

§ 207.22

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 mill license application, or a biologics license application. 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; 64 FR 400, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 64 FR 63203, Nov. 19, 1999]

§ 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 name and full address of the drug establishment; all trade names used by the establishment; the kind of ownership or operation (that is, individually owned, partnership or corporation); and the name of the owner or operator of the establishment. The term *name of the owner or operator* includes in the case of a partnership the name of each partner, and in the case of a corporation the name and title of each corporate officer and director and the name of the State of incorporation.

(b) Form FDA-2657 (Drug Product Listing) provides that information required by the act be furnished as follows:

(1) A list of drugs, including bulk drug substances and Type A articles for use in the manufacture of animal feeds as well as finished dosage forms, by established name and by proprietary name, that are being manufactured or processed for commercial distribution and that have not been included in any list previously submitted to FDA on Form FDA-2657 or in conjunction with the FDA voluntary inventory on Form FDA-2422 (Survey Report of Marketed