

(v) A list of drug products newly marketed or for which marketing is resumed.

(vi) A list of drug products discontinued.

(vii) Labeling.

(viii) Advertising.

(ix) Information that has become a matter of public knowledge.

(x) A list of drug products containing a particular active ingredient.

(xi) A list of all code imprints.

(2) The following types of information submitted in accordance with the drug listing requirements will not be available for public disclosure (except that any of the information will be available for public disclosure if it has become a matter of public knowledge or if FDA finds that confidentiality would be inconsistent with protection of the public health):

(i) Any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505 or 512 of the act.

(ii) A list of a drug product's inactive ingredients.

(iii) A list of drugs containing a particular inactive ingredient.

(b) Requests for information about registrations and drug listings of an establishment should be directed to Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or, with respect to the information described in paragraph (a) of this section, to the FDA district office responsible for the geographical area in which the establishment is located.

[45 FR 38043, June 6, 1980, as amended at 50 FR 8996, Mar. 6, 1985; 55 FR 11577, Mar. 29, 1990; 58 FR 47959, Sept. 13, 1993; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999]

**§ 207.39 Misbranding by reference to registration or to registration number.**

Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of

registration number or NDC number is misleading and constitutes misbranding.

**Subpart D—Procedure for Foreign Drug Establishments**

**§ 207.40 Drug listing requirements for foreign drug establishments.**

(a) Every foreign drug establishment whose drugs are imported or offered for import into the United States shall comply with the drug listing requirements in subpart C of this part, unless exempt under subpart B of this part, whether or not it is also registered.

(b) No drug, unless it is listed as required in subpart C of this part, may be imported from a foreign drug establishment into the United States except a drug imported or offered for import under the investigational use provisions of part 312 of this chapter. Foreign drug establishments shall submit the drug listing information in the English language.

(c) Every foreign drug establishment shall submit, as part of drug listing, the name and address of the establishment and the name of the individual responsible for submitting drug listing information. The establishment shall report to FDA any changes in this information at the intervals specified in § 207.30(a) for updating drug listing information.

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

**PART 208—MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS**

**Subpart A—General Provisions**

Sec.

208.1 Scope and purpose.

208.3 Definitions.

**Subpart B—General Requirements for a Medication Guide**

208.20 Content and format of a Medication Guide.

208.24 Distributing and dispensing a Medication Guide.

208.26 Exemptions and deferrals.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360, 371, 374; 42 U.S.C. 262.