

part of and contiguous to any bar-code symbol for any drug product if two conditions are met. First, the symbol appears prominently on the immediate container and on any outside container or wrapper and in a conspicuous location; this condition is not satisfied by the appearance of the symbol only on the natural bottom of a container or wrapper. Second, the bar-code symbol is compatible with the NDC, i.e., the symbol provides a format capable of encoding the numeric characters of an NDC Number. The term *principal display panel*, as used in this paragraph, means that part of a label most likely to be displayed, presented, shown, or examined under customary conditions of display to the consumer (for over-the-counter drug products) or to the dispenser (for prescription drug products).

(ii) The NDC number shall be preceded by the prefix "NDC" or "N" when it is used on a label or in labeling. The prefix used for a drug product shall be used consistently on the label of the immediate container, outside container, or wrapper, if any, and on other labeling for that drug product.

(iii) The Product-Package Code configuration shall be indicated and the segments of the number shall be separated by a dash, e.g., NDC 15643-542-12 or N 15643-542-12.

(iv) All 10 characters shall appear and the leading zeros in any segment of the NDC number shall be shown, except that leading zeros may be omitted from any segment of the NDC number when the NDC number is used for product identification by direct imprinting on dosage forms or in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear both required and optional labeling information.

(v) The placing of the assigned NDC number on a label or in other labeling does not require the submission of a supplemental new drug application, supplemental new animal drug application, or supplemental antibiotic application.

(4)(i) If any change occurs in those product characteristics that clearly distinguish one drug product version from another, the registrant shall assign a new NDC number to the new

product version and submit that information to FDA. Such a change includes, but is not limited to, a change in active ingredient(s); strength or concentration of active ingredient(s); dosage form; route of administration, if it also includes a change in product formulation; product name; and a change in marketing status from prescription to over-the-counter or over-the-counter to prescription. If, by notice in the FEDERAL REGISTER, FDA requires a change in drug product characteristics and determines the change will require assignment of a new product code to the reformulated product, FDA will announce its determination in the FEDERAL REGISTER publication that requires the change, setting forth its reasoning and justification for its determination. If a change only in the trade package is involved, the registrant may revise the trade package code without the assignment of a new product code segment, but shall inform FDA of the new code for the trade package and the characteristics of the new trade package.

(ii) When a registrant has discontinued a drug product, its product code may be reassigned to another drug product 5 years after the expiration date of the discontinued product, or, if there is no expiration date, 5 years after the last shipment of the discontinued product into commercial distribution. Reuse of product codes may occur, under the specified conditions, regardless of the NDC, Product Code, and Package Code configuration used.

(c) Although registration and drug listing are required to engage in the drug activities described in § 207.20, validation of registration and the assignment of a drug listing number do not, in themselves, establish that the holder of the registration is legally qualified to deal in such drugs.

[45 FR 38043, June 6, 1980, as amended at 48 FR 54007, Nov. 30, 1983; 52 FR 2682, Jan. 26, 1987; 55 FR 11577, Mar. 29, 1990]

§207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA-2656 (Registration of Drug Establishment) filed by the registrant will be available

for inspection in accordance with section 510(f) of the act, at the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. In addition, there will be available for inspection at each of the FDA district offices the same information concerning firms within the geographical area of each district office. Upon request and receipt of a self-addressed stamped envelope, the Drug Listing Branch, Center for Drug Evaluation and Research or appropriate FDA district office will verify registration number or provide the location of a registered establishment.

(1) The following types of information submitted under the drug listing requirements will be available for public disclosure when compiled:

- (i) A list of all drug products.
 - (ii) A list of all drug products arranged by labeled indications or pharmacological category.
 - (iii) A list of all drug products arranged by manufacturer.
 - (iv) A list of a drug product's active ingredients.
 - (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, 506, 507, 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]

§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