

REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000 & 589.2001
(Version 6.1, 10/09/2009; FDA/CVM, HFV-230, www.fda.gov/cvm/Documents/BSE_V61.doc)

FEI #: _____

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

Firm (Physical) Address: _____ Lead Investigator: _____

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

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

GPS Coordinates of Inspected Site: _____ FDA District Office: _____

Name and title of person(s) interviewed: _____

Name and title of most responsible person at this site: _____

Operational Status: (**Check only one**) Operational Seasonal Inactive Out of Business
(See **Instructions**) [If firm is OOB, Skip ALL Sections!]

Information above includes changes to firm's name and/or address

Section 1 – Complete for ALL firms

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

- | | | |
|---|--|---|
| <input type="checkbox"/> Renderer | <input type="checkbox"/> Feed Mill (FDA Licensed) | <input type="checkbox"/> On-farm Feed Mixer |
| <input type="checkbox"/> Protein Blender | <input type="checkbox"/> Feed Mill (not FDA Licensed) | <input type="checkbox"/> Feeder of Ruminants |
| <input type="checkbox"/> Transporter (Hauler) | <input type="checkbox"/> Pet Food Manufacturer | <input type="checkbox"/> Human Food Processor |
| <input type="checkbox"/> Distributor/Retailer | <input type="checkbox"/> Animal Feed/Pet Food Salvager | <input type="checkbox"/> Other: _____ |

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

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

d) Is the firm aware of the BSE rule, 21 CFR 589.2000? YES NO

2. If the firm is manufacturing feed, do they use tallow (animal fat from cattle) in animal feed formulations? YES NO

Firm does not manufacture feed

a) If yes, does the tallow used in ruminant feed contain not more than 0.15% insoluble impurities? YES NO

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

YES, but PM is Only in Retail Pet/Lab Feed YES NO

a) If Question 3 is “**YES, but PM is only in Retail Pet/Lab Feed**” or “**NO**”, check all of the following that describe voluntary safeguards the firm has in place to assure they do not receive prohibited material.

- Written assurance from suppliers that they no longer manufacture/distribute any products containing prohibited materials
- Written assurance from transporters that they do not transport products containing prohibited materials
- Written assurance from transporters that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination
- Written procedures for the label review of incoming materials
- Uses only vegetable source proteins and uses no animal proteins
- Uses animal proteins only from exempted sources

(**Circle all that apply:** blood milk plate waste porcine equine poultry fish gelatin)

Testing of incoming materials, (*please describe*) _____

Other, (*please describe*) _____

[If Q3 = "No" or if Q1a) is only "Feeder of Ruminants", skip to Section 4] -----

b) If Question 3 is either "YES, but PM is Only in Retail Pet/Lab Feed" or "YES", is imported prohibited material (not originating in the United States) used? YES NO Unknown

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

4. Is the received product containing prohibited material intended **ONLY** for further distribution? YES NO

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

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

PM is Only for Rendering PM is Only in Retail Pet/Lab Feed YES NO

Section 2 – Complete for ALL firms EXCEPT: Firms that are ONLY Q1a) Firm Type = "Other" OR Firms that are ONLY Q1a) Firm Type = "Feeder of Ruminants"

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

No Outgoing Feeds/Ingredients containing PM PM is Only in Retail Pet/Lab Feed YES NO

8. Describe records the firm maintains in tracking prohibited materials throughout their receipt, processing and distribution:

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 purchaser 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 feed sales involved? YES NO

h) Are **ONLY** retail feed sales of pet food involved? YES NO

9. a) Does the firm manufacture, process, blend, repackage, or transport **BOTH** products containing prohibited materials **AND** products containing **only** non-prohibited materials? YES NO

b) Does the firm manufacture, process, blend, repackage, or transport **BOTH** products containing prohibited materials **AND** feeds or feed ingredients that may be used for ruminants? YES NO

10. a) If the answer to Q9a) is "NO," then **SKIP to Question 11.**

If the answer to Q9a) is "YES", does the firm have a system in place to avoid commingling and cross-contamination? YES NO

b) If the answer to Q9a) is "YES," check **ALL** of the following that describe the measures the firm has in place to avoid commingling or 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

Product containing prohibited material is always in packaged form when in the firm's possession

Other, (*please describe*) _____

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

(If none, please enter "None")

Section 3 -- Complete this section ONLY if the firm is marked as: Q1a) Firm Type = "Renderer"

12. Describe the firm type: (check one, or more if appropriate)
- Independent Renderer (rendering facility not affiliated with a slaughter facility)
 - Livestock Slaughter Facility with On-Site Rendering
 - Transfer Station, Transporter
 - 4-D Processor (non-cooking facility)
 - Other (please describe) _____
13. Does the firm process cattle and/or cattle offal, with or without other livestock species? YES NO
- [If Q13)="NO", then skip to Section 4]**
14. Does the firm collect, receive or process material (including dead stock cattle 30 months of age or older) that contains "cattle material prohibited in animal feed" (CMPAF)? YES NO
15. a) Does the firm produce tallow for use in animal feed? YES NO
b) If yes, does the tallow contain less than 0.15% insoluble impurities? YES NO
c) If 15(b) is "NO", is outgoing tallow containing more than 0.15% insoluble impurities labeled with the caution statement "Do Not Feed To Cattle Or Other Ruminants"? YES NO
16. Does the firm differentiate cattle less than 30 months old from those that are 30 months of age or older? YES NO
- a) If yes, check all of the following methods that the firm uses to differentiate cattle by age.
- Dentition (examination of teeth)
 - Affidavit from supplier
 - Livestock producer herd records
 - Other (please describe) _____
- b) Does the firm have written procedures explaining the process(es) used above? YES NO
- c) Does the firm maintain records for at least one year documenting the methods noted above? YES NO
17. Does the firm separate CMPAF from material that may be used in animal feed? YES NO
- a) If yes, check all of the following methods that the firm uses to separate CMPAF from material that may be used in feed.
- Remove striated muscle and offal from the carcass
 - Remove the vertebral column and head from the rest of the carcass
 - Remove only the brain and spinal cord
 - Other (please describe) _____
- b) Does the firm have written procedures explaining the process(es) used above? YES NO
- c) Does the firm maintain written records for at least one year documenting the methods noted above? YES NO
- d) Does the firm have separate equipment for handling CMPAF once removed from the whole carcass? YES NO
- e) Is the CMPAF labeled "do not feed to animals"? YES NO
- f) Is the CMPAF marked with an agent that can be seen by visual inspection? YES NO
18. Does the firm generate CMPAF? YES NO
- a) If yes, what method does the firm use to dispose of the CMPAF? (check all that apply)
- Landfill
 - Incineration
 - Alkaline or thermal digestion
 - Rendering
 - Other (please describe) _____
- b) Does the firm have records that document disposition of CMPAF? YES NO
- c) Do the records demonstrate that CMPAF is not going into animal feed? YES NO

**Section 4 – SKIP this section when the firm is ONLY marked as: Q1a) Firm Type = "Other" OR
Q1a) Firm Type = "Transporter (Hauler)"**

19. a) Are any incoming feeds or feed ingredients transported in bulk form? YES NO
- b) Are any incoming feeds or feed ingredients transported in packaged form? YES NO
- c) Does the firm utilize **its own** transportation vehicles for the delivery of any bulk incoming feeds or feed ingredients? YES NO
- d) Does the firm utilize **other firms'** transportation vehicles for the delivery of any bulk incoming feeds or feed ingredients? YES NO
- e) If 19(d) is "YES," do **ALL inbound** transporters provide written assurance that they utilize dedicated transport equipment OR utilize measures that adequately prevent commingling or cross-contamination with prohibited material? YES NO
20. a) Are any outgoing feeds or feed ingredients transported in bulk form? No Outgoing Feeds/Ingredients YES NO
- b) Are any outgoing feeds or feed ingredients transported in bagged/packaged form? No Outgoing Feeds/Ingredients YES NO
- c) Does the firm utilize **its own** transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients? No Outgoing Feeds/Ingredients YES NO
- d) Does the firm utilize **other firms'** transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients? No Outgoing Feeds/Ingredients YES NO
- e) If 20(d) is "YES," do **ALL outbound** transporters provide written assurance that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination with prohibited material? YES NO

Section 5 – Complete this section ONLY if the firm is marked as: Q1a) Firm Type = “Feeder of Ruminants”

21. Are ruminant feeders doing the following?
- a) Observing the caution statement on feeds containing prohibited material (**PM**) 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
(**Not including** retail pet food for cats and dogs)
- c) Maintaining copies of purchase invoices for feeds containing animal protein YES NO No AP-feeds on premises
(**Not including** retail pet food for cats and dogs)
- d) Feeding non-ruminant species (**Not including** cats and dogs) YES NO
- e) Feeding non-ruminant species (**Not including** cats and dogs) feeds containing prohibited material YES NO No PM-feeds on premises
- f) Feeding cats and/or dogs YES NO

Section 6 – Complete for ALL Firm Types

22. 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,
- _____
- _____
23. Are you attaching any descriptions, exhibits, records, labeling, reports or supplemental information? YES NO