# Guidance for Compliance with the Current Good Manufacturing Practices (CGMP) for Medicated Feed Manufacturers Not Required to Register and be Licensed with the FDA

The text of the CGMP regulations for non-registered mills, as printed in Title 21 of the Code of Federal Regulations (CFR), is reproduced below. Self-inspecting your establishment can help you comply with these regulations. Non-compliance may result in product adulteration and unacceptable risks to animal and/or public health. Ensure that all employees involved in the manufacture of medicated feeds have an understanding of the manufacturing and control operation(s) which they perform, including the location and proper use of equipment, and that all necessary procedures and controls are in place and followed. Self-inspection tips to help you meet them and examples of conditions that can result in non-compliance follow each regulation.

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| **225.120 Buildings and Grounds.**<br>Buildings used for production of medicated feed shall provide for adequate space for equipment, processing, and orderly receipt and storage of medicated feed. Areas shall include access for routine maintenance and cleaning of equipment. Buildings and grounds shall be constructed and maintained in a manner to minimize vermin and pest infestation. | ***Self-Inspect:*** *Is there adequate space for equipment, and processing and storage of medicated feeds? Does construction and maintenance minimize vermin and pest infestation?*<br><br>*Don't allow the mill and storage facilities to become dirty and disorganized. There should be little or no evidence of the presence of birds, rodents, or other mammals.* |
| **225.130 Equipment.**<br>Equipment shall be capable of producing a medicated feed of intended potency and purity, and shall be maintained in a reasonably clean and orderly manner. Scales and liquid metering devices shall be accurate and of suitable size, design, construction precision, and accuracy for their intended purposes. All equipment shall be designed, constructed, installed and maintained so as to facilitate inspection and use of cleanout procedure(s). | ***Self-Inspect:*** *Can your mixers produce medicated feed with the intended drug level and without contamination? Are adequate cleanout procedures used to avoid unsafe contamination of both medicated and non-medicated feeds, such as physical cleanout, flushing, or production sequencing? Are scales and metering devices accurate and suitable for measuring intended quantities?*<br><br>*Make sure mixers, flighting, ribbons, and augers are clean and free of buildup from molasses, fats or other products that may cling to them. Scales must be working properly. Verify by testing with known weights.* |
| **225.135 Work and Storage Areas.**<br>Work areas and equipment used for the production or storage of medicated feeds or components thereof shall not be used for, and shall be physically separated from, work areas and equipment used for the manufacture and storage of fertilizers, herbicides, insecticides, fungicides, rodenticides, and other pesticides unless such articles are approved for use in the manufacture of animal feed. | ***Self-Inspect:*** *Are work areas, drug storage, and equipment free of pesticides, fertilizers and other toxic substances that could contaminate feeds?*<br><br>*Don't use the same mixers, bins, augers, conveyors, or trucks to manufacture and/or move feeds and non-feed products such as fertilizers or pesticides. Don't store pesticides and/or fertilizers in areas where feeds are being manufactured or stored.* |
| **225.142 Components**<br>Adequate procedures shall be established and maintained for the identification, storage, and inventory control (receipt and use) of all Type A medicated articles and Type B medicated feeds intended for use in the manufacture of medicated feeds to aid in assuring the identity, strength, quality, and purity of these drug sources. Packaged Type A medicated articles and Type B medicated feeds shall be stored in designated areas in their original closed containers. Bulk Type A medicated articles and bulk Type B medicated feeds shall be identified and stored in a manner such that their identity, strength, quality, and purity will be maintained. All Type A medicated articles and Type B | ***Self-Inspect:*** *Have adequate written procedures been established and maintained for the identification, storage and inventory control of all drug sources intended for use in the manufacturing of medicated feeds? Are your procedures and records adequate to permit detection of mixing errors (too much, too little, or none added) or inclusion in the wrong feed?*<br><br>*Category II Type A drugs must not be used unless the firm is licensed with FDA. The integrity and identity of medicated feed components must be maintained. Is drug packaging clean, legible and closed to prevent contamination? Are cans or tubs used to protect the medicated feed* |

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| medicated feeds shall be used in accordance with their labeled mixing directions. | *components adequately tagged to identify the product? It is the firm's responsibility to make sure that any drug or combination of drugs being used is permitted by Federal regulation. If you have a question regarding drug approvals, contact your supplier or state feed inspector.* |
| **225.158 Laboratory Assays.**<br>Where the results of laboratory assays of drug components, including assays by State feed control officials, indicate that the medicated feed is not in accord with the permissible limits specified in the CFR's, investigative and corrective action shall be implemented immediately by the firm and such records shall be maintained on the premises for a period of 1 year. | ***Self-Inspect:*** *While not specifically required, assays are highly recommended as a means of determining if medicated feeds are being manufactured correctly. Have necessary corrective actions been determined and taken when laboratory assays of drug components indicated a medicated feed was not within permissible limits? Are these records kept for at least one year?*<br><br>*If a medicated feed was assayed and found to be out of tolerance, there must be a record of any actions taken to determine the cause and that the feed is accounted for.* |
| **225.165 Equipment Cleanout Procedures.**<br>Adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and non-medicated feeds. | ***Self-Inspect:*** *Have adequate procedures been established to prevent contamination of subsequent feed batches with unsafe drug residues? Are procedures for flushing, sequencing, and/or physical cleanout in writing? Are they being followed?*<br><br>*Make sure all flush material is properly identified, stored, and used in subsequent feeds or is properly disposed of.* |
| **225.180 Labeling.**<br>Labels shall be received, handled, and stored in a manner that prevents label mix-ups and assures that the correct labels are used for the medicated feed. All deliveries of medicated feeds, whether bagged or in bulk, shall be adequately labeled to assure that the feed can be properly used. | ***Self-Inspect:*** *Are labels received, handled and stored in a manner that ensures correct labeling and prevents mix-ups? Are all medicated feeds adequately labeled?*<br><br>*Don't deliver or have unlabeled or incorrectly labeled medicated feeds on the premises. Remember that changes in formulation or ingredient sources are likely to require a change in the feed label. Labels missing the actual name of the drug (e.g. Chlortetracycline, not Aureo, Aureomycin, crumbles, etc.), level of drug in the batch, warning and/or caution statements (if required), indications for use, and feeding instructions are not permitted. Invoices used as custom formula feed labels must be accompanied by the same information as stock formulas. Some feed manufacturers will supply a checklist of drugs with this information. The firm checks the box that applies to the drug in the batch and all the pertinent information is listed. It is your responsibility to make sure this information is complete and correct.* |
| **225.202 Formula, Production, and Distribution Records.**<br>Records shall be maintained identifying the formulation, date of mixing, and if not for own use, date of shipment. The records shall be adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Such records shall be retained on the premises for 1 year following the date of last distribution. | ***Self-Inspect:*** *Are written batch records kept containing the formula, date of mixing, and date of shipment (if not for own use)? Are lot numbers from each drug, medicated supplement or concentrate used being recorded so that you can locate and recall product if necessary?*<br><br>*Batch cards, mixing logs, or copies of the customer invoice are examples of places where this may be recorded.* |

***Additional references - CFR 21, Parts 200-299 and 500-599, The FEED ADDITIVE COMPENDIUM.***