REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000

(Version 4.2, 10/01/03; FDA/CVM, HFV-230, www.fda.gov/cvm/forms/forms.html)

FEI # (*required*):

Firm (Legal) Name: _____ Date Inspection Ended: _____

Firm (Physical) Address: _____ Lead Investigator: _____

Firm City: _____ Lead Affiliation (***check one***):

❑ Federal

Firm State: _____ ZIP Code: _____ Phone #: _____ ❑ State Agency, (*name*) _____

FDA District Office (***required***): _____

Name and title of person interviewed: _____

Inspection Conclusion: (***Check only one***) ❑ RTC ❑ NAI ❑ CI ❑ Inactive ❑ Out of Business

[**Read Instructions**] [**If firm is OOB, Skip ALL Sections!]**

Section 1 – Complete for ALL firms

1. a) Type of firm inspected? (***Check all that apply***)

❑ Renderer	❑ FDA Licensed Feed Mill	❑ On-farm Feed Mixer
❑ Protein Blender	❑ Non-FDA Licensed Feed Mill	❑ Feeder of Ruminants
❑ Transporter (Hauler)	❑ Pet Food Manufacturer	❑ Feeder of Ruminants **and** Other Species
❑ Distributor/Retailer	❑ Animal Feed/Pet Food Salvager	❑ Other: _____

b) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed ingredients or feeds that are intended for the feeding of ruminant animals? ❑ YES ❑ NO

2. Does the firm receive feed ingredients or feeds that contain or may contain prohibited material? (***Check only one***)

❑ Retail Pet/Lab Feed Only ❑ YES ❑ NO

a) If "**NO**," check all of the following that describe any safeguards the firm has in place to assure they do not receive prohibited material.

- ❑ Assurance from supplier that they no longer manufacture any products containing prohibited materials
- ❑ Labeling review of incoming materials
- ❑ Uses only vegetable source proteins
- ❑ Uses pure animal proteins only from exempted sources (examples: such as porcine, equine, poultry, fish, gelatin)
- ❑ Other, (please describe) _____

_____

[For Question 2 = NO - If Feeder of Ruminants (with or without Other Species), SKIP to Section 3; Otherwise, SKIP to Section 4.]

b) If "**YES or Retail Pet/Lab Feed Only**," is imported (not originating in the United States) prohibited material used?

❑ YES ❑ NO ❑ Unknown

Please list the country/ies of origin for the imported prohibited material, _____

3. Does the firm receive prohibited material for further distribution **ONLY**? ❑ YES ❑ NO

4. Does the firm manufacture or process products containing prohibited materials? ❑ YES ❑ NO

5. Are the received feed ingredients or feeds containing prohibited materials (referred to in **#2** above) labeled with the caution statement, "**Do not feed to cattle or other ruminants**"? (***Check only one***)

❑ Renderer Only ❑ Retail Pet/Lab Feed Only ❑ YES ❑ NO

(continued)

Section 2 – Complete for ALL firm types EXCEPT: Firms that are ONLY described as "Other" Firm Type OR Firms that are ONLY Feeders of Ruminants (with or without Other Species)

6. Are the outgoing feed ingredients or feeds containing prohibited materials labeled with the caution statement, "**Do not feed to cattle or other ruminants**"? (***Check only one***)

❑ No Outgoing Ingredients/Feeds ❑ Retail Pet/Lab Feed Only ❑ YES ❑ NO

7. Does the firm maintain records to track the prohibited materials throughout their receipt, processing and distribution, specifically:

a) Date of receipt **or** purchase **or** sale **or** delivery	❑ YES	❑ NO
b) Name and address of the seller	❑ YES	❑ NO
c) Name and address of the consignee	❑ YES	❑ NO
d) Identification of the product	❑ YES	❑ NO
e) Quantity	❑ YES	❑ NO
f) Copies are available for inspection and copying	❑ YES	❑ NO
g) Are **ONLY** retail sales involved?	❑ YES	❑ NO

8. Does the firm manufacture, process, blend or repackage **BOTH** products containing prohibited materials **AND** products containing **only** non-prohibited materials? ❑ YES ❑ NO

9. **a)** If the answer to **#8** is "**NO**," then **SKIP to Question #10**.

If the answer to **#8** is "**YES**," does the firm have a system in place to avoid commingling and cross-contamination? ❑ YES ❑ NO

b) Check all of the following that describe the separation system or clean-out processes and any procedures to avoid commingling and cross-contamination.

❑ Sequencing of feeds
❑ Flushing the system, (*please describe*) _____
❑ Written sequencing and flushing procedures
❑ Documentation maintained of sequencing and flushing
❑ Flushed materials discarded or labeled with the caution statement
❑ Physical clean-out (e.g. vacuuming, cleaning)
❑ Dedicated equipment used for prohibited materials
❑ Other, (*please describe*) _____

_____

10. Please describe any additional safeguards the firm has in place to assure that outgoing feed ingredients or feeds containing prohibited material are not shipped to ruminant feeders, _____

(If None, please Enter "None") _____

Section 3 – Complete for ALL Feeders of Ruminants (with or without Other Species)

11. Are ruminant feeders doing the following?

a) Observing the caution statement on feeds containing prohibited material	❑ YES	❑ NO	❑ No PM-feeds on premises
b) Maintaining copies of labeling for feeds containing animal protein (**AP**)	❑ YES	❑ NO	❑ No AP-feeds on premises
c) Maintaining copies of purchase invoices for feeds containing animal protein	❑ YES	❑ NO	❑ No AP-feeds on premises

Section 4 – Complete for ALL firm types (except OOB firms)

12. **a)** Check all deviations that were noted at the time of inspection. ❑ Commingling ❑ Labeling ❑ No Deviations Noted ❑ Recordkeeping ❑ Feeding Ruminants Prohibited Material

b) If any deviations were noted above, describe the deviations, and the actions and commitments made to correct each deviation,

_____

_____

_____

13. Are you attaching any further descriptions or any exhibits or records and/or labeling? ❑ YES ❑ NO

CHANGES from Version 4.1

The changes in the present version of the BSE Checklist/Report consist entirely of rewording to questions, directions and instructions. No questions or question responses have been added or deleted. The rewording changes have been made for the purpose of clarifying question content and improving the flow of the document. These changes have been made in response to the feedback CVM received during BSE/Ruminant Feed Inspection training sessions that have been held over the past year throughout the country. CVM thanks all state and federal investigators who have provided their valuable input.

Since the document has been revised throughout, we recommend that all investigators read the entire document carefully, including the attached instructions. Some of the main changes are provided below:

Question 1b – The question further defines "handling" for better clarification.

Question 2 – The previous parenthetical statement has been removed for better clarification. Further, the user is specifically instructed to check only **ONE** answer.

Question 2a DIRECTIONS – The directions for **NO** responses to Question 2 has been revised for better clarification. An important point to note is that Section 4 should be completed for **ALL** firms, regardless of the firm type (with the exception of firms that are Out of Business).

Question 5 – The previous parenthetical statement has been removed for better clarification. Further, the investigator is specifically instructed to check only **ONE** answer.

Question 6 – The previous parenthetical statement has been removed for better clarification. Further, the investigator is specifically instructed to check only **ONE** answer.

Question 7 – The word "sufficient" has been removed for better clarification. The purpose of the question is for the user to simply note the types of recordkeeping that are being utilized and not to indicate their adequacy with respect to the BSE/Ruminant Feed Regulation (21 CFR 589.2000). Recordkeeping inadequacies should instead be indicated and described in **Section 4**.

Question 8 – The question was revised for better clarification. Commingling and cross-contamination can occur when products are processed, such as with manufacturing, blending, repackaging or otherwise manipulating the product. Commingling and cross-contamination generally does not occur with the distribution of bagged products (i.e. non-bulk products), although the investigator should be aware of the potential for commingling or cross-contamination associated bag breakage and certain storage methods.

Question 9 – The previous parenthetical statement has been removed for better clarification.

Section 4 – Directions are revised to complete Section 4 for all firms (with the exception of firms that are Out of Business) in order to provide clarity in flow and completeness of information collected.

Question 12b – The question was revised to encourage investigators, especially state investigators, to record any enforcement actions taken to address or correct any noted deviations.

INSTRUCTIONS – Instructions were revised throughout for better clarification. Please carefully read all instructions before utilizing this new version.

INSTRUCTIONS – For the Lead Investigator

BSE District Coordinator. The FDA BSE District Coordinator is responsible for communicating and receiving information related to the BSE Checklist/Report. Questions, comments and concerns should be directed to this individual. All completed BSE Reports of Inspection should be mailed **only** to the BSE District Coordinator, and not to CVM.

BSE Checklist/Report Version. Please make sure you are using the most current BSE Checklist/Report version. The version date is located at the top of the form. Check with your BSE District Coordinator or the FDA/CVM website (www.fda.gov/cvm/form/forms.html) to make sure that you are using the most recent version. Other versions may not be compatible with the BSE Checklist/Report Database and may invalidate the information collected.

BSE Checklist/Report Alterations. Some agencies may need to alter the BSE Checklist/Report to better fit their own operations. While CVM does not necessarily object to such alterations, all changes must be added to the end of the form. No additions, deletions or revisions should be made to the main body of the CVM-version of the BSE Checklist/Report.

Legibility. Illegible writing results in inaccurate data, which compromises the BSE Compliance Program. If at all possible, type in your responses. If handwritten, please print letters rather than using longhand.

Completing Sections. Sections should be fully completed for each of the firm types indicated in the header of each Section. Sections that are inappropriately skipped (based on the firm type) will cause the BSE Checklist/Report to be considered incomplete. Incomplete BSE Reports of Inspection may require a follow-up with the investigator and may require a follow-up inspection of the firm.

Completing Questions. The BSE Checklist/Report instructions and flow of questions must be followed. Blank or unanswered required questions will cause the BSE Checklist/Report to be considered incomplete. Incomplete BSE Reports of Inspection will require a follow-up with the investigator and may require a follow-up inspection of the firm.

Descriptive Fields. For those questions that ask for an explanation or description, please be brief and capture the essential elements with as few words as possible. If you feel that certain answers require a more lengthy description, please consider recording the answer on a separate page, which should be attached to the BSE Checklist/Report and so noted in **Question 13**.

Additional Narrative. For those state BSE/Ruminant Feed inspections that are not being done under federal contract or those state contract BSE/Ruminant Feed inspections that do not include a FDA-481, it is strongly encouraged and recommended that a brief narrative report accompany the BSE Checklist/Report that summarizes the inspection. A brief summary should capture the inspection in total and should include other details not captured in the Checklist/Report.

FEI Number. The FEI number is absolutely required. You may need to contact your BSE District Coordinator for this information; however, it is the District's responsibility to provide this critical information. In many cases, the District may assign a FEI number after the inspection is completed.

Firm Name. For the firm name, use only the accurate legal name as used by the establishment. Caution should be used in describing the establishment name. Do not use "Doing Business As" (DBA).

Firm Address. The address should reflect the physical location of the firm's activities. Post Office Box numbers are unacceptable.

Inspection Conclusion. This code represents the investigator's reported conclusion and is generally recorded in the FDA FACTS database. You many need to consult with your BSE District Coordinator. **RTC** = Referred to Center; **NAI** = No Action Indicated; **CI** = Correction Indicated. Forms should be completed for **Inactive** firms since they might begin production at any time. **Out of Business** firms require no more information gathering.

Firm Type. Please understand the firm type categories provided and use these categories whenever applicable.

Considerations:

- A single firm can be categorized as one or more firm types.
- The BSE Checklist/Report may not fully describe the activities of certain multiple firm type combinations. Please contact your BSE District Coordinator if additional guidance is needed.
- Feed mills should be described on the basis of FDA licensure and NOT on whether the firm produces medicated feeds.
- Ruminant feeders (e.g. dairy farms) might also be On-farm Mixers.
- On-farm Mixers might not be ruminant feeders (e.g. swine farms).
- On-farm Mixers, regardless of the species being fed, are subject to the requirements of the BSE/Ruminant Feed regulation (21 CFR 589.2000).
- On-farm Mixing applies to mixing that is not performed for the purpose of commercial distribution. Generally the use of on-farm mixed feeds is limited to the same farm premises and so requires minimal controls. However, on-farm mixed feeds that

are utilized off-premises and/or outside the direct supervision of the farm manager (e.g., a farm where mixed feeds are delivered for feeding at physically different farm locations, perhaps under a contract arrangement) should be produced under all control measures required by the BSE/Ruminant Feed regulation (21 CFR 589.2000).

- The "Other" category should be used only for firm operations that are not described by the other categories. Improper use of the "Other" category may cause inaccurate and/or inadequate information to be collected in the remaining Sections.

Feed Ingredients and Feeds. This category refers to substances that are utilized in the manufacture of animal feeds or that are intended to be fed to animals. Substances intended solely for other purposes (e.g. fertilizers) are not included in this category.

Question 12a. Keep in mind that potential sources of prohibited materials in ruminant feeds include pet foods, distressed/salvaged pet foods, and other distressed/salvaged food.

Section 4. Section 4 should be completed for all firms, except Out of Business (OOB) firms. Deviations outside of 21 CFR 589.2000 may be noted even for firms that are not handling prohibited material. An example is the use of the caution statement when the firm is not handling prohibited material. In addition, the investigator may be attaching other descriptions or exhibits such as assurances, labeling or a narrative.

INSTRUCTIONS – For the BSE District Coordinator

The BSE District Coordinator has a key role and overall responsibility for ensuring that BSE Reports of Inspection are completed fully and accurately, which is vital to the success of BSE compliance efforts. The BSE District Coordinator should pay particular attention to ensuring the following:

- Familiarity with the Instructions for the Lead Investigator.
- The most recent version of the BSE Checklist/Report and accompanying instructions are distributed and utilized.
- The BSE Checklist/Report has not been unacceptably altered.
- All required sections are completed. All questions within a required section are completed.
- Handwritten forms are legible.
- The FEI number is provided
- The FDA District Office identity is provided.
- The Inspection Conclusion is provided.
- Response inconsistencies are resolved.

All completed BSE Reports of Inspection should be sent **only** to the BSE District Coordinator, and not to CVM. The Districts will have the responsibility for checking the forms for completeness and accuracy, and for entering the information into FACTS.

Any questions, concerns or comments regarding the BSE Checklist/Report or the BSE/Ruminant Feed Inspection Compliance Program should be directed to the appropriate BSE District Coordinator. The following individuals are additional BSE/Ruminant Feed Inspection Compliance Program contacts:

CVM: Neal Bataller
Nbatalle@cvm.fda.gov
301-827-0163

ORA: Jim Dunnie
Jdunnie@ora.fda.gov
301-827-5652