

§ 207.31

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.

(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]

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§ 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 assign a permanent registration number to each drug establishment registered in accordance with these regulations.

(b) Using the National Drug Code (NDC) numbering system, FDA assigns a drug listing number to each drug or class of drugs listed as follows:

(1) If a drug is already listed in the National Drug Code System or in the National Health Related Items Code System, the number is the same as that assigned under those codes. FDA adds a lead zero to the first three characters of the code, which identifies the manufacturer or distributor, to expand the "Labeler Code" segment to four characters. The National Drug Code, Product Code, and Package Code configurations used to describe these drugs, or any drugs added to the product line, remain the same, i.e., a four-character Product Code and a two-character Package Code. A manufacturer or distributor may either retain alphanumeric characters that are already used in the Product Code and Package Code segments of the National Drug Code or convert these alphanumeric characters to all numeric digits. The manufacturer or distributor shall inform FDA of a decision to convert the alphanumeric characters to all numeric digits.

(2) If a registered establishment or distributor has not previously participated in the National Drug Code System or in the National Health Related Items Code System, FDA uses the National Drug Code numbering system in assigning a number, as follows (only numerals are used):

(i) The first 5 numeric characters of the 10-character code identify the manufacturer or distributor and are known as the Labeler Code. FDA will expand the Labeler Code from five to six numeric characters when the available five-character code combinations are exhausted. FDA will assign Labeler