

MEDICATED FEED MILL INSPECTIONS

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The North Carolina Department of Agriculture is conducting medicated feed establishment inspections to determine compliance with the Current Good Manufacturing Practice Regulations (GMPs). The GMPs require that adequate precautions and manufacturing controls be employed to ensure medicated feeds produced are both safe and effective to the consuming animal and the consumer of livestock products. One of the reasons for this program is to help assure that safe and effective medications remain available to the agricultural industry.

The North Carolina Feed Inspectors are commissioned as officers of HEW and inspection may be made under contract with the FDA or under State Law.

There are approximately 400 medicated feed establishments in North Carolina. The North Carolina Department of Agriculture will conduct a routine inspection of each of these establishments at least once every two years. Those not in compliance will be subject to follow-up inspections or other regulatory action to ensure compliance.

Any feed manufacturer who mixes any drug into feed must be registered with the Food and Drug Administration as a Drug Establishment. Persons who manufacture medicated feed only for their own animals and who do not mix medicated feeds that require an approved Medicated Feed Application (Form FD-1800) or sell medicated feeds are not required to register. An approved Medicated Feed Application is required prior to mixing any New Drug into feeds.

The method used in, or the facilities or controls used for the manufacture, processing, packing, or holding (including distribution) medicated feed are important factors in assuring that the feed meets the requirements of the Federal Food, Drug and Cosmetic Act. The Good Manufacturing Practice Regulations set forth the criteria for determining whether medicated feeds meet the requirements of the Act as to safety, have the identity and strength, and meet the quality and purity characteristics which they are represented to possess.

The GMPs provide that the building used in the manufacturing of medicated feed must be suitable for that purpose. It must be kept in a reasonably clean and orderly manner. It must provide adequate space for the orderly placement of equipment and materials used in the receiving, processing, packaging, labeling, and storage of components or finished products. Adequate washroom facilities are required as a safeguard to the health of those who handle drugs and medicated feed. The building should have adequate lighting and other physical facilities necessary to prevent unsafe contamination of components and finished feeds before, during, and after production. Insecticides, fungicides and rodenticides should not be stored in areas where feed or feed components are stored or processed.

The types of equipment and its capacity to perform the job for which it is intended is important in the manufacturing of medicated feed. Highly significant in this regard are the scales used to weigh out bulk drugs. One would not expect much accuracy from a scale graduated in one pound increments that is used to weigh out drugs in terms of ounces. Serious errors may result from inaccurate scales or inaccurately used scales, and drug deficiencies or overages may occur. Mixing equipment must be designed and installed in a manner to facilitate inspection and cleaning of all parts that come in contact with medicated feed. Ledges or shelves where feed from previous batches may accumulate are a source of potential cross-contamination. All equipment must be maintained in a reasonably clean and orderly manner.

Qualified personnel are essential for the proper formulation, manufacture, and control of medicated feeds. Training and experience are necessary for the proper use of equipment and maintenance of accurate records.

The receipt, storage, inventory, and handling of drug components must be adequate to assure their integrity and identity. Non-drug components must be stored and handled in a manner to avoid unsafe contamination. Inventory records are necessary. Drug accountability should be maintained for each lot of drug by means of a comparison of the actual drug used with the theoretical drug usage. The inventory record should also show the batches of feed in which the drugs were used. These records must be kept for a period of one year.

The master formula record provides a procedure setting forth the theoretical yield for the manufacture of a production run of medicated feed. The master formula and a system of maintaining the integrity of the formula down to the operating or production formula is important. A perfect formula in the safe or at the home office does little good if the mixer man is deviating from the approved formula to fit his daily operating needs. A transposition error from the master formula to the operating or production formula could be a major error and result in violative feed. The production record should include: (1) product identification, (2) date of production, (3) amount of drug components used, and (4) amount of feed produced. In the case of customer-formula feeds the formula and production records may consist of copies of the invoices or purchase orders.

It is important that the manufacturer of medicated feed observe every precaution and take all steps necessary to avoid contamination of his product with drug residue. Each critical step in the processing of medicated feed must be performed in a manner to assure integrity of the final product. The manner in which drugs are handled, weighed out, and introduced into feed has great bearing on the accuracy of a firm's activities. All containers of drugs and feeds should be identified at all times. Failure to clean equipment between batches of feed, by whatever methods shown effective, is a serious violation of the GMPs; and the deliberate use of contaminated flushings in dissimilar feed could have serious consequences both to animals and to humans consuming animal products. Dust, spilled feed ingredients and flushing material should be properly identified and/or disposed of to prevent contamination. Much of what constitutes controls taken by a firm to preserve the integrity of their product is just good common sense.

Complete labeling must accompany all medicated feed. In the case of feed distributed in bulk, the labeling may consist of an invoice or placard bearing the adequate information for the safe and effective use of the medicated feed. Provisions should be made for the proper storage of labels so as to prevent mix-ups.

A periodic assay of medicated feeds for drug components is required. For feeds containing New Animal Drugs, the sampling and assay schedule is set forth in the approved Form FD-1800. For other medicated feeds three appropriately drawn samples for every 400 tons of production or not less than three samples per year shall be assayed.

A complete record must be maintained for each shipment of medicated feed. Such records permit the manufacturer to relate complaints to specific production runs and will facilitate recall, diversion, or destruction of medicated feed if it should become necessary.

A complaint file is mandatory. A record of each written or verbal complaint and the action taken must be maintained for a period of two years. These records may reveal the existence of problems not otherwise detected by normal quality control procedures.