OMB Number: 0910-0909 Exp Date: XX/XX/XXXX
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION ANIMAL FOOD SAFETY INSPECTION AUDIT FORM

CONTACT INFORMATION

AUDITOR		STATE INSPECTOR
FIRM NAME		FEI #
FIRM ADDRESS		
PRODUCT(S) COVERED		DATE
TIME IN	TIME OUT	OVERALL RATING ☐ Acceptable ☐ Needs Improvement

I. PREINSPECTION 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)?

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

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

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA jurisdiction established?

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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.)

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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.)

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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?

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

II. INSPECTION OBSERVATIONS AND PERFORMANCE *(Continued)*

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?

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS (required for Needs Improvement)

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION

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

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

2. Did the inspector use suitable interviewing techniques?

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

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

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

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

   ☐ Acceptable ☐ Needs Improvement

   COMMENTS *(required for Needs Improvement)*

III. ORAL AND WRITTEN COMMUNICATION *(Continued)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

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

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

IV. ADDITIONAL ANIMAL FOOD REGUALTORY 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?

☐ Acceptable ☐

COMMENTS *(required for Needs Improvement)*

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 a facility?

☐ Acceptable ☐ Needs Improvement

COMMENTS *(required for Needs Improvement)*

IV. NOTES

NOTE: EVERY ITEM MARKED "NEEDS IMPROVEMENT" MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS MARKED AS NEEDING IMPROVEMENT.

Overall Rating:

If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement." The overall rating must be marked in the space provided in the header on the first page.

All questions must be answered “acceptable” or “needs improvement.”

If four or more evaluated items are marked as “needs improvement”, the State Program Manager must be notified by the appropriate FDA liaison that additional training or other performance measures for the inspector being audited should be initiated. All contract inspectors who receive an overall audit score of “needs improvement” shall receive remedial training in deficient areas or as agreed upon by the FDA Division and OP Project Managers prior to resuming contract inspection duties.

ADDITIONAL COMMENTS

SIGNATURE OF AUDITOR	DATE