

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

**BSE/ ANIMAL FOOD ESTABLISHMENT AUDIT FORM**

**I. CONTACT INFORMATION**

FDA Auditor:		State Inspector:	
Firm Name:		FEI#:	
Firm Address:			
Product(s) Covered:			Date:
Time In:	Time Out:	Overall Rating: <input type="checkbox"/> Acceptable <input type="checkbox"/> Needs Improvement	

**II. 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)?

Acceptable       Needs Improvement

Comments (required for Needs Improvement):

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

Acceptable       Needs Improvement

Comments (required for Needs Improvement):

### III. INSPECTION OBSERVATIONS AND PERFORMANCE

1. Was FDA jurisdiction established?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

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

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

3. Was a copy of the Feed Mill License (FML) and drug registration verified to be active and current?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

4. Is the firm required to be registered under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act) and if so, was BT registration verified?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

5. Did the inspector select appropriate product(s) during the inspection, and if necessary, make appropriate adjustments based on what the firm was producing?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

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 federal 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):

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 given the nature of the inspectional findings?

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):

#### **IV. ORAL AND WRITTEN COMMUNICATION**

1. Did the inspector identify herself/himself 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, clearly, and adequately throughout the inspection?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

4. Did the inspector notify the most responsible person at the firm when an immediate corrective action was necessary?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

5. Did the inspector answer questions and provide information in an appropriate manner?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

6. Did the inspector write his/her findings accurately, clearly, and concisely on inspection report?

Acceptable                       Needs Improvement

Comments (required for Needs Improvement):

## V. NOTES

**NOTE: EVERY ITEM MARKED “NEEDS IMPROVEMENT” MUST BE ACCOMPANIED BY AN EXPLANATION OF WHY THE ITEM WAS JUDGED 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 Project and Co-Project Officers prior to resuming contract inspection duties.

**VI. ADDITIONAL COMMENTS**

**VII. SIGNATURE**

FDA Auditor Signature:

Date: