

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

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 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

Sec.

210.1 Status of current good manufacturing practice regulations.

210.2 Applicability of current good manufacturing practice regulations.

210.3 Definitions.

AUTHORITY: 21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374.

SOURCE: 43 FR 45076, Sept. 29, 1978, unless otherwise noted.

§ 210.1 Status of current good manufacturing practice regulations.

(a) The regulations set forth in this part and in parts 211 through 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

§ 210.2 Applicability of current good manufacturing practice regulations.

(a) The regulations in this part and in parts 211 through 226 of this chapter as they may pertain to a drug and in parts 600 through 680 of this chapter as

they may pertain to a biological product for human use, shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event that it is impossible to comply with all applicable regulations in these parts, the regulations specifically applicable to the drug in question shall supersede the more general.

(b) If a person engages in only some operations subject to the regulations in this part and in parts 211 through 226 and parts 600 through 680 of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.

§ 210.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part and in parts 211 through 226 of this chapter.

(b) The following definitions of terms apply to this part and to parts 211 through 226 of this chapter.

(1) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*).

(2) *Batch* means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(3) *Component* means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

(4) *Drug product* means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(5) *Fiber* means any particulate contaminant with a length at least three times greater than its width.

(6) *Non-fiber-releasing filter* means any filter, which after any appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is