

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

OMB No. 0910-XXXX
Expiration Date: XXXXX
See OMB Statement on Page 6

**VOLUNTARY INSPECTION REPORT FOR FDA
NON-LICENSED MEDICATED FEED ESTABLISHMENTS**

NAME OF PERSON(S) CONDUCTING THE INSPECTION

DATE OF INSPECTION

FIRM NAME

NUMBER AND STREET

CITY AND STATE

ZIP CODE

COUNTY

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

PHOTO

2007D-0027

BKG 1

If No is checked anywhere in this Inspection Report, explain in comments.

SECTION I. INSPECTION (Follows format of 21 CFR 225, Subparts F, G, H, I)

225.120 BUILDINGS AND GROUNDS

1. Yes No Provide appropriate space for equipment, processing and orderly receipt and storage of medicated feed.
2. Yes No Provide access for routine maintenance and cleaning of equipment.
3. Yes No Constructed and maintained in a manner to minimize vermin and pest infestation.

COMMENTS:

225.130 EQUIPMENT

1. Yes No Capable of producing medicated feed of intended potency, safety and purity.
2. Yes No Designed, constructed, installed and maintained to facilitate inspection and use of cleanout procedures.
3. Yes No Maintained in a reasonably clean and orderly manner.
4. Yes No Scales and liquid metering devices are of suitable size, design, construction, precision and accuracy for their intended purpose.

COMMENTS:

225.135 WORK AND STORAGE AREAS

1. Yes No Work area and equipment for the production or storage of medicated feeds or components are not used for manufacturing or storing of fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides unless such articles are approved for use in the manufacture of animal feeds.
2. Yes No Work area and equipment for the production or storage of medicated feeds or components are physically separated from work areas and equipment used for the manufacture or storage of fertilizers, herbicides, insecticides, fungicides, rodenticides and other pesticides unless such articles are approved for use in the manufacture of animal feeds.

COMMENTS:

SECTION I. INSPECTION *(Continued)*

225.142 COMPONENTS

1. Yes No Firm uses only drug products not requiring an approved FDA license.
2. Yes No Control procedures for receipt, identification, storage and use of drug products exempt from the requirements of an approved license have been established and maintained to assure the identity, strength, and purity of each drug.
3. Yes No Drug products are used only in accordance with their labeled mixing directions.
4. Yes No Packaged drug products in the storage areas are stored in original closed containers.
5. Yes No Bulk drug products are identified and stored in a manner to maintain their identity, strength, quality and purity.

COMMENTS:

PROOF

225.158 ASSAYS

- Yes No Where assays indicate medicated feed is not in accord with permissible limits, an investigation and corrective action was implemented and records of such were maintained on the premises for a period of one year.

COMMENTS:

225.165 EQUIPMENT CLEANOUT PROCEDURES

- Yes No Adequate procedures are 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.

COMMENTS:

SECTION I. INSPECTION *(Continued)*

225.180 LABELING

1. Yes No Labels and labeling are received, handled and stored in a manner which prevents label mix-ups and assures that the correct labels and labeling are used for the medicated feed.
2. Yes No All deliveries of medicated feed, whether bagged or bulk, are adequately labeled to assure that the feed can be safely and effectively used.

COMMENTS

225.202 RECORDS

1. Yes No Records showing the formulation, date of mixing and distribution of each medicated feed are maintained for one year after the last date of shipment.
2. Yes No Records are adequate to facilitate the recall of specific batches of medicated feed that have been produced and distributed by the firm.

COMMENTS

PROOF

SECTION II. DISCUSSIONS WITH UPPER MANAGEMENT / MOST RESPONSIBLE PARTY

- OBSERVATIONS AND FINDINGS REVIEWED WITH UPPER MANAGEMENT
- FIRM'S RESPONSE/COMMENTS BY UPPER MANAGEMENT

(Continued)

SECTION II. DISCUSSION WITH UPPER MANAGEMENT *(Continued)*

PROOF

MOST RESPONSIBLE PARTY / UPPER MANAGEMENT

NAME *(Please type or print)*

SIGNATURE

DATE

MOST RESPONSIBLE PARTY / UPPER MANAGEMENT

NAME *(Please type or print)*

SIGNATURE

DATE

Public reporting burden for this collection of information is estimated to average 4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Division of Animal Feeds (HFV-220)
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, Rockville, MD 20855

PROOF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

GMB No. 0910-XXXX
Expiration Date: XXXXX
See GMB Statement below

**VOLUNTARY INSPECTION REPORT FOR
FDA LICENSED MEDICATED FEED ESTABLISHMENTS**

NAME OF INSPECTORS

DATE OF INSPECTION

FIRM NAME

NUMBER AND STREET

CITY AND STATE

ZIP CODE

COUNTY

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

PROOF

Public reporting burden for this collection of information is estimated to average 9 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Division of Animal Foods (HFV-220)
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, Rockville, MD 20855

HISTORY OF BUSINESS

1. PARENT FIRM, if applicable

Name

2. CORPORATE OFFICERS

Name and Title

Address

Business Address

3. FDA REGISTRATIONALICENSE STATUS

(Check appropriate status)

- a. Unknown
- b. Non-registered
- c. Registered (as a drug establishment)
Registration no.: _____
- d. Licensed
License no.: _____

4. TYPE OF FIRM

(Check appropriate type)

- a. Commercial Feed Mill
- b. Mixer-Feeder
- c. Mixer-Feeder
- d. Other (Please specify): _____

5. FEED PREPARED FOR

(Check all that apply)

- a. Beef cattle e. Poultry
- b. Dairy cattle f. Fish
- c. Swine g. Other (Exotic/
Species): _____
- d. Sheep/Goats _____

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: 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.
- 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:

NARRATIVE

Note: If the response to 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 (s.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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Date of treatment and, if different, date of prescribing the VFD drug.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Name of the animal drug.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Level of animal drug in the feed and the amount of feed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Feeding instructions with withdrawal time.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
g. Expiration date of the VFD.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
h. Any special instructions necessary for use of the drug in conformance with the approval.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
i. Required cautionary statements.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
j. Number of refills, if permitted by the approval.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
k. Signature of the veterinarian.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
l. The veterinarian's license number and the name of the State issuing the license.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
m. Other information as required by the individual drug approval.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

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 (in the narrative)

NARRATIVE

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. Routing maintenance of equipment?

NARRATIVE

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 inspections 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.?

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

PROOF

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 cleanout 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 cleanout procedure appear adequate to prevent unsafe contamination? If no, explain (in the narrative).
- Yes No 33. Is there documentation that equipment cleanout procedures are actually being performed?
- Yes No 34. Describe disposition of cleanout material (in the narrative).

CONTROL OPERATIONS

- Yes No 35. Are feeds stored in a manner to prevent mixups 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 12).

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?)

NARRATIVE

PROOF

DRUG COMPONENTS (21 CFR 225.42), continued

NARRATIVE

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.

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

Yes No a. Identify and quantify?

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?

PROOF

LABORATORY CONTROLS (21 CFR 225.58)

NARRATIVE

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?

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 (in the narrative) the following information on any confirmed "out of limits" results:

- a. Name of feed(s) and drug(s).
- b. Production date or code.
- c. Drug guarantee and assay result.

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 initiated 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 the procedures the firm uses for providing the consignee with labeling upon delivery (in the narrative)

PROOF

MASTER RECORD FILE (21 CFR 225.102)

NARRATIVE

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?

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 initiated 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?

PROOF

PRODUCTION RECORDS (21 CFR 225.102)

Yes No 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?

PRODUCTION RECORDS (21 CFR 225.102), continued

NARRATIVE

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

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

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 at which the 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 lead?

79. Calculate drug levels in a representative number of leads, 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 the 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 lead involved?

Yes No d. Specific details of the complaint?

PROOF

COMPLAINT FILES (21 CFR 225.115), continued	NARRATIVE
<input type="checkbox"/> Yes <input type="checkbox"/> No e. Correspondence, including memoranda of conversations, from the complainant?	
<input type="checkbox"/> Yes <input type="checkbox"/> No f. Description of all investigations?	
<input type="checkbox"/> Yes <input type="checkbox"/> No g. Method of disposition of the complaint?	
<input type="checkbox"/> Yes <input type="checkbox"/> No 85. Are reports of adverse experiences, drug mixups, and other failures of the drug to meet specifications reported as required to CVM?	

NARRATIVE

PROOF

NARRATIVE, continued

PROOF

DRUG COMPONENTS ON HAND

TRADENAME	DISTRIBUTOR	DRUG	POTENCY

PROOF

DISCUSSION WITH UPPER MANAGEMENT / MOST RESPONSIBLE PARTY

Describe in detail all recommendations given to upper management and their response(s).

PROOF

DISCUSSION WITH UPPER MANAGEMENT, continued

PROOF

MOST RESPONSIBLE PARTY / UPPER MANAGEMENT	MOST RESPONSIBLE PARTY / UPPER MANAGEMENT
NAME <i>(Please type or print)</i>	NAME <i>(Please type or print)</i>
SIGNATURE	SIGNATURE
DATE	DATE