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; 66 FR 59157, Nov. 27, 2001; 72 FR 69120, Dec. 6, 2007]

§ 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 Records Repository Team (HFD–143), 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 Records Repository Team (HFD–143), 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; 69 FR 48775, Aug. 11, 2004]

§ 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 Drugs), or Form FDA–2250 (National Drug Code Directory Input).

(2) For each drug listed that the registrant regards as subject to section 505 or 512 of the act, the new drug application number, abbreviated new drug application number, new animal drug application number, or abbreviated new animal drug application number and a copy of all current labeling, except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement.

(3) For each drug listed that the registrant regards as subject to section 351 of the Public Health Service Act, the license number of the manufacturer.

(4) For each human prescription drug listed that the registrant regards as not subject to section 505 of the act or 351 of the Public Health Service Act, and that is not manufactured by a registered blood bank, a copy of all current labeling (except that only one representative container or carton label need be submitted where differences exist only in the quantity of contents statement) and a representative sampling of advertisements.

(5) For each human over-the-counter drug listed, or each animal drug listed, that the registrant regards as not subject to section 505 or 512 of the act or 351 of the Public Health Service Act, a copy of the label (except that only one representative container or carton label need be submitted where differences exist only in the quantity of

contents statement), the package insert, and a representative sampling of any other labeling.

(6) For each prescription or over-the-counter drug so listed that the registrant regards as not subject to section 505 or 512 of the act or 351 of the Public Health Service Act, and that is not manufactured by a registered blood bank, a quantitative listing of the active ingredient(s). Unless the quantitative listing is expressed as a percentage in the offical compendium or the ingredient is a nonantibiotic ingredient in a Type A medicated article for use in the manufacture of animal feeds, the quantity of an ingredient shall be expressed in terms of the amount, not the percent, of that ingredient in each dosage unit or, if the drug is not in unit dosage form, the amount of the ingredient in a specific unit of weight or measure of the drug. For a drug formulation that is a Type A medicated article subject to §207.35(b)(2)(iii), the registrant may limit the quantitative listing of ingredients to each variation of level of active drug ingredient.

(7) For each drug listed, the registration number of every drug establishment within the parent company at which it is manufactured or processed.

(8) For each drug listed, the National Drug Code (NDC) number. If FDA has not assigned an NDC Labeler Code, the registrant shall include a Product Code and Package Code and FDA will assign a Labeler Code as described in §207.35(b)(2)(i).

(c) For each drug product listed that is subject to the imprinting requirements of part 206 of this chapter, including products that are exempted under §206.7(b), drug companies must submit a document that provides the name of the product, its active ingredient(s), dosage strength, National Drug Code number, the name of its manufacturer or distributor, its size, shape, color, and code imprint (if any), and any other characteristic that identifies the product as unique.

[45 FR 38043, June 6, 1980, as amended at 52 FR 2682, Jan. 26, 1987; 55 FR 11577, Mar. 29, 1990; 58 FR 47959, Sept. 13, 1993; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999; 66 FR 59157, Nov. 27, 2001]

§ 207.26 Amendments to registration.

Changes in individual ownership, corporate or partnership structure location or drug-handling activity, shall be submitted by Form FDA–2656 (Registration of Drug Establishment) as amendment to registration within 5 days of such changes. A change in a registered establishment's firm name within 6 months of the registration of the establishment is required to be supported by a signed statement of the establishment's owner or operator that the change is not made for the purpose of changing the name of the manufacturer of a drug product under §201.1 of this chapter. Changes in the names of officers and directors of the corporations do not require such amendment but must be shown at time of annual registration.

[45 FR 25777, Apr. 15, 1980, as amended at 55 FR 11577, Mar. 29, 1990]

§ 207.30 Updating drug listing information.

(a) After submitting the initial drug listing information, every person who is required to list drugs under §207.20 shall submit on Form FDA–2657 (Drug Product Listing) during each subsequent June and December, or at the discretion of the registrant when the change occurs, the following information:

(1) A list of each drug introduced by the registrant for commerical distribution which has not been included in any list previously submitted. The registrant shall provide all of the information required by §207.25(b) for each such drug.

(2) A list of each drug formerly listed in accordance with §207.25(b) for which commercial distribution has been discontinued, including for each drug so listed the National Drug Code (NDC) number, the identity by established name and by proprietary name, and date of discontinuance. It is requested but not required that the reason for discontinuance of distribution be included with this information.

(3) A list of each drug for which a notice of discontinuance was submitted under paragraph (a)(2) of this section and for which commercial distribution has been resumed, including for each