Appendix C

BSE/Feed Establishment Audit Form

FDA Auditor _____State Inspector _____

Firm _____FEI#_____

Firm Address_____

Product(s) Covered _____Date_____

Time In:_____ Time Out:_____ Overall Rating: Acceptable____ Needs Improvement_____

I. Pre Inspection Assessment

	Acceptable	Needs Improvement
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)?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

II. Inspection Observations and Performance

	Acceptable	Needs Improvement
1. Was FDA jurisdiction established?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

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?	[ ]	[ ]

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?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

6. Did the inspector evaluate employee activities that may effect safe production and storage of feed?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

8. Did the inspector recognize significant violative conditions or practices, if present, and record findings consistent with federal procedures?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

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?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

11. Did the inspector collect adequate evidence and documentation given the nature of the inspectional findings?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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	Acceptable	Needs Improvement
12. Did the inspector verify that deficiencies from the previous inspection were corrected?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

III. Oral and Written Communication

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

2. Did the inspector use suitable interviewing techniques?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

3. Did the inspector explain findings accurately, clearly, and adequately throughout the inspection?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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	Acceptable	Needs Improvement
4. Did the inspector notify the most responsible person at the firm when an immediate corrective action was necessary?	[ ]	[ ]

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Comments (required for Needs Improvement):
_____
_____
_____
_____

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

Overall Rating:

All questions must be answered "acceptable" or "needs improvement. 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.

Instructions to the Auditor:

All questions must be answered "acceptable" or "needs improvement." If four or more evaluated items are marked as "needs improvement," remedial training should be considered when serious deficiencies occurred during the inspection. District and state agency managers will agree on the training needed to enable the state inspector to resume conducting inspections under FDA contract. The FDA project and co-project contract officers should be notified and included in discussions between FDA and the state agency.

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Additional Comments:

_____

_____

Signature of FDA Auditor