Department of Health and Human Services
Public Health Service
Food and Drug Administration

MEDICATED FEEDS INSPECTION REPORT

DATE OF INSPECTION	NAMES OF INSPECTORS	
FIRM NAME	FIRM ADDRESS	
	ZIP CODE	COUNTY

SUMMARY of FINDINGS

Summarize the inspection factually and objectively from observations of the condition and practices of the firm.

HISTORY of BUSINESS

1. PARENT FIRM, If applicable *(Name / Address)*

2. CORPORATE OFFICERS *(Name, title, business address)*

3. FDA REGISTRATION/LICENSE STATUS
(Check appropriate status)

- ☐ a. Unknown
- ☐ b. Non-registered
- ☐ c. Registered (as a drug establishment)
  Registration number or FEI: _____
- ☐ d. Licensed
  License number: _____

4. TYPE of FIRM
(Check appropriate type)

- ☐ a. Commercial Feed Mill
- ☐ b. Custom Formula Mixer
- ☐ c. Mixer-Feeder
- ☐ d. Other *(Please specify)*

5. FEED PREPARED FOR
(Check all that apply)

- ☐ a. Beef Cattle
- ☐ b. Dairy Cattle
- ☐ c. Swine
- ☐ d. Sheep/Goats
- ☐ e. Poultry
- ☐ f. Fish
- ☐ g. Other *(Exotic / Species)*

6. VOLUME of BUSINESS

- ☐ a. Annual tonnage of all MEDICATED feeds manufactured
- ☐ b. Annual tonnage of all Non-MEDICATED feeds manufactured

7. INTERSTATE BUSINESS

- a. Interstate business received? ☐ Yes ☐ No
- b. Interstate business sold? ☐ Yes ☐ No
  If yes, percentage sold? _____%

RESPONSIBLE PERSONNEL

8. NAME AND TITLE of MOST RESPONSIBLE INDIVIDUAL AT THIS PLANT TO RECEIVE COPY of REPORT *(If more than one person, list)*

9. INDICATE TO WHOM FDA FORMS WERE ISSUED *(If more than one person, list all)*

NOTES: The key CGMP elements are designated on this form with asterisk (**).

Items not covered on this form should be marked with N/C.

Each of the following questions shall be answered. Each "NO" answer shall be explained in the narrative block. Precede any explanation with appropriate item/question number.

VETERINARY FEED DIRECTIVE (VFD) DRUGS / FEEDS

☐ Yes ☐ No 10. Does firm manufacture feeds containing VFD drugs? If the answer is yes, continue with question 11-15. If the answer is no, skip to item number 16.	NARRATIVE
☐ Yes ☐ No 11. Does the firm distribute VFD feeds to other distributors or manufacturers?	
☐ Yes ☐ No 12. Has the firm supplied to CVM a written letter of intent to distribute VFD Feeds?	
☐ Yes ☐ No 13. Are copies of letters of acknowledgement maintained on file at this firm?	

14. State the number of VFD orders reviewed during inspection: _____

Note: If the response is "yes" to any part of item 15 but errors were found in what was observed/provided, please describe and elaborate in the narrative section below. Additionally, report in the narrative if firms are found to be operating outside of the VFD approval; for instance, is there evidence that there are other products being used, promoted or handled as VFD drugs? If more than 3 VFD orders are examined, please record findings using additional narrative page(s) or sheets of paper.

15. For the VFD orders reviewed (e.g., up to three in number), did they contain the following information:	VFD order #1	VFD order #2	VFD order #3
a. The name, address and telephone number for the veterinarian and client.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
b. Identification of the animals to be treated, including the identification of the species, number of animals, and the specific location of the animals.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
c. Date of treatment and, if different, date of prescribing the VFD drug.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
d. Name of the animal drug.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
e. Level of animal drug in the feed and the amount of feed.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
f. Feeding instructions with withdrawal time.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
g. Expiration date of the VFD.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
h. Any special instructions necessary for use of the drug in conformance with the approval.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
i. Required cautionary statements.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
j. Number of refills, if permitted by the approval.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
k. Signature of the veterinarian.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
l. The veterinarian's license number and the name of the State issuing the license.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
m. Other information as required by the individual drug approval.	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No

NARRATIVE

PERSONNEL (21 CFR 225.10)

☐ Yes ☐ No 16. Do the employees involved in the manufacture of medicated feed understand the manufacturing or control functions they perform, including the proper use and location of the equipment? For either response (i.e., "yes" or "no"), elaborate in the narrative section.

☐ Yes ☐ No 17. Are the employees provided with on-going evaluation and supervision? If yes, include how assessed.

BUILDINGS (21 CFR 225.20)

☐ Yes ☐ No 18. Are the grounds of the facility adequately drained and maintained?

19. In regards to the buildings:

☐ Yes ☐ No a. Are they clean, orderly and suitably constructed?

☐ Yes ☐ No b. Are the control practices for rodents, birds, insects, and other pests effective?

☐ Yes ☐ No c. Do they have facilities to promote personal hygiene?

20. Do the buildings provide adequate space for:

☐ Yes ☐ No a. Receipt, inspection, storage, and processing of components?

☐ Yes ☐ No b. Manufacturing, packaging, and labeling of medicated feeds?

☐ Yes ☐ No c. Storage of containers, packaging materials, labeling, and products?

☐ Yes ☐ No d. Routine maintenance of equipment?

EQUIPMENT (21 CFR 225.30)

21. Describe equipment used for mixing/blending of feeds in the narrative.

22. With regards to assuring the uniformity of medicated feeds:

☐ Yes ☐ No a. When installed, was/were the mixer(s)/blender(s) evaluated for their ability to produce feeds of uniform quality?

☐ Yes ☐ No b. Since installation, has the firm determined that the mixer's ability to produce a uniformly mixed feed has not changed? Explain.

☐ Yes ☐ No 23. Has all production equipment, particularly those that are automated and/or computerized, been properly installed and verified to be able to reliably perform as intended?

☐ Yes ☐ No 24. Whether manually or by automated means, are drugs accurately weighed?

☐ Yes ☐ No **25. Are ALL scales and metering devices tested for accuracy upon installation and at least once per year thereafter?

☐ Yes ☐ No 26. Is equipment constructed to allow inspection and use of clean-out procedures?

☐ Yes ☐ No 27. Is all equipment reasonably clean and properly maintained?

☐ Yes ☐ No 28. Is all equipment constructed to prevent contamination with lubricants, coolants, etc.?

NARRATIVE

EQUIPMENT (21 CFR 225.30), continued

☐ Yes ☐ No 29. Is all equipment of suitable size, design, construction, and precision for the intended purpose?

USE of WORK AND STORAGE AREAS FOR OTHER PURPOSE (21 CFR 225.35)

☐ Yes ☐ No **30. Does the firm avoid storage or handling of toxic or unapproved feed additives (i.e., fertilizers, herbicides, insecticides, rodenticides and pesticides not approved for use in feed) in the same equipment or areas as medicated feeds?

EQUIPMENT CLEANOUT (21 CFR 225.65)

☐ Yes ☐ No 31. Do clean out procedures exist for all equipment used in the manufacture and distribution of medicated feeds? If procedures exist, specify the methods, for example: physical, flushing, sequencing, etc.

☐ Yes ☐ No **32. Does the clean out procedure appear adequate to prevent unsafe contamination? If no, explain.

☐ Yes ☐ No 33. Is there documentation that equipment clean out procedures are actually being performed?

34. Describe disposition of clean out material in the narrative.

CONTROL OPERATIONS

☐ Yes ☐ No 35. Are feeds stored in a manner to prevent mix-ups with other feeds?

☐ Yes ☐ No 36. Is the method of dust control adequate to minimize potential contamination?

37. Is there adequate disposition of:

☐ Yes ☐ No a. Spillage?

☐ Yes ☐ No b. Leaks?

☐ Yes ☐ No c. Broken Bags?

☐ Yes ☐ No d. Floor sweepings?

☐ Yes ☐ No e. Returns?

☐ Yes ☐ No 38. Are drugs used in accordance with their labeled directions, including appropriate species, drug levels, and use?

DRUG COMPONENTS (21 CFR 225.42)

39. Report “DRUG COMPONENTS ON HAND” in self-titled section of this report (page 11).

☐ Yes ☐ No **40. Are drugs properly identified, handled and controlled to maintain their integrity and identity?

☐ Yes ☐ No 41. Are drugs properly stored? (e.g., Are drugs labeled “Store in a cool, dry place”, or “Store between 32° -81° F”, so stored?)

☐ Yes ☐ No 42. Are all drugs within their expiration date?

☐ Yes ☐ No 43. Are there RECEIPT RECORDS for incoming lots of drugs? If yes, answer item 44 a-f below.

NARRATIVE

DRUG COMPONENTS (21 CFR 225.42), continued

NARRATIVE

44. Do the Receipt Records show for each lot of drugs:

☐ Yes ☐ No a. Identity and Quantity?

☐ Yes ☐ No b. Name of supplier?

☐ Yes ☐ No c. Supplier's lot number or number assigned by the manufacturer

☐ Yes ☐ No d. Date received?

☐ Yes ☐ No e. Condition of drug received?

☐ Yes ☐ No f. Return of damaged goods?

☐ Yes ☐ No **45. Is there a DAILY INVENTORY RECORD for each lot of drug (separate from the production record)?

46. Do the Daily Inventory Records for each drug show:

☐ Yes ☐ No a. Quantity of drug on hand at beginning and end of the work day?

☐ Yes ☐ No b. The amount of each drug used, sold or otherwise disposed of?

☐ Yes ☐ No c. The batches or production runs of medicated feed in which each drug was used?

☐ Yes ☐ No d. Actions taken to reconcile any discrepancies in the daily inventory record?

**47. Does the firm's DRUG INVENTORY system:

☐ Yes ☐ No a. Make a daily comparison between actual amount of drug used and theoretical drug usage?

☐ Yes ☐ No b. Have drug inventory records that agree with calculated usage?

☐ Yes ☐ No c. Include a working definition of what it considers as constituting a significant discrepancy in its drug inventory?

☐ Yes ☐ No d. Include procedures for holding feeds on the premises until a significant discrepancy is reconciled?

☐ Yes ☐ No 48. Are there any documented significant discrepancies in the firm's drug inventories? If yes, answer a-b below; If not, skip to item 49.

☐ Yes ☐ No a. were documented discrepancies investigated?

☐ Yes ☐ No b. was corrective action taken?

☐ Yes ☐ No 49. Do the firm's current drug inventories agree with the amount of drug currently on hand?

☐ Yes ☐ No 50. Are all required drug records kept on the premises for at least one year after complete use of a specific lot of drug component?

LABORATORY CONTROLS (21 CFR 225.58)

☐ Yes ☐ No **51. Are assays performed on all medicated feeds/manufactured according to the schedule specified in CFR 225.58?

☐ Yes ☐ No **52. Are investigations performed and appropriate corrective actions taken in response to "out of limits" assay reports?

LABORATORY CONTROLS (21 CFR 225.58), continued

NARRATIVE

☐ Yes ☐ No 53. Are all investigations documented in writing?

☐ Yes ☐ No 54. Are results of assays kept on the premises for not less than one year after distribution of that feed?

☐ Yes ☐ No **55. When Category I drugs are assayed and found to be out of limits, are investigations performed?

☐ Yes ☐ No 56. Are reports made to CVM of confirmed "out of limits" assays of medicated feeds that have been distributed?

57. Provide the following information on any confirmed "out of limits" results:

a. Name of feed(s) and drug(s) (enter in narrative)

b. Production date or code (enter in narrative)

c. Drug guarantee and assay result (enter in narrative)

LABELING (21 CFR 225.80)

☐ Yes ☐ No 58. Does the accompanying labeling (including invoices if used as labeling) include drug level, directions for use and any required withdrawal or warning statements for safe, effective use of the medicated feed?

☐ Yes ☐ No 59. Upon receipt from either an outside printer or in-house print shop, are labels and labeling (including placards and pre-printed bags) proofread against the MASTER RECORD FILE to verify their suitability and accuracy?

☐ Yes ☐ No 60. Is the proofread label/labeling/pre-printed bag initialed by a responsible individual, dated and kept one year after all labels from that batch have been used?

☐ Yes ☐ No **61. Are labels handled and stored in a manner to prevent mixups and periodically reviewed to discard discontinued labels?

**62. Does the firm adequately label the following:

☐ Yes ☐ No a. Bagged feeds?

☐ Yes ☐ No b. Bulk feeds?

☐ Yes ☐ No c. Custom formula feeds?

63. When the firm distributes medicated feed in bag or bulk:

☐ Yes ☐ No a. Does complete labeling accompany the shipment?

(**Note:** The 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 and includes adequate information for the use of the medicated feed.)

b. Describe what procedures does the firm use for providing the consignee with labeling upon delivery in the narrative.

MASTER RECORD FILE (21 CFR 225.102)

☐ Yes ☐ No 64. Is there a Master Record File or its equivalent for each medicated feed?

**65. Does the Master Record File contain the following for each medicated feed:

☐ Yes ☐ No a. Name of medicated feed?

MASTER RECORD FILE (21 CFR 225.102), continued

NARRATIVE

65. (Continued)

☐ Yes ☐ No b. An accurate formula, including the appropriate levels of drugs and non-drug ingredients under 21 CFR 573 (Food Additives) and 21 CFR 582 (GRAS).

☐ Yes ☐ No c. A copy or description of the label or labeling that will accompany the medicated feeds.

☐ Yes ☐ No d. A copy of NADA approved Blue Bird Labeling, or a reference to electronic access to such labeling.

☐ Yes ☐ No e. Manufacturing procedures including mixing steps, mixing times, assay requirements and the appropriate control directions?

☐ Yes ☐ No f. Procedures for estimating quantity produced for bulk feeds?

☐ Yes ☐ No 66. Is each Master Record File prepared, checked and signed or initialed by a qualified person?

67. If all or portions of the Master Record File are computerized and/or electronically transmitted from another location, what steps are in place to protect the integrity of the data and signatures?

Describe in the narrative.

☐ Yes ☐ No 68. Is each MASTER RECORD FILE kept on the premises for one year after production of the last batch or production run to which it pertains?

PRODUCTION RECORDS (21 CFR 225.102)

69. Is there a production record prepared for each batch or production run of medicated feed produced?

☐ Yes ☐ No a. Are the records generated/maintained electronically?

☐ Yes ☐ No b. Do those records include alarms or error messages that occurred during production and any actions taken to clear the error or override the operation of the computer?

**70. Does the production record provide:

☐ Yes ☐ No a. A complete and traceable history of the production of a batch or production run?

☐ Yes ☐ No b. Product identification?

☐ Yes ☐ No c. Date of production?

☐ Yes ☐ No d. Written endorsement by a responsible person?

☐ Yes ☐ No e. Name and quantity of drug components used?

☐ Yes ☐ No f. Theoretical quantity of medicated feed to be produced?

☐ Yes ☐ No g. Actual quantity of medicated feed produced?

☐ Yes ☐ No 71. Do production records identify specific equipment and bins used in that production if the firm has multiple pieces of the same equipment and multiple bins?

☐ Yes ☐ No 72. Are steps in place to minimize mixups, such as running feeds into the wrong bins?

☐ Yes ☐ No 73. Does the production formula agree with the formula in the MASTER RECORD FILE?

PRODUCTION RECORDS (21 CFR 225.102), continued

NARRATIVE

☐ Yes ☐ No 74. Are production records checked by a responsible individual at the end of the working day to determine that all required production steps have been performed?

75. Mixing:
Provide in the narrative block the:
a. Point in at which drug is added.
b. Mixing time
c. Manner in which mixing is timed.

☐ Yes ☐ No 76. Has the firm defined what constitutes a significant discrepancy in production? (Including such aspects as theoretical vs. actual production yield, actual drug usage, etc.)

☐ Yes ☐ No 77. Are significant discrepancies immediately investigated and do production records show the corrective actions taken?

☐ Yes ☐ No 78. Is an individual batch or production run number, code, date or other suitable identification which permits tracing of the manufacturing history applied to the labeling of the medicated feed?

79. Calculate drug levels in a representative number of feeds, and:
a. State the number checked that were right. (In narrative).
b. Report any discrepancies found. Provide evidence of the discrepancy, including formula.

☐ Yes ☐ No 80. Is the original, copy, or electronic version of the production record kept on the premises for not less than one year from the date of production?

DISTRIBUTION RECORDS (21 CFR 225.110)

☐ Yes ☐ No **81. Does each distribution record provide sufficient information, to relate complaints to specific batches or production runs?

☐ Yes ☐ No 82. Are distribution records kept on the premises for not less than one year after the date of shipment?

COMPLAINT FILES (21 CFR 225.115)

☐ Yes ☐ No 83. Does the firm have procedures to use as follow-up in response to product complaints and reports of experiences of product defects?

☐ Yes ☐ No 84. Is a file kept for each oral and written complaint or report of product defects? If, yes, does it contain:

☐ Yes ☐ No a. Date of complaint?

☐ Yes ☐ No b. Complainant's name and address?

☐ Yes ☐ No c. Name and lot or number or date of manufacture of the medicated feed involved?

☐ Yes ☐ No d. Specific details of the complaint?

☐ Yes ☐ No e. Correspondence, including memoranda of conversations, from the complainant?

☐ Yes ☐ No f. Description of all investigations?

☐ Yes ☐ No g. Method of disposition of the complaint?

☐ Yes ☐ No 85. Are reports of adverse experiences, drug mixups, and other failures of the drug to meet specifications reported as required to CVM?

DRUG COMPONENTS ON HAND

TRADE NAME	DISTRIBUTOR	DRUG	POTENCY	EXPIRATION DATE

DISCUSSION WITH MANAGEMENT

Describe in detail all recommendations and warnings given to management and their response to each deviation listed on the FDA 483.