

§ 225.80

in contact with the active drug component, feeds in process, or finished medicated feed shall be subject to all reasonable and effective procedures to prevent unsafe contamination of manufactured feed. The steps used to prevent unsafe contamination of feeds shall include one or more of the following, or other equally effective procedures:

(1) Such procedures shall, where appropriate, consist of physical means (vacuuming, sweeping, or washing), flushing, and/or sequential production of feeds.

(2) If flushing is utilized, the flush material shall be properly identified, stored, and used in a manner to prevent unsafe contamination of other feeds.

(3) If sequential production of medicated feeds is utilized, it shall be on a predetermined basis designed to prevent unsafe contamination of feeds with residual drugs.

Subpart D—Packaging and Labeling

§ 225.80 Labeling.

(a) Appropriate labeling identifies the medicated feed, and provides the user with directions for use which, if adhered to, will assure that the article is safe and effective for its intended purposes.

(b)(1) Labels and labeling, including placards, shall be received, handled, and stored in a manner that prevents labeling mixups and assures that correct labeling is employed for the medicated feed.

(2) Labels and labeling, including placards, upon receipt from the printer shall be proofread against the Master Record File to verify their suitability and accuracy. The proofread label shall be dated, initialed by a responsible individual, and kept for 1 year after all the labels from that batch have been used.

(3) In those instances where medicated feeds are distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery. Such labeling may consist of a placard or other labels attached to the invoice or delivery ticket, or manufacturer's invoice that identifies the medicated feed

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and includes adequate information for the safe and effective use of the medicated feed.

(4) Label stock shall be reviewed periodically and discontinued labels shall be discarded.

Subpart E—Records and Reports

§ 225.102 Master record file and production records.

(a) The Master Record File provides the complete procedure for manufacturing a specific product, setting forth the formulation, theoretical yield, manufacturing procedures, assay requirements, and labeling of batches or production runs. The production record(s) includes the complete history of a batch or production run. This record includes the amounts of drugs used, the amount of medicated feed manufactured, and provides a check for the daily inventory record of drug components.

(b) The Master Record File and production records shall comply with the following provisions:

(1) A Master Record File shall be prepared, checked, dated, and signed or initialed by a qualified person and shall be retained for not less than 1 year after production of the last batch or production run of medicated feed to which it pertains. The Master Record File or card shall include at least the following:

(i) The name of the medicated feed.

(ii) The name and weight percentage or measure of each drug or drug combination and each nondrug ingredient to be used in manufacturing a stated weight of the medicated feed.

(iii) A copy or description of the label or labeling that will accompany the medicated feed.

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