§ 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.


§ 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 commercial 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 drug so listed the NDC number, the identity by established name and by proprietary name, the date of resumption, and any other information required by §207.25(b) not previously submitted.

(4) Any material change in any information previously submitted.

[45 FR 38043, June 6, 1980, as amended at 55 FR 11577, Mar. 29, 1990]