§ 121.200 of this chapter, which feed contains one or more drugs as defined in section 201(g) of the act. The term "medicated feed" does not include any undiluted drug or "premix," as defined in § 121.200 of this chapter, intended for manufacturing use in the production of a medicated feed, since these are subject to §§ 133.3–133.14, inclusive.

FINISHED PHARMACEUTICALS; MANUFACTURING PRACTICE

§ 133.2 Current good manufacturing practice.

The criteria in §§ 133.3–133.13, inclusive, shall apply in detersining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements 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, as required by section 501(a)(2)(B) of the act. The regulations in this Part 133 permit the use of precision automatic mechanical or electronic equipment in the production of drugs when adequate inspection and checking procedures are used to assure proper performance.

§ 133.3 Buildings.

Buildings in which drugs are manufactured, processed, packaged, labeled, or held shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The buildings shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which it is employed, to minimize any risk of mixups between different drugs, their components, packaging, or labeling, and to control the possibility of cross-contamination of one drug by another drug that is manufactured, stored, or handled on the same premises:

(1) The receipt, sampling, or storage of components.

(2) Any manufacturing and processing operations performed on the drug.

(3) Any packaging and labeling operations.

(4) Storage of containers, packaging materials, labeling, and finished products.

(5) Control and production-laboratory operations.

(b) Provide adequate lighting and ventilation, and when necessary for the intended production or control purposes, adequate screening, filtering, dust, humidity, temperature, and bacteriological controls, as for example, to prevent contamination of products by extraneous adulterants (including the prevention of cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage, or handling of another drug); to prevent the dissemination of micro-organisms from one area to another; to facilitate the sterilization of special work areas, such as those used for production of parenteral preparations; to provide suitable housing for any animals; and to avoid other conditions unfavorable to the safety and integrity of the product.

(c) Provide for adequate washing, cleaning, toilet, and locker facilities.

§ 133.4 Equipment.

Equipment used for the manufacture, processing, packaging, labeling, holding, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location in relation to surroundings to facilitate maintenance and operation for its intended purpose. The equipment shall:

(a) Be so constructed that any surfaces that come into contact with drugs are suitable, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the drug or its components.

(b) Be so constructed that any substances required for the operation of the equipment, such as lubricants or coolants, may be employed without hazard of becoming additive to drug products.

(c) Be constructed to facilitate adjustment, cleaning, and maintenance as necessary to assure the reliability of control procedures, to assure uniformity of production, and to assure the exclusion from drugs of contaminants, including those from previous and current manufacturing operations.

(d) Be of suitable size and accuracy for use in any intended measuring, mixing, or weighing operations.