Subpart B—Construction and Maintenance of Facilities and Equipment

225.20 Buildings.
225.30 Equipment.
225.35 Use of work areas, equipment, and storage areas for other manufacturing and storage purposes.

Subpart C—Product Quality Control

225.42 Components.
225.58 Laboratory controls.
225.65 Equipment cleanout procedures.

Subpart D—Packaging and Labeling

225.80 Labeling.

Subpart E—Records and Reports

225.100 Master record file and production records.
225.110 Distribution records.
225.115 Complaint files.

Subpart F—Facilities and Equipment

225.120 Buildings and grounds.
225.130 Equipment.
225.135 Work and storage areas.

Subpart G—Product Quality Assurance

225.142 Components.
225.158 Laboratory assays.
225.165 Equipment cleanout procedures.

Subpart H—Labeling

225.180 Labeling.

Subpart I—Records

225.200 Formula, production, and distribution records.

Source: 41 FR 52618, Nov. 30, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 225.1 Current good manufacturing practice.

(a) Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act provides that a drug (including a drug contained in a medicated feed) shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that such drug meets the requirement of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(b)(1) The provisions of this part set forth the criteria for determining whether the manufacture of a medicated feed is in compliance with current good manufacturing practice. These regulations shall apply to all types of facilities and equipment used in the production of medicated feeds, and they shall also govern those instances in which failure to adhere to the regulations has caused nonmedicated feeds that are manufactured, processed, packed, or held to be adulterated. In such cases, the medicated feed shall be deemed to be adulterated within the meaning of section 501(a)(2)(B) of the act, and the nonmedicated feed shall be deemed to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the act.

(2) The regulations in §§225.10 through 225.115 apply to facilities manufacturing one or more medicated feeds for which an approved medicated feed mill license is required. The regulations in §§225.120 through 225.202 apply to facilities manufacturing solely medicated feeds for which an approved license is not required.

(c) In addition to the recordkeeping requirements in this part, Type B and Type C medicated feeds made from Type A articles or Type B feeds under approved NADAs or indexed listings and a medicated feed mill license are subject to the requirements of §510.301 of this chapter.


§ 225.10 Personnel.

(a) Qualified personnel and adequate personnel training and supervision are essential for the proper formulation, manufacture, and control of medicated feeds. Training and experience leads to proper use of equipment, maintenance of accurate records, and detection and prevention of possible deviations from current good manufacturing practices.

(b)(1) All employees involved in the manufacture of medicated feeds shall