

§ 225.120

from the complainant and/or memoranda of conversations with the complainant, and a description of all investigations made by the manufacturer and of the method of disposition of the complaint.

(2) For medicated feeds whose manufacture require a medicated feed mill license (Form FDA 3448), records and reports of clinical and other experience with the drug shall be maintained and reported, under § 510.301 of this chapter.

[41 FR 52618, Nov. 30, 1976, as amended at 51 FR 7390, Mar. 3, 1986; 57 FR 6475, Feb. 25, 1992; 64 FR 63203, Nov. 19, 1999]

Subpart F—Facilities and Equipment

SOURCE: 51 FR 7390, Mar. 3, 1986, unless otherwise noted.

§ 225.120 Buildings and grounds.

Buildings used for production of medicated feed shall provide adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation.

§ 225.130 Equipment.

Equipment shall be capable of producing a medicated feed of intended potency and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction, precision, and accuracy for their intended purposes. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of cleanout procedure(s).

§ 225.135 Work and storage areas.

Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are ap-

21 CFR Ch. I (4–1–03 Edition)

proved for use in the manufacture of animal feed.

Subpart G—Product Quality Assurance

SOURCE: 51 FR 7390, Mar. 3, 1986, unless otherwise noted.

§ 225.142 Components.

Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B medicated feeds shall be used in accordance with their labeled mixing directions.

§ 225.158 Laboratory assays.

Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in this chapter, investigation and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year.

§ 225.165 Equipment cleanout procedures.

Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and nonmedicated feeds.

Subpart H—Labeling

§ 225.180 Labeling.

Labels shall be received, handled, and stored in a manner that prevents label