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 updatings 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