

§ 207.30

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 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.

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(b) When no changes have occurred since the previously submitted list, no report is required.

§ 207.31 Additional drug listing information.

(a) In addition to the information routinely required by §§207.25 and 207.30, FDA may require submission of the following information by letter or by FEDERAL REGISTER notice:

(1) For a particular prescription drug so listed that the registrant regards as not subject to section 505 of the act, upon request by FDA for good cause, a copy of all advertisements.

(2) For a particular drug product so listed that the registrant regards as not subject to section 505 or 512 of the act, upon a finding by FDA that it is necessary to carry out the purposes of the act, a quantitative listing of all ingredients.

(3) For a particular drug product, upon request by FDA, a brief statement of the basis for the registrant's belief that the drug product is not subject to section 505 or 512 of the act.

(4) For each registrant, upon a finding by FDA that it is necessary to carry out the purposes of the act, a list of each listed drug product containing a particular ingredient.

(b) It is requested but not required that a qualitative listing of the inactive ingredients be submitted for all listed drugs in the format prescribed in Form FDA-2657 (Drug Product Listing).

(c) It is requested but not required that a quantitative listing of the active ingredients be submitted for all drugs listed that are subject to section 505 or 512 of the act or section 351 of the Public Health Service Act.

[45 FR 38043, June 6, 1980, as amended at 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999]

§ 207.35 Notification of registrant; drug establishment registration number and drug listing number.

(a) FDA will provide to the registrant a validated copy of Form FDA-2656 (Registration of Drug Establishment) as evidence of registration. This validated copy will be sent to the mailing address shown on the form. FDA will