SMG 8076 FDA State Contract Audit Program Appendix C.1

Instructions for Completing the Animal Food Safety Inspection Audit Form

This document provides instructions on assigning ratings during an audit for each of the performance factors listed on the *Appendix C, Animal Food Safety Inspection Audit Form*. For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided.

General References:

Applicable compliance programs referenced in the contract:

- Medicated Feeds CPG 7371.004
- BSE CP 7371.009

Applicable current inspection assignment memorandums:

- Medicated Feeds (FDA website)
- BSE (FDA website)
- IOM 166 – Official credentials and badges
- IOM 501 – Authority to enter and inspect
- IOM 511 – Notice of inspection
- IOM 582 – Medicated Animal Foods and Type A Articles
- IOM 701 – Statutory Authority
- FD&C Act – Section 501 Adulterated Drugs and Devices
- FD&C Act – Section 704 Factory Inspection
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Guidance for Industry: Determination of Status as a Qualified Facility

Appropriate reference material for approved medicated feeds, options include:

- 21 CFR 225 for the medicated feed CGMP regulations
- 21 CFR 500-599 (hard copy volume of the Code of Federal Regulations)
- Current edition of the Feed Additive Compendium
- Access to the eCFR
- Blue Bird Label website
- 21 CFR 507 – Preventive Controls for Animal Foods regulation
- 21 CFR 558 – Drugs approved for use in Medicated Feeds, VFD regulations
- 21 CFR 589.2000/2001 Substances Prohibited from Use in Animal Food or Feed (BSE regulations)
- Hard copy volume of 21 CFR 500 to 599 includes all of the feed manufacturing regulations, except medicated feed CGMPs
- Hard Copy volume of 21 CFR 200 to 299 includes the medicated feed CGMPs found in 21 CFR 225

Pre-Inspection Assessment

1. Did the inspector prepare for the establishment inspection (e.g., review the previous inspection report, possible complaints, and/or access other available resources in preparation for the inspection)?

References

State's establishment files
Previous FDA report

Examples of a “needs improvement” rating:

a. The inspector does not review the previous inspection report, including previously cited deficiencies and regulatory history.

b. The inspector does not review a firm’s response letter to the previous establishment inspection in which corrective actions were promised.

c. The inspector does not verify the days of operation for a firm that closes for a period of time during the winter.

d. The inspector does not follow-up a consumer complaint contained in the state's establishment file.

2. Did the inspector have the appropriate equipment and resource materials to properly conduct the inspection?

Examples of a “needs improvement” rating:

a. During an inspection of an animal foods manufacturer, the inspector does not have a calculator and current Animal Food Additive Compendium (or a copy of 21 CFR 225 and Chapter 500).

b. The inspector does not have a camera to document violations.

c. The inspector does not have a flashlight to examine poorly lit raw material storage areas.

II. Inspection Observations and Performance

1. Was FDA jurisdiction established?

Examples of a “needs improvement” rating:

a. The inspector fails to confirm the interstate movement of product or ingredients.

b. The inspector conducts an inspection of an animal food manufacturing facility. The inspector fails to determine that product or ingredients have not been received or shipped in interstate commerce by the manufacturer since the last inspection.

c. State inspector selects a product or raw ingredient that isn’t under FDA jurisdiction.

2. Were appropriate credentials (FDA or state) presented and Notice of Inspection (FDA 482 or state equivalent) with attachments issued to the firm?

Examples of a "needs improvement" rating:

a. Inspector fails to present their credentials to the owner, operator, or most responsible person of the establishment.

b. Inspector enters the firm through the rear entrance and immediately begins the inspection without issuing a Notice of Inspection.

c. Upon entering the firm, the inspector fails to issue the Notice of Inspection to the most responsible person.

3. If the firm is a Licensed Medicated Feed Mill, was a copy of the Feed Mill License (FML) and drug registration verified to be active and current? (If this question does not apply, mark as Acceptable)

Examples of a "needs improvement" rating:

a. The inspector failed to verify the firm's medicated animal food mill license was current and active.

b. The inspector failed to verify the medicated animal food manufacturer drug registration was current and active.

4. If applicable, did the inspector verify the food facility registration and/or attestation to be a qualified facility? (If this question does not apply, mark as Acceptable)

Examples of a "needs improvement" rating:

a. The inspector failed to verify if the animal food manufacturer was required to be registered under the BT Act.

b. Although the firm met the registration requirements, the inspector failed to verify the status of the firm's registration.

c. Inspector failed to verify the firm's qualified facility attestation was submitted or didn't inquire under which section the firm filed under.

5. Did the inspector select appropriate product(s) during the inspection focusing on the firm's products and processes determined to be high risk, and if necessary, make appropriate adjustments based on the type of firm being inspected?

Examples of a "needs improvement" rating:

a. The inspector covers only a feed containing a Category I Type A Medicated Article when the firm is also producing feeds containing Category II Type A Medicated Articles on the day of the inspection.

b. The inspector does not cover a small medicated premix operation in a complete feed processing plant.

c. While inspecting a pet food manufacturing plant making extruded animal food, the inspector does not question the firm about sanitation practices.

d. The inspector selected and covered animal foods that contained no prohibited materials (PM) when products containing PM were being processed.

6. Did the inspector evaluate employee activities that may affect safe production and storage of animal food?

Examples of a “needs improvement” rating:

a. The inspector observes a trash bin and a reclaim bin in the same area, but he fails to evaluate practices sufficiently to identify an employee placing trash in the reclaim bin, which subsequently re-enters the process flow.

b. The inspector fails to recognize the significance of an employee loading medicated feed into an uncovered feed truck in a rainstorm.

c. The inspector fails to recognize distressed dog food being placed into a re-grinder bin containing regrinds for ruminant feed.

d. The inspector fails to note an employee using Rumensin in a lamb feed when the formula did not call for the addition of this drug product.

7. Did the inspector evaluate conditions, practices, components, and/or labeling that may cause the product to be adulterated or misbranded?

References:

- Applicable compliance programs referenced in the contract

Examples of a “needs improvement” rating:

a. Inspector fails to identify feed containing an unapproved drug combination.

b. The inspector fails to recognize when a firm’s finished medicated product labeling does not contain a drug declaration.

c. The inspector fails to note the significance of “back hauling” prohibited materials in a bulk truck used to carry ruminant feeds.

d. The inspector fails to recognize the addition of a drug during the production of a complete animal food and fails to review the animal food label.

8. Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with FDA or state reporting procedures?

Examples of a “needs improvement” rating:

a. The inspector fails to recognize that the firm’s clean out procedure is inadequate, because the equipment is used for products containing PM and products containing only non-prohibitive materials.

b. The inspector fails to review the firm’s daily drug inventory records.

c. The inspector does not document the firm’s failure to maintain records for PM through receipt, processing, and distribution of the feed materials.

d. The inspector fails to recognize PM is used regularly as a component of an animal food ingredient.

9. Did the inspector demonstrate the ability to distinguish between significant versus insignificant observations and isolated incidents versus trends?

References:

21 CFR 225, cGMP for Medicated Animal Foods

Examples of a "needs improvement" rating:

a. The inspector observes minor deficiencies, such as dusty equipment, but overlooks areas where cross contamination of prohibited materials and ruminant feed product might occur.

b. The inspector identifies recordkeeping deficiencies in two-month-old records. The inspector objects to these recorded deficiencies without considering corrective actions have been implemented by the firm and the deficiencies have not been repeated.

c. During the inspection of a warehouse, the inspector observes products stored away from the wall but fails to see several pallets of pet food are covered with dead moths, bird droppings, and rodent droppings.

10. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operation and effectively apply the information obtained from this review?

Examples of a "needs improvement" rating:

a. During record review, the inspector detects actual mixing times routinely fail to meet or exceed master record file mixing times but does not inquire about the corrective measures the firm has taken.

b. The inspector discovers swine feed mix containing PM but fails to check the finished label for the required cautionary statement.

c. Mixer cleanout records are reviewed, but the inspector fails to note cleanout procedures were not done according to the firm's SOPs.

d. The inspector fails to confirm the required number of assays collected and performed. Furthermore, the inspector fails to report the finding on the FDA 483 and forgets to discuss it with the firm's managers.

e. Inspector identifies PM in protein premix for ruminant feeds but fails to notify firm management and record the finding on the FDA483.

11. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with procedures, if violative conditions were encountered?

Examples of a "needs improvement" rating:

a. The inspector fails to collect labels from animal food to document a violation according to FDA requirements.

b. The inspector fails to take photographs or otherwise document spilled feed, damaged bags, bird and rodent feces, or other indicators of an exceptionally dirty warehouse to document a violation according to FDA requirements.

c. In a medicated animal food processing plant, the final product drug levels are questionable. The inspector, however, fails to collect a copy of the daily drug inventory showing that an incorrect amount of medicated article was used in the product.

d. The inspector fails to obtain records that document the receipt and use of prohibited material in dairy feed.

12. Did the inspector verify that deficiencies from the previous inspection were corrected?

Examples of a "needs improvement" rating:

a. Although significant cleanout material handling deficiencies were identified during the previous inspection, the inspector does not determine whether these deficiencies have been corrected.

b. The previous inspection of a firm listed inaccurate drug levels on labeling of several feed products. During the current inspection, the manager informs the inspector that the problem has been corrected and the lab results are acceptable. The inspector reviews these lab results but does not review the feed labels to verify they are correct.

c. The inspector fails to follow up on deficiencies from the previous inspection for palletized cross-contaminated product because the product is not being processed at the time of the inspection. The inspector does not review process records related to this product to determine if the firm took appropriate corrective actions.

13. Did the inspector act in a professional manner and demonstrate proper safety practices during the inspection?

Examples of a "needs improvement" rating:

a. The inspector does not use the boot bath when entering in the firm's processing areas.

b. At the conclusion of an inspection, the inspector accepts dog food as a gift from a manager at the firm.

c. The inspector fails to wear protective safety devices that are required by the firm.

Oral and Written Communication

1. Did the inspector identify him/herself and make appropriate introductions, which include explaining the purpose of the inspection?

Examples of a "needs improvement" rating:

a. The inspector fails to explain the reason and the purpose of the visit.

b. The inspector enters through the back door and begins examining a storage area without making his/her presence known to anyone in the firm.

2. Did the inspector use suitable interviewing techniques?

Examples of a "needs improvement" rating:

a. The inspector's requests for information are ambiguous, consequently, the firm provided documents that were not relevant to the inspection.

b. The inspector's requests contain jargon unfamiliar to the firm causing confusion in their responses to inspector.

c. The inspector fails to question the plant manager when his responses to questions about the equipment cleanout program were evasive.

d. After receiving information from the firm's management and production personnel,

the inspector fails to follow up on discrepancies between the two parties.

3. **Did the inspector explain findings accurately and clearly throughout the inspection?**

   Examples of a "needs improvement" rating:

   a. The inspector did not discuss the inspectional observations with the firm's managers.

   b. The inspector did not discuss a significant deficiency observed in the shelled corn storage/conveyor system before proceeding to the hammer mill area although the general manager was present at the time.

   c. The inspector's discussion of the deficiencies at the conclusion of the inspection was vague. It is unclear to management the significance of the observations and that corrective action should be taken by the firm.

   d. The inspector does not discuss a significant deficiency observed during the inspection at the conclusion of the inspection.

4. **Did the inspector notify the most responsible person at the firm if anything requiring immediate corrective action wasnecessary?**

   Examples of a "needs improvement" rating:

   a. The inspector fails to advise the firm manager that ruminant feed products containing PM are being packaged and shipped.

   b. The inspector fails to notify the firm manager that he witnessed direct contamination of bagged animal food ingredients with used motor oil.

   c. After witnessing direct product contamination with a toxic chemical, the inspector immediately notified an employee not the most responsible person of the problem.

5. **Did the inspector answer questions posed by facility personnel and provide information in an appropriate manner?**

   a. Examples of a "needs improvement" rating:

   b. The inspector revealed specific information about a pending compliance action against a competitor.

   c. The inspector gave a competitor's formulation to the facility manager.

   d. The inspector incorrectly answered a policy question that leads the firm to take an inappropriate corrective action.

6. **Did the inspector record findings accurately, clearly, and concisely on the FDA or state inspection report?**

   Examples of a "needs improvement" rating:

   a. The inspector fails to list an inspectional observation about product containing prohibited material that failed to have the cautionary statement on label.

   b. The inspector fails to record on the inspectional observation about the presence of bird or rodent excreta found in animal food or animal food ingredients.

   c. An inspectional observation states, "Firm did not control hazards", but no further explanation is provided.

   d. The inspector fails to record an inspectional observation about the significant drug discrepancies that were found in inventory records.

   e. The inspector failed to identify on the list of inspectional observations the drug

products for the three assays that were not performed.

ADDITIONAL ANIMAL FOOD REGULATORY PROGRAM STANDARDS (AFRPS) QUESTIONS:

NOTE: Only answer these two questions if the state being audited is enrolled in the AFRPS.

1. **Did the inspector follow applicable bio-security procedures required by the animal food facility and the FDA/state program?**

   Examples of a “needs improvement” rating:

   a. The inspector does not inquire if any particular bio-security protocols are mandated at the facility.

   b. The inspector does not follow the state program’s bio-security protocol.

   c. The inspector does not follow the bio-security protocols mandated by the feed facility.

2. **Did the inspector recognize relative risk (high to low) of the animal food facility based on the state program’s risk-based inspection program and categorization to a facility of a product, the manufacturing processes, and the inspection history of the facility?**

   Examples of a “needs improvement” rating:

   a. The inspector does not recognize the relative risk of the facility because the inspector is not knowledgeable with the manufacturing process involved at this facility and does not inquire with facility personnel.

   b. The inspector organizes inspection activities focused on low risk items and ignores high risk products and processes.

Reporting Instructions for States in Phase II and III

Only the state inspector, not the State auditor, will report time in eSAF. The number of hours will be reported as an audit not an inspection. At the time data is entered into eSAF, the state data entry user will change the Inspection Type field on the Add/Update Inspection Operation screen from "State" to "Audit". In Phase II, the FDA investigator will report time following the instructions in the Appendix C.2.