§ 133.104 Components.

(a) Drug components, including undiluted drugs and any intermediate mixes containing drugs used in the manufacture and processing of medicated feeds, shall be received, stored, handled, and otherwise controlled in a manner to maintain the integrity and identification of such articles. Appropriate receipt and inventory records shall be maintained for 1 year and such records shall show the origin of any drug components, the batches in which they were used, and the results of any testing of them by or on behalf of the medicated-feed manufacturer.

(b) Nondrug components shall be stored and otherwise handled in a manner to avoid unsafe contamination, including cross-contamination from manufacturing operations.

(c) Statements relating to the identification and the quantitative composition appearing on the labels of undiluted drugs or other drug components received by the medicated-feed manufacturer from other suppliers may be relied upon by the medicated-feed manufacturer as acceptable evidence of the identity and composition of the drug or drug components in lieu of actual testing of each such drug or drug component if such reliance is made in good faith.

§ 133.105 Formula and production records.

(a) For each medicated feed, a master formula record or card shall be prepared, checked, and maintained by a responsible key employee and retained for at least 1 year after production of the last batch. The formula record or card shall include at least the following:

(1) The name of the medicated feed, together with any other information necessary for the correct identification of the feed.

(2) The weight or measure of each ingredient, adequately identified, to be used in manufacturing a stated weight of the medicated feed.

(3) A copy, description, or notation adequately identifying the label, labeling, or placard necessary to be used on or with the complete medicated feed.

(4) Manufacturing instructions for each medicated feed produced on a batch or continuous operation basis, including mixing steps, mixing times, and batch formulas that have been determined to yield an adequately mixed medicated feed; and in the case of medicated feeds produced by continuous production run, any additional manufacturing directions including, when indicated, the settings of equipment that have beeen determined to yield an adequately mixed medicated feed of the specified formula.

(5) Appropriate control directions, including the manner and frequency with which any necessary samples of the medicated feed are to be taken for specified laboratory tests, the criteria for using laboratory test results to change formulations or manufacturing procedures, and the procedures to be observed to avoid unsafe contamination of the medicated feed with other medicated feeds or drug components.

(b) A production record shall be prepared for each batch or run of medicated feed produced, and shall be retained for at least 1 year. The production record shall include:

(1) Product identification, date of production, and endorsement by a responsible individual.

(2) A record of the quantity of drug components used.

(3) A record of the quantity of medicated feed produced.

(c) In the case of a customer-formula feed made to the specifications of a customer, the formula and production records required by this section may consist of copies of customers' purchase orders and sellers' invoices bearing the information required by this section.

§ 133.106 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the medicated feeds produced are of proper composition and labeling:

(a) Each critical step in the process, such as the selection, weighing, and measuring of components; the addition of drugs or components during the process; the control of mixing times; the adjustment of the equipment involved in continuous production processes; and the determination of the finished yield, shall be performed in a manner that has been determined by appropriate methods, including laboratory testing of the medicated feed, to be adequate to assure the integrity of the final product. If such steps in the processing are