it: a new drug application, a new animal drug application, a medicated feed application, an antibiotic application, or an establishment license application to manufacture a biological product.

(d) No registration fee is required.

(e) Registration and listing do not constitute an admission, or agreement, or determination that a product is a drug as defined in section 201(g) of the act.

[45 FR 38043, June 6, 1980, as amended at 45 FR 32293, May 16, 1980; 52 FR 2682, Jan. 26, 1987; 55 FR 11576, Mar. 29, 1990]

§207.21 Times for registration and drug listing.

(a) The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall 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 an operation, the owner or operator shall register within 5 days after submitting a new drug application, new animal drug application, medicated feed application, antibiotic application, or an establishment license application to manufacture a biological product. Owners or operators of all establishments engaged in the drug activities described in §207.3(a)(8) shall register annually within 30 days after receiving registration forms from FDA. FDA will mail Forms FDA-2656 (Registration of Drug Establishment) to registered establishments according to a schedule based on the first letter of the name of the establishment's parent company as stated on the firm's registration form. If no parent company name is given on that form, the schedule is based on the first letter of the establishment's name. In scheduling the mailing of forms based on the first letter of the company name, FDA will not consider the word "the" when it appears as the first word in the name of the parent company or establishment.

The schedule is as follows:

First letter of company name	Date FDA will mail forms
A or B	January
C, D, or E	February
F, G, or H	March
I, J, K, L, or M	April
N, O, P, Q, or R	May
S or T	June
U, V, W, X, Y, or Z	July

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

[45 FR 38043, June 6, 1980, as amended at 55 FR 11576, Mar. 29, 1990]

§207.22 How and where to register and list drugs.

(a) An establishment shall register the first time on Form FDA-2656 (Registration of Drug Establishment), obtainable on request from the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or from FDA district offices. An establishment whose drug registration for that year was validated under §207.35 shall make subsequent annual registration on Form FDA-2656 as described in §207.21(a) by mailing the completed form to the above address within 30 days after receipt from FDA.

(b) The first list of drugs and later June and December updates shall be on Form FDA-2657 (Drug Product Listing), obtainable upon request as described in paragraph (a) of this section. An establishment may submit, in lieu of Form FDA-2657, tapes for computer inputs containing the information specified in Form FDA-2657 if formats proposed for this use were reviewed and approved by the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, FDA.

[45 FR 38043, June 6, 1980, as amended at 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990]

§207.25 Information required in registration and drug listing.

(a) Form FDA-2656 (Registration of Drug Establishment) provides for furnishing or confirming information required by the act. This information includes, for each establishment, the