

**§ 225.58**

**21 CFR Ch. I (4-1-01 Edition)**

be correct); the quantity shall be determined by weighing, counting, or measuring, as appropriate.

(ii) The amount of each drug used, sold, or otherwise disposed of.

(iii) The batches or production runs of medicated feed in which each drug was used.

(iv) When the drug is used in the preparation of a semiprocessed intermediate mix intended for use in the manufacture of medicated feed, any additional information which may be required for the purpose of paragraph (b)(7) of this section.

(v) Action taken to reconcile any discrepancies in the daily inventory record.

(7) Drug inventory shall be maintained of each lot or shipment of drug by means of a daily comparison of the actual amount of drug used with the theoretical drug usage in terms of the semiprocessed, intermediate and finished medicated feeds manufactured. Any significant discrepancy shall be investigated and corrective action taken. The medicated feed(s) remaining on the premises which are affected by this discrepancy shall be detained until the discrepancy is reconciled.

(8) All records required by this section shall be maintained on the premises for at least one year after complete use of a drug component of a specific lot number or feed manufacturer's shipment identification number.

**§ 225.58 Laboratory controls.**

(a) The periodic assay of medicated feeds for drug components provides a measure of performance of the manufacturing process in manufacturing a uniform product of intended potency.

(b) The following assay requirements shall apply to medicated feeds:

(1) For feeds requiring a medicated feed mill license (Form FDA 3448) for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter. At least one of these assays shall be performed on the first batch using the drug. If a medicated feed contains a

combination of drugs, only one of the drugs need be subject to analysis each time, provided the one tested is different from the one(s) previously tested.

(2) [Reserved]

(c) The originals or copies of all results of assays, including those from State feed control officials and any other governmental agency, shall be maintained on the premises for a period of not less than 1 year after distribution of the medicated feed. The results of assays performed by State feed control officials may be considered toward fulfillment of the periodic assay requirements of this section.

(d) Where the results of assays indicate that the medicated feed is not in accord with label specifications or is not within permissible assay limits as specified in this chapter, investigation and corrective action shall be implemented and an original or copy of the record of such action maintained on the premises.

(e) Corrective action shall include provisions for discontinuing distribution where the medicated feed fails to meet the labeled drug potency. Distribution of subsequent production of the particular feed shall not begin until it has been determined that proper control procedures have been established.

[41 FR 52618, Nov. 30, 1976, as amended at 51 FR 7390, Mar. 3, 1986; 55 FR 11577, Mar. 29, 1990; 64 FR 63203, Nov. 19, 1999]

**§ 225.65 Equipment cleanout procedures.**

(a) Adequate cleanout procedures for all equipment used in the manufacture and distribution of medicated feeds are essential to maintain proper drug potency and avoid unsafe contamination of feeds with drugs. Such procedures may consist of cleaning by physical means, e.g., vacuuming, sweeping, washing, etc. Alternatively, flushing or sequencing or other equally effective techniques may be used whereby the equipment is cleaned either through use of a feed containing the same drug(s) or through use of drug free feedstuffs.

(b) All equipment, including that used for storage, processing, mixing, conveying, and distribution that comes