SUBJECT:	**IMPLEMENTATION DATE:**
BSE/Ruminant Feed Ban Inspections	**10/21/2003**
	COMPLETION DATE:
	Continuous

DATA REPORTING

PRODUCT CODES	**PRODUCT/ASSIGNMENT CODES**
INDUSTRY CODES: 67, 68, 69, 70, 71, 72	**71009** BSE/Ruminant Feed Ban Inspections Program **71R844** BSE Import Activities CVM Products **71S007** BSE Medicated Feed State Contract Inspections (Licensed) **71S008** BSE Medicated Feed State Contract Inspections (Unlicensed) **71S009** BSE Illegal Tissue Residue State Contract Inspections

1. Field Reporting

a. Hardcopy Reports

Copies of all Warning Letters should be submitted to CVM, Division of Compliance (HFV-230) and ORA, Office of Enforcement (HFC-210)

Hardcopies of other investigational reports, including checklists and State reports should be submitted to the appropriate FDA District Office. Copies should not be submitted to CVM (HFV-230).

b. FACTS Reporting

All BSE inspections reported in FACTS should also have a BSE checklist reported. Similarly, no checklist can be entered in FACTS without an accompanying BSE inspection.

Report domestic sample collections/analyses under PAC 71009, and import sample collections/analyses under PAC 71R844.

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Part I - Background

Bovine Spongiform Encephalopathy (**BSE**) is the bovine form of a group of uniformly fatal neurological diseases known as Transmissible Spongiform Encephalopathies (**TSEs**). BSE appears to be spread through the feeding of infected material to cattle. BSE is a public health issue for the U.S. This disease has been linked to the human TSE known as variant Creutzfeldt-Jakob Disease (**vCJD**), presumably through people consuming ruminant tissues infected with the BSE agent. In addition, BSE has had a devastating economic effect on the livestock industry in countries where it has been identified or suspected.

On August 4, 1997, the "Animal Proteins Prohibited From Use In Animal Feeds" regulation, 21 CFR §589.2000, became effective. This regulation is designed to prevent the establishment and amplification of BSE through animal feed, by prohibiting the use of certain proteins derived from mammalian tissue in the feeding of ruminant animals. This regulation affects renderers, protein blenders, commercial animal feed manufacturers, distributors (including retailers), transporters of animal feed and feed ingredients, on-farm animal feed mixers, and ruminant feeders. Based on the acute need to control the entry and spread of this disease, the Agency has set a goal of full compliance with the regulation.

At the present time, the causative agent for BSE is not fully understood, although prions are the suspected mode of transmission of this disease. Currently, there is no direct test for the presence of the BSE prion agent in animal feed, feed ingredients, and other animal feed products. In lieu of an FDA-validated test method for detecting the presence of the agent that causes BSE, efforts are focused on prohibiting the inclusion of certain mammalian proteins in ruminant feed. Tests are presently available for identifying mammalian proteins in animal feeds. Feed microscopy is one such test method for mammalian proteins. Feed microscopy analysis is a useful tool to help ensure that product potentially contaminated with prohibited materials does not enter the U.S., and to help assure that domestic and imported products also are not adulterated with prohibited materials. Additional analytical methods are in development.

In January 1998, the FDA undertook an initiative to prevent the establishment and amplification of BSE and other TSE's through animal feed. The Agency's approach strongly emphasized education and incorporated training seminars, guidance documents, and the distribution of various written and printed materials. The initiative combined these educational efforts with an inspectional approach to all renderers, feed mills, protein blenders and other firms subject to this regulation.

On December 7, 2000, the USDA/APHIS enacted regulations prohibiting on the importation into the United States of all meat and bone meal (**MBM**), meat meal, bone meal, blood meal, tankage, offal, tallow, or any product containing such, which originated directly from countries identified as having BSE, or from countries having inadequate systems in place to prevent BSE

(See 9 CFR §94.18 and 9 CFR §95.4). The prohibitions included all products of animal origin that were rendered or processed in these countries, regardless of species of origin, and including poultry and fishmeal unless the material is from a non-ruminant species and meets certain conditions assuring no contamination with ruminant material. These prohibitions were deemed necessary by APHIS because of the possibility of cross contamination with the BSE agent. Subsequently, on January 20, 2001, the FDA issued Import Alert #99-25, "Detention Without Physical Examination of Animal Feed, Animal Feed Ingredients and Other Products for Animal Use Consisting or Containing Ingredients of Animal Origin."

This compliance program guidance should be used by federal and state investigators to conduct inspections or investigations of renderers, protein blenders, licensed and unlicensed feed manufacturers, distributors, retailers, on-farm feed mixers, and ruminant feeders. The purpose of these inspections is to assess compliance with 21 CFR §589.2000. The program provides guidance for collecting evidence to support regulatory action when non-compliance is found.

In addition, this compliance program guidance should be used by import personnel in determining the appropriateness of animal feeds and feed ingredients coming into the United States. Import personnel should ensure that prohibited material does not enter the U.S from BSE-at-risk countries, unless accompanied by all relevant federally required certificates and documentation. Import personnel should also ensure that labeling for products coming in from non-BSE-at-risk countries is in full compliance with 21 CFR §589.2000 and animal feed labeling requirements.

Part II - Implementation

1. Objectives.

The primary goal of this compliance program is to enhance the FDA's uniformity in inspection and compliance of firms subject to the regulation prohibiting the utilization of specified animal proteins in ruminant feeds, 21 CFR §589.2000. The purpose of these regulations is to prevent the establishment and/or amplification of BSE within the United States. Additional features of the compliance program are as follows:

- To provide guidance to federal, state, and local officials for conducting on-site inspections of a variety of firm types, as described by the regulation.
- To provide guidance for determining the need and type of enforcement action based on inspection findings.
- To provide guidance on sampling and analytical methods for supporting inspection findings.
- To emphasize the need for using this compliance program as a part of other inspections and compliance programs that are conducted by federal, state and local officials.

Since the threat of the introduction of BSE within the United States is an ever-present and continuing concern, this compliance program will be used on a continuing basis and incorporated into standard inspectional protocols.

2. Program Management Instructions.

a. Inspection Priorities.

The first inspectional priority under this program is to inspect those firms that have a violative history that has been classified by the FDA as "Official Action Indicated" or OAI. These inspections should be conducted with the intent that regulatory action will be pursued should the firm be unwilling or unable to take immediate actions to correct the violations.

21 CFR §589.2000 pertains to a variety of firms and animal production operations that involve the manufacture, distribution, transportation, and feeding of animal feeds. Although the intent of the rule is to ensure that specified animal proteins are not fed to ruminant animals, the regulation is written broadly in such a way as to include some operations that do not necessarily involve ruminant feeds or the feeding of ruminant animals. Inspectional resources for surveillance are to be spent covering those firms or industries potentially having the most adverse affect on BSE prevention efforts should

non-compliance with the regulations be encountered. In planning and prioritizing inspections, the following firm/industry types should be considered, in order of descending priority:

- Follow-up to 'OAI' inspections
- Firms that have a violative history
- Firms handling prohibited materials (Renderers, Protein Blenders, and Feed Mills)
- Rendering operations
- Protein blenders
- Commercial feed mills (licensed and unlicensed)
- Animal feed distributors/retailers (ruminant feeds involved)
- Pet food/animal feed salvage operations
- On-farm feed mixers (ruminant and non-ruminant animals on farm premises)
- Haulers/transporters of animal feeds (ruminant feeds involved)
- Ruminant feeders (dairy cattle)
- Ruminant feeders (ruminants other than dairy cattle)
- Animal feed distributors/retailers (no ruminant feeds involved)
- Haulers/transporters of animal feeds (no ruminant feeds involved)
- On-farm feed mixers (only ruminant or no ruminant animals on farm premises)

b. Planning Instructions.

Inspection planning should generally be based on the priority of firms as listed above. Information should be collected on whether a firm has been documented as receiving, processing or distributing prohibited material. This information can be obtained directly through the FACTS database, and through the BSE District Coordinator. A listing of these firms can also be found through the CVM Website (http://www.accessdata.fda.gov/BSEInspect/).

c. Program Interactions.

The success of this program to support the prevention of the introduction and amplification of BSE in the United States is dependent on the ability of investigators to identify violative firms and operations. While initial efforts by Federal and State investigators have identified and inspected most renderers and commercial feed mills, continued efforts are needed to identify and continue to inspect all firms subject to the regulation. Mobile feed mills, animal feed salvagers, feed distributors, feed transporters, and ruminant farms are areas that should receive additional attention. When appropriate, add-on BSE inspections should be conducted under this present program whenever the

opportunity presents itself and resources allow through inspections that are conducted under the following programs:

Compliance Programs
7318.003 Milk Safety Program
7371.003 Feed Contaminants Program
7371.004 Feed Manufacturing Compliance Program
7371.006 Illegal Drug Residues in Meat & Poultry Program

Guidance on inspections addressing FDA BSE efforts involving human dietary supplements can be found in the CFSAN-administered, "Dietary Supplements – Import and Domestic" compliance program (Compliance Program 7321.008).

Part III – Inspectional

1. Operations.

a. Definitions.

(1) **Prohibited Material –** Any protein derived from mammalian animals (Examples: meat and bone meal; organs; offal; hair; collagen), with the following exclusions:

- Blood and blood products
- Gelatin
- Inspected meat product which has been cooked and offered for human food, AND which has been further heat processed for animal feed (Examples: restaurant plate waste; cellulosic food casing; surplus from manufacturers or distributors of human food products that are prepared or offered for sale.)
- Milk products (Examples: milk; milk-derived products)
- Any product whose ONLY mammalian protein consists entirely of porcine (pig) or equine (horse) protein.

(2) **Non-Prohibited Material –** For purposes of clarification, the following materials are not prohibited for use in ruminant feed under 21 CFR §589.2000:

- Non-protein ingredients (Examples: fat; amino acids, bone ash; bone phosphate; bone charcoal)
- Non-mammalian sources of protein (Examples: fish, poultry, vegetable)
- Products of mammalian origin that are not intended for use in animal feeds or feed ingredients (Example: bone meal labeled for use as a fertilizer)

These examples are not all inclusive. Any questions concerning whether certain ingredients should be considered as prohibited material should be directed to CVM, Division of Compliance.

(3) **Pet Food** – For the purposes of this guidance, pet food is any feed that is commercially prepared and distributed for consumption by pets. A pet is any domesticated animal normally maintained in or near the household(s) of the owner(s) thereof. Examples include dogs, cats, rats, mice, hamsters, gerbils, rabbits, ferrets, nonhuman primates, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes, and turtles. Horses or other equids are not considered to be pets within this guidance because they are routinely slaughtered for human food.

(4) **Ruminant** - Ruminant includes any member of the order of animals that has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through

which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(5) **Renderer** - Renderer means any firm or individual that processes slaughter byproducts, animals unfit for human consumption or meat scraps. The term includes persons who:

- Collect such materials and subject them only to minimal processing. With respect to rendering practices, "minimal processing" should be considered as the process of applying heat to raw materials for the purpose of removing the moisture and fat from the solid protein portion of animal tissues.
- Collect such materials and distribute them to firms *other than* renderers (as defined here) whose intended use for the products may include animal feed. This definition should be interpreted to include any firm or individual that provides ingredients or raw materials to a pet food manufacturer, regardless of whether the material has been minimally processed.
- Are renderers that also blend animal protein products.

Collectors are generally not subject to the regulation since (1) they do not minimally process their collected animal waste materials; and (2) they distribute their collected animal waste materials only to renderers. However, any collector who additionally distributes collected material directly to a non-rendering firm (e.g., a pet food manufacturer) should also be considered a renderer under 21 CFR §589.2000(a)(2), and, therefore, subject to the full provisions of the regulation.

While pet food manufacturing may involve the application of heat to raw materials, pet food manufacturing operations are not generally considered as rendering, unless the purpose of the process is to produce product that contains a stable protein ingredient. Cooking is not necessarily synonymous with rendering. As such, collectors or firms distributing animal waste materials directly to pet food manufacturers should not seek to avoid the requirements of 21 CFR §589.2000(d) by claiming that the pet food manufacture destination solely consists of rendering operations.

Slaughter facilities do not collect animal waste materials, but rather generate these materials as byproducts of their operations. In contrast, dead stock processing operations (e.g., 4-D plants) are subject to the regulation, since they process animal waste materials or byproducts (e.g. dead animals, animal carcasses), but do not produce them themselves. The rule regulates firms beginning at the level of the renderer. Outgoing materials from inspected slaughter facilities, therefore, **do not require** the caution statement under the regulation, regardless of their destination. However, we recognize that in some instances, both slaughter and rendering

operations may take place on the same premises. In these instances, the regulation will apply to all operations that occur within the recognized rendering facilities.

In general, a slaughterhouse, collector, dealer, hauler or anyone else who supplies a renderer with material to be rendered is not subject to the specific requirements of this regulation. However, the renderer has a responsibility to seek assurance from the supplier of non-prohibited material that the nonmammalian, pure porcine or pure equine materials come from single-species slaughter facilities. Assurance might include a certificate from the supplier, or specification of source in a business contract.

Note: Collectors are generally not subject to the regulation since (1) they do not minimally process their collected animal waste materials; and (2) they distribute their collected animal waste materials only to renderers. Collecting activities might include processes such as skinning, salting, cutting, or trimming. Nevertheless, while collectors may not be subject to the regulation, the responsibility is placed on renderers to ensure that all carcasses and waste products obtained from collectors indeed do not contain any prohibited material. This could include a certification from the supplier, or specification of source in a business contract.

(6) **Feed Manufacturer** - Feed manufacturer includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm, in addition to off-farm, feed manufacturing and mixing operations. The term includes manufacturers of pet food and laboratory animal feed.

(7) **Distributor** - Distributors include persons who distribute or transport feeds or feed ingredients intended for animals. The term includes retailers of feeds and feed products; the distribution activities of blenders and feed manufacturers; and transporters of animal feed and feed ingredients.

(8) **Transporter** – Transportation may occur by roads, rails, water or air. While the regulation covers all transportation activities, inspectional efforts should be preferentially directed to activities in which loose or bulk animal feeds or feed ingredients are handled, since these activities may result in commingling or cross-contamination of feeds **not containing** prohibited materials with feeds **containing** prohibited material.

(9) **Ruminant Feeder** – A ruminant feeder is any establishment or individual that is responsible for feeding ruminant animals. Examples include, but are not limited to: dairies, cattle feedlots, calf and lamb raising operations, and the general feeding of ruminants, such as cattle, buffalo, sheep, goats, deer, elk, and antelopes.

b. Domestic Inspection Approach.

Investigators are encouraged to use their knowledge, training, and experience in assessing compliance with the BSE regulations, as the requirements pertain to a wide variety of firm types. Although inspections will focus on key operational areas such as raw materials, processing methods and equipment, record keeping and labeling, **investigators are cautioned to be alert and pursue any information that might indicate a potential violation of** 21 CFR §589.2000. Investigators are expected to assess current systems of the firm (operational practices and procedures), to ensure they are effective and being followed. The results of inspections conducted under this program should be recorded on the checklist (See Attachment B), and violative observations noted in the FDA form 483, AND fully described in the EIR.

Federal-State Interactions - Districts are strongly encouraged to work with their State counterparts in trying to address any violative situation through a joint State enforcement approach. If a District encounters a violative operation that does not engage in interstate commerce and the State is unable to take action, contact CVM, Division of Compliance for further instructions. Examples of when State involvement should be considered include:

- Obtaining embargoes or stop-sale orders in advance of a seizure;
- Seeking state intervention if their laws or regulations can lead to removal of product from distribution channels in a more expedient manner;
- Obtaining suspension or withdrawal of a State feed manufacturing license;
- When interstate commerce cannot be established.

Conducting a Domestic Inspection:

(1) Does the firm receive and/or process prohibited material?

In obtaining an answer to this question, also ask

- What kind of protein do they receive?
- If they receive mammalian protein, what kind of mammalian protein?

If the answer to question (1) is **NO** or **DON'T KNOW**, proceed to Section (1)(a).
If the answer to question (1) is **YES**, proceed to Section (1)(b).

Note: If this is an initial inspection, be sure to discuss the requirements of the BSE regulation and leave a copy of the regulation and appropriate Small Entities Compliance Guides, which are located on the CVM website.

(a) Does the firm handle prohibited material? – NO or DON'T KNOW

If the answer to (1) Is NO, they do **not** receive and/or process prohibited material, OR they **do not know**, verify the firm's status by means of the following:

i. Inspect the facility, carefully observing the materials in the receiving and storage areas. Pay particular attention to the raw material coming in and any material waiting to be processed.

ii. Do you see any prohibited material? If YES, copy the records showing receipt of this material, including, if available, documentation of inter-state commerce, document for possible enforcement action, and proceed to Section (1)(b).

iii. Review a representative number of the firm's receiving records and/or invoices for the incoming material, going back up to one year or to the last inspection date. Do these records show receipt of prohibited material? If YES, copy the records, begin documenting for possible enforcement action, and proceed to Section (1)(b).

iv. If the firm is a renderer, protein blender, or feed mill, list and document all animal species for which feeds are manufactured by the firm. Does the firm manufacture and/or distribute feed or feed ingredients intended for ruminant animals?

v. Determine what procedures or safeguards, if any, the firm has in place to ensure it does not receive prohibited material. Describe the safeguards or procedures in your report. Examples of safeguards and procedures are as follows:

- Written 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: porcine, equine, poultry, fish, gelatin)
- Analyzes incoming product

(b) Does the firm handle prohibited material? – YES

i. Obtain information about the source of the prohibited material.

Is it from a domestic, single source? Is it from a domestic, mixed source? Is it from a foreign source and if so, from what country or countries?

Note: The firm bears the burden of ensuring the safety of its products. This includes the ability to identify the source of the prohibited material.

ii. Inspect the facility, carefully observing the materials in the receiving and storage areas. Pay particular attention to the raw material coming in and any material waiting to be processed.

iii. List and document all the species for which animals feeds are manufactured by the firm.

iv. The remaining inspection should focus on the three primary aspects of the regulation:

- Label caution statement requirement
- Recordkeeping requirements
- Requirements for avoiding commingling

v. **Label Caution Statement** -

A. Review a representative copy of the label for each INCOMING product (raw materials and finished products) that contains prohibited material. Note whether each label bears the required caution statement, “Do not feed to cattle or other ruminants." In the case of raw or bulk ingredients, labeling may consist of a placard or other labels attached to the invoice or delivery ticket, or manufacturer's invoice that identifies the animal feed or feed ingredient. If the required caution statement is not present, collect copies of all violative labels, document for possible enforcement action, and perform a trace back/trace forward as indicated by the findings. If, through tracing, it is determined that prohibited material was used in the production of ruminant feeds or was fed to ruminants, proceed to document for legal action and as directed under the BSE recall strategy (See Part V – Section 3, “Recalls”).

Note: Since collectors who do **not** minimally process their collected animal waste materials AND who distribute their collected animal waste materials **only** to renderers are not subject to 21 CFR §589.2000, prohibited materials received by renderers from collectors are not expected to bear the caution statement.

Note: All products received at pet food/animal feed salvagers that contain or may contain prohibited material must bear the required caution statement. Only pet food that is intended for retail sale and nonrumimant laboratory animal feed are exempt from this requirement. Pet foods sold as distressed or salvaged items are not considered intended for retail sale as pet foods, and therefore must be labeled with the required caution statement.

B. Review a representative copy of the label for each OUTGOING product that contains prohibited material. Note whether each label bears the required caution statement, “Do not feed to cattle or other ruminants." In the case of raw or bulk ingredients, labeling may consist of a placard or other labels attached to the invoice or delivery ticket, or manufacturer's invoice that identifies the animal feed or feed ingredient. If the required caution statement is not present, document for possible enforcement action, and perform a trace back/trace forward as indicated by the findings. If through tracing, it is determined that prohibited material was used in the production of ruminant feeds or was fed to ruminant animals,

proceed with evidence collection to support legal action and as directed under the BSE recall strategy (See Part V – Section 3, "Recalls").

Is the caution statement displayed in a conspicuous or prominent manner? If the answer is NO, collect evidence for evaluation. Discuss with the firm as to their rationale or intent in displaying the statement in this manner.

Note: Only pet food that is intended for retail sale and nonrumimant laboratory animal feed are exempt from the caution statement requirement. Pet foods sold as distressed or salvaged items are no longer intended for retail sale as pet foods, and therefore must be labeled with the required caution statement. Manufacturers, distributors and retailers of pet food should be evaluated for existing procedures/controls to ensure that the required caution statement is placed on pet foods that are salvaged or distressed.

Product for Export - Prohibited material products destined for export must be labeled that they are intended for export, such as with the statement, "For Export Only." This marking should be clear and conspicuous. The label should be placed on the shipping packages or, if the exported product does not have a shipping package or container, on shipping invoices or other documents accompanying the exported product, as allowed under 21 CFR 1.101(b)(3). Other legal requirements for exported products should also be met. The caution statement is not required on products for export.

Any prohibited material product that was destined for export but is diverted back into domestic commerce for any reason (e.g. salvage, quality), will be subject to all the requirements of the regulation.

vi. **Recordkeeping** -

A. Review a representative number of receipt, processing, and distribution records for **incoming** prohibited material AND **outgoing** processed product containing the prohibited material. Records may include invoices, receiving tickets, receiving logs,

disbursement records, weight tickets, purchase orders, and other business records or documents.

An invoice or other similar document reflecting receipt of purchase, and sale or delivery of the products usually satisfies this requirement by the firm. The documents should be available for inspection and copying. Specifically, you should note whether the documents include:

- Date of receipt or purchase or sale or delivery of the product
- Name and address of the seller
- Name and address of the consignee
- Identification of the product
- Quantity of the product

Note additionally whether ONLY retail sales of prohibited material are involved. You should take into consideration whether recording the name and address of the consignee may not be feasible or practical for firms that are only involved with retail sales.

B. The firm must maintain records sufficient to track the prohibited material through the receipt, processing and distribution of the feed material, and make these records available for inspection and copying per 21 CFR §589.2000(c)(1)(ii), and also required by 21 CFR §589.2000(d)(1) and 21 CFR §589.2000(e)(1)(i). The required records must be kept for a minimum of one year per 21 CFR §589.2000(h)(1). More specifically, all records related to the receipt, processing, and distribution of a single outgoing product should be retained on the premises for not less than one year after the date of the shipment of the product. The records should be legible and kept in a clean and orderly manner.

Note: Pet food that is intended for retail sale and non-ruminant laboratory animal feed is exempt ONLY from the caution statement requirement. All firms manufacturing and/or distributing pet food and non-ruminant laboratory animal feed are subject to ALL recordkeeping requirements described above per 21 CFR §589.2000(c)(1)(ii), as required by 21 CFR §589.2000(d)(1) and 21 CFR §589.2000(e)(1)(i).

C. If the firm fails to meet some or all of the above requirements, document for possible enforcement action.

D. Records of the interstate movement of food and the holding thereof during and after such movement must be made available for inspection and copying under Section 704 of the Act. Should the firm refuse access to or copying of such records, Districts should contact the FDA/Office of Enforcement (**OE**) to determine whether it would be appropriate to obtain an inspection warrant under Section 704. The investigator should first make a verbal request for the records. If this request is refused, recommend to OE/DCMO that an administrative inspection warrant be obtained to gain access to the required records (See Chapter 6, Regulatory Procedures Manual (RPM)) for instructions on recommending inspection warrants).

E. These records are used to determine current compliance with the rule. If there are NO RECORDS, document for possible enforcement action

vii. **Avoiding Commingling** -

A) Determine whether the firm manufactures, processes, blends and distributes **BOTH** products containing prohibited material **AND** products containing only non-prohibited materials. If the answer is **YES**, consider the following:

The firm can only avoid commingling or cross-contamination of ruminant feed with prohibited material by one of two methods, either:

- the use of separate equipment [21 CFR 589.2000(e)(1)(iii)(A)];

or

- the use of the same equipment with adequate clean-out procedures that prevent carry-over of prohibited material into the ruminant feed [21 CFR §589.2000(e)(1)(iii)(B)]

B) Inspect incoming material receipt and storage areas, product processing and finished product storage areas. Describe the separation system and procedures to avoid commingling and cross contamination (dust control, separate equipment and/or buildings,

and other controls on incoming and finished product identification and storage).

C) **For Renderers**, determine whether the firm receives non-prohibited material that consists ONLY of non-mammalian protein, pure pork, or pure-equine materials from single-species slaughter facilities, as is required by 21 CFR §589.2000(e)(1)(ii).

D) **Firms Avoiding Commingling with Separate Equipment** – Firms might use separate equipment or facilities for the intended manufacture, processing, and blending (including storage) of products containing prohibited material **AND** products containing only non-prohibited materials. Separation can consist of entirely separate buildings, rooms or other locations; or separate storage containers for incoming material and finished product, and separate manufacturing lines.

Separate equipment should be clearly identified to ensure that prohibited material is not accidentally added to non-prohibited material production runs.

E) **Firms Avoiding Commingling with Adequate Clean-out Procedures** - If the same equipment is shared for **BOTH** products containing prohibited material **AND** products containing only non-prohibited material, describe the clean-out procedures. Clean-out can consist of physical cleaning (e.g. vacuuming, sweeping, washing), flushing, sequencing, or other means, either alone or in combination with separation measures, that are adequate to prevent carryover of prohibited material into runs that are intended to be free of prohibited material. Clean-out procedures should be used on all equipment and conveyances (e.g. trucks, rail cars) that handle both prohibited material and non-prohibited material.

Flushing with a complete change of operating volume will generally be considered as adequate clean-out. However, other practices used by the firm may also be considered as adequate clean-out. These firms should consider the unique characteristics of their operational equipment in determining alternative clean-out procedures. Any practice ultimately used for cleaning out the system should be based on a documented rationale, analysis, or tests by the firm of the adequacy of the clean-out process. Try to obtain documentation of sequencing practices.

Flushing procedures, in particular, should take into account the type of flush material used, and the time and volume requirements of the flush as is appropriate for the operational equipment. Firms should also have documented procedures describing how the flush materials are subsequently processed, including storage and labeling of the materials, utilization in other feeds, and/or appropriate disposal (e.g., incineration, landfill).

Determine whether the firm maintains written procedures or SOPs specifying all aspects of clean-out and other practices for separating prohibited material from non-prohibited material from the time of receipt until the time of shipment as required in 21 CFR §589.2000(e)(1)(iv) and, if so, try to collect a copy of the SOPs. SOPs or documentation for clean-out should include:

- how the clean-out is implemented;
- who is responsible;
- how the clean-out is monitored, recorded, and verified;
- a description of how flush material is subsequently handled;
- the rationale, analysis or test for determining the adequacy of the clean-out process.

F) If the inspection finds no controls or inadequate controls in place to prevent commingling or cross-contamination between product containing prohibited material and product containing non-prohibited material, document the violation(s) for regulatory action.

(2) **Ruminant Feeders.**

The regulation, 21 CFR §589.2000(f), requires that ruminant feeders:

- Maintain copies of purchase invoices of all feeds containing animal proteins received;
- Maintain labeling for all feeds containing animal protein products received;
- Make all copies available for inspection and copying;
- Maintain these records for a minimum of one year.

The primary intent of 21 CFR §589.2000 is to prevent prohibited material products being fed or recycled back to ruminant animals. However, the above regulatory requirements for ruminant feeders primarily address recordkeeping, and do not directly address some of the feeding and storage practices that occur in ruminant operations. The investigator should be aware of the actual requirements under this regulation. Nevertheless, the investigator should take the opportunity to observe whether on-farm practices are sufficient for ensuring that prohibited material is not fed, intentionally or unintentionally, to ruminant animals. While the regulation may not necessarily address all aspects of the following observational areas, the investigator should nevertheless consider discussing the importance of these areas with the ruminant feeder.

a. Prohibited Material.

The investigator should determine whether any feed containing prohibited material is present on the farm premises. 21 CFR §589.2000(f) states that establishments and individuals are responsible for maintaining copies of purchase invoices and labeling for **all** feeds containing animal protein products received.

Investigators encountering situations where prohibited material has been fed to ruminants should consult with CVM. CVM will consult with the USDA, Food Safety and Inspection Service (**FSIS**) for determining the most appropriate course of regulatory action.

b. Feed Storage.

Feed storage, particularly in operations where both ruminant and non-ruminant species are being fed, should be examined. If ruminant feeds and non-ruminant feeds are stored in the same location, the investigator should note the procedures used for ensuring that ruminant animals are not fed non-ruminant feeds and should take photographs or draw diagrams of feed bins and equipment. In particular, investigators should note whether:

- Feed bins are labeled to identify ruminant and non-ruminant feed. (This is not required by 21 CFR §589.2000 but will help the investigator determine whether ruminants have been fed non-ruminant feed.)
- Bulk feeds for ruminants are separated from non-ruminant feeds for preventing mix-up, commingling and/or cross-contamination (This is not required by 21 CFR §589.2000 but will help the investigator determine whether ruminants have been fed non-ruminant feed.)
- Transportation and feed equipment handling both ruminant and non-ruminant feeds is either separate or adequately cleaned (See Section (2)(c)).

c. On–Farm Mixing.

Special attention should be placed on farm operations that are mixing rations for both ruminant and non-ruminant animals particularly if prohibited materials are contained in any of the feeds or feed ingredients. On-farm mixing operations should be examined in a manner and to an extent similar to that for commercial feed mills. If prohibited materials are involved in on-farm mixing operations, the farm is subject to the manufacturing requirements of commercial feed mills. If prohibited materials are involved, refer to Section (1)(b) of this guidance subpart.

(3) **Investigative notes.**

(a) Records of the interstate movement of food and the holding thereof during and after such movement must be made available for inspection and copying under Sections 703 and/or 704 of the Act. Should the firm refuse access to or copying of such records, Districts should contact the FDA/Office of Enforcement (**OE**) to determine whether it would be appropriate to obtain an inspection warrant under Section 704. If, however, FDA relies on Section 703 to inspect the records, the agency may not use the records or any evidence derived from the records in a criminal prosecution of the person from whom the records were obtained. The investigator should first make a verbal request for the records. If this request is refused, recommend to OE that an administrative inspection warrant be obtained to gain access to the required records (See Chapter 6, Regulatory Procedures Manual (RPM)) for instructions on recommending inspection warrants).

(b) Any violation of the requirements of 21 CFR §589.2000 should be listed on the FDA-483 and fully documented. Collect documentary (DOC) samples to support possible regulatory action. (See IOM, Chapter 4 for instructions on collecting DOC samples.)

(c) All violations of 21 CFR §589.2000 should be considered as potentially serious. However, in consideration of the wide variety of violative situations possible, the investigator should use the attached prioritized listing of possible situations (See Part V, Section 2c – Prioritized Inspectional Violative Situations). The investigator should note the observations and collect documentary samples required for each situation.

(d) Certain violative situations may later require feed analysis to determine whether the suspect feed or feed ingredient may contain prohibited material. In anticipation of case development, the investigator should consider obtaining feed samples for analysis (See Part IV – Analytical).

(4) Reporting.

(a) Checklist - Report of Inspection For Compliance With 21 CFR §589.2000.

The checklist entitled, "Report of Inspection For Compliance With 21 CFR §589.2000 (See Attachment B)," should be completed for all inspections or investigations conducted under this Compliance Program.

The most recent version of the checklist is available at the CVM Website (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052412.pdf). Periodically reference this Website to ensure that you are using the most current version. The checklist is accompanied by instructions. The difficulties in using a simple checklist to adequately describe the operations of a large variety of firm types necessitate that the instructions be understood. All investigators should be provided with a copy of the checklist that includes these instructions.

The primary purpose of the checklist is to provide general guidance to investigators to assess firm operations and to facilitate quality assurance in the administration of this Compliance Program. While all deviations from the Ruminant Feed Ban regulation should be clearly noted on the checklist, investigators should not depend solely on the checklist to determine compliance status. Ascertaining the initial classification of compliance status will depend primarily on the experience of the investigator and familiarity with this Compliance Program, with subsequent supervisory and compliance review.

Districts are responsible for archiving all inspectional documents and for entering information into FACTS. No materials should be sent to CVM, unless otherwise requested. All completed checklists, along with endorsed EIRs or memos of investigation, and FDA-483 forms should be sent by States to the FDA District BSE Monitor and not to CVM. The BSE District Monitors, or their designees, will be responsible for checking the State checklists and inspectional information for completeness and accuracy. Timeliness of entry into FACTS should take into consideration the type of violations that were noted during the inspections. In general, inspections and checklists for violative firms should be entered into FACTS within ten (10) days after receipt.

Checklists for FDA-conducted inspections should be entered into FACTS by the lead investigator. Checklists for State-conducted inspections should be entered into FACTS by District personnel having the appropriate FACTS BSE entry role. The anticipated development of the new e-SAF system (electronic State access to

FACTS) should provide States with the capability of direct checklist input into the FACTS system.

The full and accurate completion of the checklist is essential to successfully maintain this compliance program. Entry of the checklist information allows for further analysis of inspectional findings on a nationwide basis. In addition to identifying firms requiring additional enforcement action, the database allows for trend analysis of certain segments of the industry and of compliance with certain aspects of the Ruminant Feed Rule. No inspections or investigations conducted under this program can have an administrative status of 'completed' unless an accompanying checklist has been entered into the FACTS system. Similarly, based on database design requirements, incomplete checklists cannot be entered into the FACTS module.

The checklists and other information submitted under this program are used solely within the confines of this Compliance Program. Information that pertains to other Compliance Programs or FDA activities generally will not be forwarded to those respective programs. Information should not be submitted that is intended for review under other compliance programs. Copies should be made of all necessary documents for simultaneous submission to those other programs, as required.

(b) Other Reporting Requirements.

Be sure to report time spent on the inspection under the PAC Code for BSE inspections. Note that the FACTS BSE module will not be available unless a BSE PAC code has been identified on the FACTS inspectional coversheet. If the inspection covers multiple programs, report time spent on this part of the inspection separately. Individual FDA District Offices and States may have additional reporting requirements. Any questions or problems that arise concerning inspections, reporting, or enforcement issues should be directed to the contacts listed in this program (See Part VI – Section 1, "Program Contacts").

c. Import Approach.

(1) **BSE affected and BSE-at-risk countries**

Import Alert #99-25 ("Detention Without Physical Examination of Animal Feed, Animal Feed Ingredients and Other Products for Animal Use Consisting or Containing Ingredients of Animal Origin") describes FDA's import enforcement efforts to detain products that appear to violate 21 CFR § 589.2000 and to support the USDA/APHIS prohibition of the importation of animal feed products that present a risk of BSE. (See 9 CFR §94.18 and 9 CFR §95.4). The import alert covers all meat and bone meal (MBM), meat meal, bonemeal, blood meal, tankage, offal, or any product containing such from countries in which BSE exists or from designated BSE-at risk countries or that was rendered/processed in BSE at-risk countries' plants processing animal materials, regardless of species of origin, including poultry and fish meal. In implementing the Import Alert, import entry reviewers should consider the following:

- The Import Alert addresses all sources of animal protein, including non-ruminant, fish, poultry, and all non-mammalian sources without regard to the prohibited material exemptions provided in 21 CFR §589.200(a)(1). The USDA/APHIS Import Permit process is the primary means of assuring that animal byproduct meals imported from BSE-at-risk countries into the U.S. are free of ruminant protein sources.

- Unprocessed non-ruminant products that are in a form that can be plainly ascertained through direct observation to be free of ruminant material (e.g., frozen whole fish, dried pig ears) should not be considered "Detained Without Physical Examination" (DWPE), as directed by the Import Alert. Import entry reviewers, however, should be vigilant to attempts to intentionally smuggle ruminant-source products into shipments of unprocessed non-ruminant material.

- All product codes addressed by the Import Alert should be reviewed, including pet foods, amino acids, and the various dietary supplements. Ingredient listing should be examined, whenever available.

- All incidents involving the entry of products addressed by the Import Alert should be considered as serious and warranting assessment under the BSE Recall Strategy (See Part V – Section 3, "Recalls").

(2) **Non-BSE at-risk countries**

Countries, other than those listed in Import Alert #99-25, are not subject to the import prohibition. Nonetheless, import entry reviewers should ensure that all animal feed and feed ingredients that contain or may contain prohibited material are in compliance with the label caution statement requirements of the 21 CFR §589.2000 (See Part III – Section 1b(1)(b)v, "Label Caution Statement"). Regardless, feed and feed ingredient labeling should be in compliance with FDA labeling requirements. Import entry reviewers should especially ensure that ingredient listings meet U.S. requirements and sufficiently allow reviewers to ascertain whether the product contains or may contain prohibited material. Reviewers especially need to be vigilant for transshipments of products that may have originated in the BSE-at-risk countries and countries with BSE listed in the Import Alert.

Part IV – Analytical

1. Analysis to be Conducted.

a. Samples should be analyzed for the presence of animal tissue using the feed microscopy procedure outlined in "Modified AOAC Official Method 964.07, Microscopy of Animal Feed, Basic Microscopic Examination" (Attachment C), and "Modified AOAC Official Method 970.09, Microscopy of Animal Feed, Identification of Mammalian Tissues and Mineral Constituents" (Attachment D), with the following modifications:

1) It is not necessary to determine the weight of animal tissue fragments found

2) Filters may be wet with glycerin/alcohol to prevent loss of dry material in airflow

3) No action should be taken based on normal filth items such as rodent hair or excreta. Identification of ruminant hair would warrant Lab Classification 2, so hair identification is desirable. The presence of hair or excreta from rodents, cats, dogs, humans, and other species would not be considered for classification of the sample.

4) Analysis should be based on a composite of the subs in each sample. **Note:** Samples collected according to the sampling instructions above should already be composited when received by the lab.

5) Violative or potentially violative findings should be confirmed by a second analyst. Check analysis (i.e., analysis of a new portion of composite) is not required.

2. Sample Size

a. If the product is in bulk, collect sixteen (16) one-ounce subs from various locations in the shipment. The sample subs should be combined in one whirl-pak bag.

b. If the product is in discrete retail packages (i.e., may be as large as 50 lb. bags), collect one (1) one-ounce sub from each of sixteen (16) retail packages. Combine the subs in one whirl-pak bag.

CAUTION: This material may be dusty and consist of fine particles, especially if the product is in bulk. Exercise appropriate precautions when collecting samples of dusty, loose material**.** Refer to "Safety Information for Imported Feeds Assignment - Collection and Analysis" (Attachment E).

3. Sample Preparation and Submission

a. These samples should not require any special temperature conditions or shipping containers. Room temperature and packing in regular cardboard containers should be sufficient.

b. Samples collected in the following Districts should be submitted to the indicated labs for analysis:

SERVICING LABORATORIES:

Northeast Regional Laboratory (NRL)
New England District (NWE), New York District (NYK), New Jersey District (NWJ) and Philadelphia District (PHI)

Southeast Regional Laboratory (SRL)
Atlanta District (ATL), Baltimore District (BLT), Cincinnati District (CIN), Florida District (FLA), New Orleans District (NOL), and San Juan District (SJN)

Arkansas Regional Laboratory (ARL)
Chicago District (CHI), Detroit District (DET), Minneapolis District (MIN), and Southwest Import District (SWID)

Denver District Laboratory (DEN-LB)
Dallas District (DAL), Denver District (DEN), and Kansas City District (KAN)

Pacific Regional Laboratory – Southwest (PRL-SW)
Los Angeles District (LOS), and San Francisco District (SAN)

Pacific Regional Laboratory – Northwest (PRL-NW)
Seattle District (SEA)

Part V - Regulatory/Administrative Strategy

1. Enforcement -

Although much of the industry has complied with the regulations as a result of education and voluntary compliance, inspections still occasionally reveal that some firms are not in compliance with 21 CFR §589.2000. Districts should prioritize their resources for dealing with these non-compliant firms before initiating routine inspections. Since analytical methods currently available do not quantify the level of prohibited material in animal feed, inspectional observations, admissions, photographs, and record review are the primary tools for documenting violations. Whenever potentially violative conditions are found, evidence should be collected to support enforcement action.

There may be situations in which a firm or individual is new to the industry and does not know of the dangers/hazards of BSE or of FDA's expectations for compliance with the regulation. In these situations, the agency believes the individual or firm should have known the dangers or hazards and our expectations, or they should not be in the business of handling or manufacturing animal feed or feed ingredients. If such a situation is encountered, or if a previously compliant firm is subsequently found to be out of compliance, Districts might consider issuing a Warning Letter or initiating other enforcement actions (See Section 2d, "Provisions for Enforcement Action"). All Warning Letters proposals will be reviewed by the centers. Firms that receive Warning Letters should be re-inspected within 90 days to verify that corrections have been fully implemented. District offices should review current instructions regarding the review and processing of warning letters prior to issuance.

Follow FDA's regulations and procedures prior to sharing non-public information with the public, or federal, state, local, and foreign government officials.

NOTE: Warning Letters should be considered for situations that involve violations that are classified as "Official Action Indicated," or OAI. See Section 2c, "Prioritized Inspectional Violative Situations" for determining the appropriateness of a Warning Letter. See Section 2d, "Provisions for Enforcement Action" for the level of documentation that would be required for other types of enforcement actions.

2. Charges and Enforcement Approach-

a. **Adulteration** - Sections 402(a)(2)(C) and 402(a)(4)

It is easier to bring an adulteration case under the legal standard of Section 402(a)(2)(C) of the Act than under Section 402(a)(4) of the Act because in the food additive context the ingredient is legally presumed to be unsafe. Consequently, the investigator's priority should be on establishing a violation of Section 402(a)(2)(C).

(1) Animal proteins prohibited from use in ruminant feeds are unapproved food additives as defined in section 201(s) of the Act. Therefore, the presence of such material(s) in ruminant feed causes the feed to be adulterated under Section 402(a)(2)(C) of the Act. This charge may be supported by evidence showing that prohibited material is being used frequently or regularly as an ingredient in ruminant feed or feed supplements, or that clean out and sequencing procedures are so inadequate that it is highly likely that the feeds will contain prohibited material. In order to support this charge, documentary evidence should be available to establish that the suspect ruminant feed or ingredient contains or likely contains prohibited material.

(2) Animal feeds and feed ingredients containing prohibited material are considered potentially injurious to ruminant and public health. Therefore the use of such material(s) in ruminant feed causes the feed to be adulterated under section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (Act). In order to support this charge, documentary evidence should be available to establish that the suspect ruminant feed or ingredient contains or may contain prohibited material. Investigators should collect supporting records documenting the labeling of the prohibited material(s) and finished product, receipt and use of the prohibited material in the production of the sampled product, and affidavits from responsible individual(s).

b. **Misbranding** -

(1) Animal feeds and feed ingredients that contain prohibited material but fail to bear the required caution statement are misbranded under section 403(a)(1) of the Act, in that the label is false and misleading because it failed to disclose a material fact, (See 201(n)).

(2) Animal feeds and feed ingredients that contain prohibited material but fail to bear the required caution statement in a conspicuous or prominent manner are misbranded under section 403(f) of the Act.

c. Prioritized Inspectional Violative Situations:

- OAI - Evidence that **prohibited material** is being used as an ingredient in **ruminant** feed or feed supplements. [**NOTE**: Addition of the caution statement at the time of inspection will not rectify this violation. The violation should be noted, regardless of any immediate corrective actions.]

- OAI - Failure to have any or having only **grossly inadequate** systems/measures in place to **prevent commingling** and cross-contamination when firm handles prohibited material and produces **both ruminant and non-ruminant** feed.

- OAI - Firm has but **fails to follow its written** systems/measures to **prevent commingling** and cross-contamination when firm handles prohibited material and produces **both ruminant and non-ruminant** feed.

- OAI - **Failure** to perform any **clean-out**, flush, and/or follow a sequencing plan to prevent commingling and cross-contamination when firm handles prohibited material and produces **both ruminant and non-ruminant** feed.

- OAI - The **clean-out**, flushing, and/or sequencing plan firm uses to prevent commingling and cross-contamination is **not adequate**; firm handles prohibited material and produces **both ruminant and non-ruminant** feed.

- OAI - The **clean-out**, flushing, and/or sequencing plan firm uses to prevent commingling and cross-contamination is **not performed on an appropriate, routine basis**; firm handles prohibited material and produces **both ruminant and non-ruminant feed**.

- OAI – **Renderer intentionally separates** mammalian and nonmammalian materials and **fails** to obtain and use non-mammalian [e.g., fish or poultry], or pure pork, or pure equine material from a single species slaughter facility.

- OAI - Evidence that **prohibited material** is being used frequently or regularly as a component of a feed ingredient or as an ingredient in **non-ruminant** feed with **no caution statement.**

- VAI - Firm has systems/measures in place to **prevent commingling** and cross-contamination **but does not have those measures in writing**, when firm handles prohibited material and produces **both ruminant and non-ruminant** feed [i.e., firm has plan but it is not in writing].

- VAI - **Failure to maintain records** to track prohibited material throughout its

receipt, processing, and distribution.

- VAI - **Incomplete records** to track prohibited material throughout its receipt, processing, and distribution.

- VAI - **Distribution records lack name and address of for each purchaser** of product containing prohibited material [especially noted with cash sales].

- VAI –Animal feed ingredients or non-ruminant feeds contain prohibited material but **fail** to bear the required **caution statement** in a **conspicuous or prominent manner.**

d. Provisions for Enforcement Action:

When conducting an inspection to determine compliance with 21 CFR §589.2000, be prepared to document significant violations for possible enforcement action. The basis of the regulation is that certain mammalian proteins, specifically prohibited materials, are unsafe food additives in ruminant feed. Inspectional efforts and documentation should be focused on demonstrating the actual or likely inclusion of those unsafe food additives in ruminant feed and/or the failure to properly label feeds containing this material.

If the violative feeds are still available, discuss the firm's intentions to rectify the situation. If the firm does not plan on destruction and/or a recall, consider the possibility of a seizure, injunction and State actions, such as embargo or stop sale. Seizures should be limited to situations where there is clear documentation that ruminant feed has likely been contaminated with prohibited material. Injunction should be considered in situations where there is evidence that the firm has not corrected its violative practices, or there is reason to believe that it will not correct its violative practices.

The following information will be important in supporting and demonstrating the conclusion that prohibited material is or is likely to be present in products manufactured, processed, or distributed by the firm or individual being inspected. Make every attempt to obtain or determine the following:

- Volume of product produced
- Frequency of production
- Describe the records kept to show product/ingredient use
- Number of employees involved with the mixing operation
- Describe the records that show how the product was mixed
- Describe the type and level of supervision of the employees during mixing
- Describe the handling of prohibited material [how it is identified, how it is stored]
- Is the firm aware of the rule?
- Does the firm understand the rule?
- Describe the training employees receive at the firm
- Describe the equipment, especially the complexity of operating and/or cleaning, including equipment design flaws
- If the firm uses flushing for clean-out, describe the flush material, the volume, how the firm validates the amount and type of flush material, and how and when do they check the completion and adequacy of the flush
- Describe how flush material is subsequently utilized or disposed of

Violations of 21 CFR § 589.2000 may result in adulteration charges under Sections 402(a)(2)(C) and 402(a)(4) of the Act and misbranding charges under Section 403(a)(1) of the Act. For adulteration charges, it is easier to bring a case under the legal standard of Section 402(a)(2)(C) of the Act than under the standard of Section 402(a)(4) of the Act because in the food additive context the ingredient is legally presumed to be unsafe. Therefore, the investigator's priority should be on establishing a violation of Section 402(a)(2)(C) alone or in combination with a violation of Section 403(a)(1).

(1) When Ruminant Feed is Involved

The investigator may establish the following violations alone or in combination:

(a) **Adulteration under 402(a)(2)(C)**:

The highest priority for an enforcement action would be those firms/individuals that are producing feed for ruminant animals containing prohibited material either in a facility producing only ruminant feed, or in a facility producing ruminant and non-ruminant feed with inadequate controls in place.

The presence of the prohibited material in the ruminant feed needs to be demonstrated and supported through direct observation by the investigator, admissions by firm's employees and managers, and/or records of receipt and use of the material and inadequate handling at the production facility. The following inspectional observations could be used to support this enforcement action:

I. Evidence that prohibited material is being used frequently or regularly as an ingredient in ruminant feed or feed supplements. Note how often this occurs. This evidence can be developed through **(a)** observations of the investigator; **(b)** admissions by firm's management/employees; and/or **(c)** records of ingredient receipt and use in feed. Records can include documents such as invoices, receiving tickets, weight tickets, purchase orders, batch production records, and mixing records.

   In addition, analytical reports from feed microscopy demonstrating the presence of mammalian tissue can be added information for support of the presence of prohibited material. [**CAUTION**: Since the analytical reports are supportive, the analytical reports should be accompanied by other supporting information that demonstrate the presence of prohibited material in order to support a 402(a)(2)(C) violation.]

(b) **Adulteration under 402(a)(4)**:

If the facility is producing both ruminant and non-ruminant feed, the following inspectional observations could be used to support this enforcement action

I. Failure to have any or having only grossly inadequate systems/measures in place to prevent commingling and cross-contamination when firm handles prohibited material and produces both ruminant and non-ruminant feed. This evidence can be developed through the same techniques noted in **402(a)(2)(C)**.

OR

I. Firm has but fails to follow its written systems/measures to prevent commingling and cross-contamination when firm handles prohibited material and produces both ruminant and non-ruminant feed. This evidence can be developed through the same techniques noted in **402(a)(2)(C)**.

OR

I. Failure to perform any clean-out, flush, and/or follow a sequencing plan to prevent commingling and cross-contamination when firm handles prohibited material and produces both ruminant and non-ruminant feed. This evidence can be developed through the same techniques noted in **402(a)(2)(C)**.

OR

I. The clean-out, flushing, and/or sequencing plan firm uses to prevent commingling and cross-contamination is not adequate and the firm handles prohibited material and produces both ruminant and non-ruminant feed. This evidence can be developed through the same techniques noted in **402(a)(2)(C)**.

OR

I. The clean-out, flushing, and/or sequencing firm uses to prevent commingling and cross-contamination is not performed on an appropriate, routine basis and the firm handles prohibited material and produces both ruminant and non-ruminant feed. This evidence can be developed through the same techniques noted in **402(a)(2)(C)**.

SUPPORTING

In addition, the following observations may be used to supplement the 402(a)(4) observations described in any of the observations above:

II. Failure to maintain records to track prohibited material throughout its receipt, processing, and distribution.

OR

II. Firm has systems/measures in place to prevent commingling and cross-contamination but does not have those measures in writing, when firm handles prohibited material and produces both ruminant and non-ruminant feed [i.e., firm has plan but it is not in writing].

OR

II. Incomplete records to track prohibited material throughout its receipt, processing, and distribution.

(c) **Misbranding Under 403(a)(1)**:

Another high priority for consideration for an enforcement action are those firms/individuals producing **feed ingredients** containing prohibited material that are likely to be incorporated into ruminant feed and the label fails to bear the required caution statement "Do Not Feed to Cattle or Other Ruminants."

The presence of the prohibited material in the feed ingredient needs to be demonstrated and supported through direct observation by the investigator, admissions by firm's employees and managers, and/or records of receipt and use of the material and inadequate handling at the production facility. **Additionally, you will need to establish the likelihood that the feed ingredient will be used in ruminant feed.** That could be established through label claims or reviewing the firm's customer base. The following inspectional observations could be used to support this enforcement action:

I. Labeling lacks the required caution statement "Do Not Feed To Cattle or Other Ruminants."

AND

II. Evidence that prohibited material is being used frequently or regularly as a component of the feed ingredient. This evidence can be developed through **(a)** observations of the investigator; **(b)** admissions by firm's management/employees; and/or **(c)** records of ingredient receipt and use in feed. Records can include documents such as invoices, receiving tickets, weight tickets, purchase orders, batch production records, and mixing records.

In addition, analytical reports from feed microscopy demonstrating the presence of mammalian tissue can be added information for support of the presence of prohibited material. [**CAUTION**: Since the analytical reports are supportive, the analytical reports should be accompanied by other supporting information that demonstrates the presence of prohibited material in order to support a 402(a)(2)(C) violation.]

(2) When Non-Ruminant Feed is Involved

(a) **403(a)(1) Case:**

Non-ruminant feed and feed ingredients may legally contain "prohibited material," but the products must bear the caution statement "Do Not Feed to Cattle or Other Ruminants."

The presence of the prohibited material in the non-ruminant feed or feed ingredient needs to be demonstrated and supported through direct observation by the investigator, admissions by firm's employees and managers, and/or records of receipt and use of the material and inadequate handling at the production facility. You are likely to find this kind of misbranding violation at a facility that is producing both ruminant and non-ruminant feed. Additionally assess whether the ruminant feed or feed ingredients are violative. See Section (1), When Ruminant Feed is Involved for inspectional observations that could be used to support the non-ruminant feed and feed ingredient misbranding enforcement action.

3. Recalls -

- When violations are encountered investigators should determine the firm's intentions concerning the recall of any and all adulterated and/or misbranded products that have entered commercial distribution.

- Give the firm an opportunity to voluntarily recall all violative feeds and feed ingredients, and dispose of the products appropriately.

- If the firm voluntarily recalls, follow the standard procedures in Chapter 7, Regulatory Procedures Manual.

- If the firm refuses to voluntarily recall, or the recall is ineffective, request State assistance with State actions such as embargo or stop sales and initiate an FDA-requested recall, with FDA press release.

- Coordinate any recall activity with State counterparts, including the possible sharing of recall audit check responsibilities.

- Make sure all States and Districts that are affected, or are potentially affected, are notified of the recall.

- The following information is intended to be used to accommodate three "generic" scenarios which to date have represented the majority of situations that FDA has confronted when dealing with the use, distribution and labeling of animal feed products containing prohibited materials. The purpose of this information is to provide guidance to assure similar recall situations will be handled in a consistent manner, and to reduce the burden on FDA of having to re-evaluate situations that present the same variables. This document is not intended to cover all situations – and any new or novel scenarios will require review and evaluation by CVM.

  Note: Due to the potential seriousness of these scenarios, they should be managed as Class I recalls requiring adequate press to alert consumers of the risks associated with these products.

Scenario # 1. Product contains Prohibited Material from a domestic or imported source.

U.S. manufacturer of animal feed received prohibited material from either a domestic or imported source, which is then used as an ingredient in the manufacture of non-ruminant feed (i.e., equine, fish, swine, poultry, etc.). The non-ruminant feed is not properly labeled with the required warning statement, "Do not feed to cattle or other ruminants".

(1) **Classification**: Class II

(2) **Reason**: The products are misbranded in that they contain prohibited materials and are not properly labeled in accordance with 21 CFR §589.2000 (See Attachment A).

(3) **Action**:

- **Production/Distribution**: Request immediate labeling of all "in stock" product awaiting shipment with the warning label, "Do not feed to cattle or other ruminants"

- **Publicity**: Press should be issued immediately by the responsible firm and/or FDA in accordance with established policy for Class I recalls. Publication in the FDA Enforcement Report once the recall action has been classified.

- **Recall:** pursue voluntary recall by the responsible firm to the retail level. Field correction by placement of adequately sized, prominently printed sticker that includes the required warning statement may be acceptable; however, return of product to the responsible firm for such relabeling activities would be preferable.

  - Depth: Retail level
  - Notification: 100%
  - Effectiveness Checks: Level A, 100% verification of consignee notification and appropriate response
  - Audit Checks: Level B modified (25%) to wholesale/distributor level. Level B (25%) at retail level
  - Inspection: Initiate establishment inspection to identify products being produced, their intended uses, and assure that product is appropriately labeled.
  - State involvement: Advise State counterparts of the situation and enlist their assistance in monitoring.
  - Animal Control: N/A. No animals involved.
  - Disposition of recalled/held product: Witness any reconditioning of product on hand.

Scenario #2. Prohibited material from domestic or from an imported source is used as an ingredient in feed, or as feed to ruminants.

U.S. manufacturer of non-ruminant animal feeds uses prohibited material from a domestic source, or from an imported source, and that feed is fed to ruminants either as a supplement (i.e., dairy cow supplement), by mistake, or unknowingly due to inadequate flushing/cleaning of equipment.

(1) **Classification**: Class II

(2) **Reason**: The ruminant feed or feed ingredient contains prohibited material, with or without a caution statement.

(3) **Action**:

- **Production/Distribution**: Pending results of the investigation.

- **Publicity**: Press should be issued immediately by the responsible firm and/or FDA in accordance with established policy for Class I recalls. Publication in the FDA Enforcement Report once the recall action has been classified.

- **Recall**: Pursue voluntary recall to the retail level by the responsible firm, or seek FDA requested recall.

  - Depth: Retail level
  - Notification: 100%
  - Effectiveness Checks: Level A, 100% verification of notification and appropriate response
  - Audit Checks: Level B (25%) to direct consignees (distributors/retailers). Level B (25%) to retail accounts of audited distributors
  - Inspection: GMP inspection is indicated to review production controls, scope of possible adulteration, extent of time such practices have been ongoing, and to obtain necessary recall information
  - State Involvement: Advise State counterparts of the situation and enlist their assistance in monitoring.
  - Animal Control: Assess control over the disposition of ruminant animals fed the prohibited protein so as to prevent their slaughter for human food or other animal feed. Coordination with States and USDA/FSIS should be considered. Consult with CVM regarding coordination and regulatory approach of animal disposition.
  - Disposition of recalled /held product: Oversee appropriate disposition of feed and status of animals that have been fed the feed. Determine if relabeling feed with the warning label is an option

4. Refusals -

Records of the interstate movement of food and the holding thereof during and after such movement must be made available for inspection and copying under Sections 703 and/or 704 of the Act. Should the firm refuse access to or copying of such records, Districts should contact the FDA/Office of Enforcement (**OE**) to determine whether it would be appropriate to obtain an inspection warrant under Section 704. If, however, FDA relies on under Section 703 to inspect the records, the agency may not use the records or any evidence derived from the records in a criminal prosecution of the person from whom the records were obtained. The investigator should first make a verbal request for the records. If this request is refused, recommend to OE that an administrative inspection warrant be obtained to gain access to the required records (See Chapter 6, Regulatory Procedures Manual (RPM)) for instructions on recommending inspection warrants).

Part VI - References, Attachments, and Program Contacts

1. Program Contacts

a. Center for Veterinary Medicine (CVM)

(1) Program Inquiries

Shannon Jordre shannon.jordre@fda.hhs.gov (240) 276-9229
Program Monitor
Office of Surveillance and Compliance, Division of Compliance, HFV-232

Eric Nelson eric.nelson@fda.hhs.gov (240) 276-9201
Division Director
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b. Office of Regulatory Affairs (ORA)

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1. Attachments

a. **Attachment A:** 21 CFR §589.2000, Animal proteins prohibited in ruminant feed
b. **Attachment B:** Checklist – Report of Inspection for Compliance with 21 CFR §589.2000
c. **Attachment C:** Modified AOAC Official Method 964.07, Microscopy of Animal Feed, Basic Microscopic Examination
d. **Attachment D:** Modified AOAC Official Method 970.09, Microscopy of Animal Feed, Identification of Mammalian Tissues and Mineral Constituents
e. **Attachment E:** Safety Guidance for Imported Feeds Assignment – Collection and Analysis
f. **Attachment F:** Import Alert #99-25
g. **Attachment G**: 9 CFR §94.18, USDA Restrictions on the Importation of Meat and Edible Products from Ruminants
h. **Attachment H:** 9 CFR §95.4, USDA Restrictions on the Importation of Processed Animal Protein and Other Animal Products
i. **Attachment I:** 21 CFR §7.40, Recall Policy

2. Applicable References or Aids

1. Inspection Operations Manual (IOM):
   a. Chapter 3 - Federal and State Cooperation
   b. Chapter 4 - Sampling
   c. Chapter 5 - Establishment Inspection
   d. Chapter 6 - Imports

2. FDA/ORA Regulatory Procedures Manual
   a. Chapter 6 – Judicial Actions
   b. Chapter 7 – Recall and Emergency Procedures

3. 21 CFR §589.2000 - Animal proteins prohibited in ruminant feed

4. AOAC Official Methods of Analysis

5. Compliance Programs
   a. 7318.003 Milk Safety Program
   b. 7371.003 Feed Contaminants Program
   c. 7371.004 Feed Manufacturing Compliance Program
   d. 7371.006 Illegal Drug Residues in Meat & Poultry Program

6. Small Entities Guidance Documents
   a. Guidance for Industry 67: Small Entities Compliance Guide for Renderers
   b. Guidance for Industry 68: Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors
   c. Guidance for Industry 69: Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations
   d. Guidance for Industry 70: Small Entities Compliance Guide for Feeders of Ruminant Animals without On-Farm Feed Mixing Operations
   e. Guidance for Industry 76 Questions and Answers BSE Feed Regulations
   f. Guidance for Industry 158 Use of Material from Deer and Elk in Animal Feed
   g. CVM GFI 195 Small Entities Compliance Guide For Renderers—Substances Prohibited From Use In Animal Food Or Feed

Attachment A

21 CFR §589.2000

Animal proteins prohibited in ruminant feed

[Code of Federal Regulations]
[Title 21, Volume 6]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE**:** 21CFR589**.**2000]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 589--SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED--Table of Contents

SUBPART B—LISTING OF SPECIFIC SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Sec. 589.2000 Animal proteins prohibited in ruminant feed.

(a) Definitions—

(1) Protein derived from mammalian tissues means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

(2) Renderer means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

(3) Blender means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.

(4) Feed manufacturer includes manufacturers of complete and intermediate feeds

intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.

(5) Nonmammalian protein includes proteins from nonmammalian animals.

(6) Distributor includes persons who distribute or transport feeds or feed ingredients intended for animals.

(7) Ruminant includes any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(b) Food additive status. The Food and Drug Administration has determined that protein derived from mammalian tissues for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of an effective notice of claimed investigational exemption for a food additive under Sec. 570.17 of this chapter.

(c) Requirements for renderers that are not included in paragraph (e) of this section.

(1) Renderers that manufacture products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed shall take the following measures to ensure that materials identified in paragraph (b) of this section are not used in the feed of ruminants:

(i) Label the materials as follows: “Do not feed to cattle or other ruminants”; and

(ii) Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the copies available for inspection and copying by the Food and Drug Administration.

(2) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section if they:

(i) Use exclusively a manufacturing method that has been validated by the Food and Drug Administration to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) and whose design has been made available to the public;

(ii) Use routinely a test method that has been validated by the Food and Drug Administration to detect the presence of the agent that causes TSE's and whose design has been made available to the public. Renderers whose products test positive for agents that cause TSE's must comply with paragraphs (c)(1)(i) and (c)(1)(ii) of this section. Records of the test results shall be made available for inspection by the Food and Drug Administration; or

(iii) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by the Food and Drug

Administration.

(3) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraph (c)(1)(ii) of this section if they use a permanent method, approved by FDA, to make a mark indicating that the product contains or may contain protein derived from mammalian tissue. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the Food and Drug Administration and whose design has been made available to the public.

(d) Requirements for protein blenders, feed manufacturers, and distributors that are not included in paragraph (e) of this section.

(1) Protein blenders, feed manufacturers, and distributors that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissues shall comply with paragraph (c)(1) of this section.

(2) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraphs (d)(1) of this section if they:

(i) Purchase animal products from renderers that certified compliance with paragraph (c)(2) of this section or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(2) of this section; or

(ii) Comply with the requirements of paragraph (c)(2) of this section where appropriate.

(3) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraph (c)(1)(ii) of this section if they:

A. Purchase animal protein products that are marked in accordance with paragraph (c)(3) of this section or purchase such materials from renderers that certified compliance with paragraph (c)(3) of this section, or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(3) of this section; or

B. Comply with the requirements of paragraph (c)(3) of this section where appropriate.

(4) Pet food products that are sold or are intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feeds for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in accordance with paragraph (c) or (d) of this section, as appropriate.

(5) Copies of certifications as described in paragraphs (d)(2) and (d)(3) of this section, shall be made available for inspection and copying by the Food and Drug Administration.

(e) Requirements for persons that intend to separate mammalian and nonmammalian materials.

(1) Renderers, protein blenders, feed manufacturers, distributors, and others that manufacture, process, blend and distribute both products that contain or may contain protein derived from mammalian tissues or feeds containing such products, and protein products from other animal tissues or feeds containing such products, and that intend to keep those products separate shall:
   (i) Comply with paragraphs (c)(1) or (d)(1) of this section as appropriate except that the labeling requirement shall apply only to products that contain or may contain protein derived from mammalian tissues or feeds containing such products;
   (ii) In the case of a renderer, obtain nonmammalian or pure porcine or pure equine materials only from single-species slaughter facilities;
   (iii) Provide for measures to avoid commingling or cross-contamination;
      (A) Maintain separate equipment or facilities for the manufacture, processing, or blending of such materials; or
      (B) Use clean-out procedures or other means adequate to prevent carry-over of products that contain or may contain protein derived from mammalian tissues into animal protein or feeds that may be used for ruminants; and
   (iv) Maintain written procedures specifying the clean-out procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment.

(2) Renderers, blenders, feed manufacturers, and distributors will be exempted from applicable requirements of paragraph (e)(1) of this section, if they meet the criteria for exemption under paragraphs (c)(2) or (c)(3) of this section, and (d)(2) or (d)(3) of this section.

(f) Requirements for establishments and individuals that are responsible for feeding ruminant animals. Establishments and individuals that are responsible for feeding ruminant animals shall maintain copies of purchase invoices and labeling for all feeds containing animal protein products received, and make the copies available for inspection and copying by the Food and Drug Administration.

(g) Adulteration and misbranding.
   (1) Animal protein products, and feeds containing such products, that are not in compliance with paragraphs (c) through (f) of this section, excluding labeling requirements, will be deemed adulterated under section 402(a)(2)(C) or 402(a)(4) of the act.
   (2) Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of this section will be deemed misbranded under section 403(a)(1) or 403(f) of the act.

(h) Inspection; records retention.
   (1) Records that are to be made available for inspection and copying, as required by this section, shall be kept for a minimum of 1 year.

(2) Written procedures required by this section shall be made available for inspection and copying by the Food and Drug Administration.

The collection of information requirements are approved under OMB Number 0910-0339.

Attachment B

Checklist – Report of Inspection for Compliance with 21 CFR §589.2000
(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052412.pdf**)**

Checklist - Version 4.2

Attachment C

Modified AOAC Official Method 964.07
Microscopy of Animal Feed
Basic Microscopic Examination

1. Apparatus

a. Magnifier and illuminator with desk base, 3X, or reading glass

b. Microscopes and illuminator.

Illuminators: Illuminator for this purpose should be compact with a flexible arm. Halogen lighting preferred. Cool white circular fluorescent acceptable. Minimum 3X magnification.

Compound microscope: The minimum specifications for this microscope should be a binocular body with adjustable focus flat widefield eyepieces (10X); parfocalized plan-acromatic objective lenses of 2.5, 10, 40 and 100X magnifications; adjustable condenser with numerical aperture to match the 100X objective lens and with an optional daylight correction filter carrier (neutral density filters should also be in the lighting assembly); mechanical stage with coaxial controls; built-in halogen light source of at least 20 watts; and options for polarization and interference contrast or phase contrast lighting.

Stereomicroscope: The minimum specifications for this microscope should be a binocular body with adjustable focus flat widefield eyepieces (10X); zoom focusing from 7X to 30X (45X preferred); lighted base with incident, transmitted and mixed halogen illumination with rheostat for adjusting light intensity; (alternative: halogen dual light pipe, objective lens mounted circle light or individual halogen lights for high intensity incident illumination) and interchangeable and removable base plates and clips.

c. Stainless Steel Sieves. A small 16 mesh sieve. (Optional) A set of 3 inch diameter or smaller sieves with cover, pan, 10, 20, 30, 40, 60 and 80 mesh.

d. Mortar and pestle. Porcelain, approximately 4 inches in diameter.

e. Spot plates. Clear glass (to be painted black on the bottom) and white porcelain. Alternative: disposable plastic spot plates.

f. Hand tools:

Dissecting kit including, but not necessarily limited to:

- Forceps, heavy blunt pair for large objects
- Forceps, fine needle tips for fine particles
- Microspatula, stainless steel
- Knife or scalpel; small size
- Glass rods drawn to a fine tip or plastic utensils with fine tip
- Dissecting needles, straight and bent

g. Plasticware:
- Dropping bottles, polyethylene and polypropylene
- 1 ounce polypropylene cup
- 1/4 teaspoon rectangular measuring spoon (any rectangular shaped stainless steel 1/4 teaspoon)
- plastic funnel

h. Glassware:
- Beakers, 150 and 250 ml

i. Miscellaneous
- coffee filters (or any hard surface, thin, rapid filter paper) set into a collection bottle
- Petri dishes (100 mm) for drying floated fractions

j. Laboratory balance.

2. Reagents

(i) Chloroform. Technical; recover by filtration and distillation.
(ii) Acetone. Technical.
(iii) Dilute hydrochloric acid. 1N (approx. 2.5 ml conc. HCl diluted to 30 ml).
(iv) Iodine solution. Use AOAC 964.01 section (B.)(f.) but without standardization.
(v) Mounting media of sufficiently different refractive index from material observed; e.g. Glycerol-phenol mountant. Dissolve 20 g of crystalline phenol in 4 ml of glycerol in a 100 ml beaker (requires time to absorb some moisture from the air or add a few drops of water to stabilize).
(vi) Silver nitrate solution. Dissolve 3 g silver nitrate in 30 ml distilled water.
(vii) Sulfuric acid, 30 N. (Alternative: Sakaguchi reagent: 1 g. boric acid in 100ml 80% sulfuric acid)
(viii) Blood peroxidase : see AAFM Manual (reference 1) p.135.
(ix) Dilute acetic acid. Dilute glacial acetic acid 1:1 with distilled water.

3. Standards

a. Feed ingredients. Collect representative samples of ingredients to be used as authentics, conforming to the definitions of the Association of American Feed Control Officials for comparison with samples. Store each ingredient in an airtight screw capped polystyrene, polypropylene or glass bottle. Control insects in the collection by placing the bottle in a zipper plastic bag and storing at 0 F for 7-10 days. Use no preservatives that will change the aroma, chemical or physical characteristics of ingredients.

Attachment D

Modified AOAC Official Method 970.09
Microscopy of Animal Feed
Identification of Mammalian Tissues and Mineral Constituents

1. Principle

Feeds containing animal tissues and mineral when suspended in CHCl3 (chloroform) readily separate into 2 fractions. The organic fraction floats and contains blood, muscle fibers, connective tissues, organ tissues, feathers, hoof and horn particles, fines thereof, all vegetative tissues from plants, and microbial residues. The minerals and mineralized materials sink. These include bones, teeth, exoskeleton, fish scales, and glass, sand and other mineral materials.

2. Preparation of Sample

Place approximately 4 g of ground (mortar and pestle) sample that passes a 16-mesh sieve into a 1 ounce polypropylene medicine cup. Place approximately 1-2 g in a 100mm Petri dish labeled "untreated" and examine stereoscopically for animal tissues, as per sections C and D, below.

If no animal tissues are detected in the untreated portion, continue on the remaining approximately 2 g sieved sample as follows, in a fume hood. Pour sufficient clean chloroform (about 15 ml) over the sample to form a distinct separation line between the floating material and the heavy mineral particles at the bottom. Stir for about 20 seconds. Squeeze the cup to conform to the shape of the 1/4 teaspoon rectangular measuring spoon (any rectangular shaped stainless steel 1/4 teaspoon). Immediately lift (or assist to decant) the floating organic fraction into a plastic funnel with a folded and trimmed coffee filter (or any hard surface, thin, rapid filter paper) set into a collection bottle. Gently pour the excess chloroform from the sample cup leaving the minerals at the lowest point of the bottom. Rinse the mineral fraction with two small washes of CHCl3. Drain excess solvent from the mineral fraction and set in the hood to dry. Remove the filter paper with the organic fraction and place in a 100 mm glass Petri dish or other container not affected by chloroform. Drying can be accelerated on a hot plate set on the lowest heat setting.

When the organic fraction is dry, scrape the filter paper gently to remove all the sample but do not remove fibers from the paper. Transfer the organic fraction to a tared 100 mm plastic Petri dish for analysis (alternatively transfer the sample to a weighing paper, weigh and then transfer the sample to a Petri dish for analysis). When the mineral fraction is dry, transfer it to a weighing paper, weigh the fraction and transfer it to a 100 mm plastic Petri dish. Record the weights of the fraction and calculate the percentages of each fraction from the total

sample weight.

3. Identification of Animal Tissues in the floating phase

Examine the dried organic fraction stereoscopically for the range of particles present. Isolate and confirm the presence of the following ingredients: hair, blood particles, and horn or hoof particles. Confirm by microchemical tests as appropriate and as described in the manual (1) and/or AOAC (2).

4. Identification of Bone and Mineral Particles in the mineral phase

Examine bones stereoscopically for the range of particles present. Take a small aliquot, prepare a slide in mounting media and examine at 100X with a compound microscope. Use the lacunae and internal structures to confirm the identity of the bone, i.e., mammalian, avian, or marine. Confirm by microchemical tests as appropriate and as described in the Manual (1) and/or AOAC (2).

References:

1) Manual of Microscopic Analysis of Feedstuffs, 3rd ed., Bates et al, American Association of Feed Microscopists (AAFM)
2) AOAC Official Methods of Analysis, 17th ed., Vol. 1., Chapter 4, sec. 4.9

Attachment E

Safety Guidance for Imported Feeds Assignment – Collection and Analysis

Safety Information – Sample Collection
The main objective of these recommendations is to minimize all exposure to feeds and feed dust at the time of sample collection and to minimize future exposure through feed dust on your clothing or equipment.

1. **Personal protective equipment (PPE) recommended for personnel collecting feed samples**:

   - Respiratory protection : minimum half-mask air-purifying respirator (face-sealing) with P100 filters (HEPA)
   - Ocular (eye) mucous membrane protection: goggles
   - Percutaneous (through skin openings such as cuts, abrasions- unbroken skin poses no known hazard) – waterproof gloves on hands; cover skin lesions, cuts, abrasions with waterproof dressing
   - Clothing contamination – disposable coveralls

2. **Collection and bagging procedures:**

   Minimize dust as much as possible when collecting 16 – 1 oz subs and combining them into one sample. Wipe the outside of whirl-pak bag with a water-dampened paper towel in a clean area, and place this bag into another whirl-pak bag (double bag the sample).

3. **Cleanup and PPE removal:**

   When in a dust-free area, remove the disposable coveralls by turning inside-out, rolling up and placing in a plastic bag for disposal. Wipe shoes with water dampened paper towel. Remove goggles and respirator; wipe outside of goggles and respirator with water-dampened paper towel. Place goggles and respirator in clean carrying bag. Place all wipes in the disposal bag with the disposable coveralls. Place the bag in a trash receptacle.

Safety Information – Laboratory Sample Processing and Analysis

1. Sample custodian

Should ensure that the paper sample bag is puncture-free indicating that the whirl pak sample bags remain sealed. If the bag is not intact contact the feed analysts for decontamination procedures.

2. Sample Preparation and Analysis (see next section for decontamination)

- Personal protective equipment: laboratory safety glasses, water impervious gloves such as latex when not working with organic solvents, viton gloves when working with chloroform, lab coats.
- Review the MSDS for chloroform, which is a suspect carcinogen and teratogen. Use chloroform only in the fume hood and wear viton gloves when working with this solvent.
- Place signage on the door to indicate biohazard work is being performed in your area.
- Discourage other lab occupants from walking near your area when you are working at the fume hood or at your stereoscope or microscope.
- Use disposable equipment whenever possible to avoid decontamination issues.
- Sample bags should be opened in a fume hood on a waterproof disposable liner. Wipe the outside of the whirl pak sample bag with 5.25% hypochlorite solution (undiluted bleach).
- Perform all sample preparation in the fume hood.
- When grinding samples with the mortar and pestle, cover the mortar with plastic wrap loosely to prevent any feed particles from leaving the mortar. Gently grind the sample. Place the plastic wrap in a temporary disposal bag until the sample is analyzed.
- The water layer in the separation step should be saved until the sample analysis is performed. If the sample is found to be violative, use paper towels to absorb the liquid, and place in the red biohazard bag for incineration.
- Perform a microscopic analysis in a HEPA-filtered cabinet or at a location approved by an ORA/FDA Industrial Hygienist. Other suitable location: slot hood exhaust away from analysts breathing zone.

3. <u>Decontamination (Violative Samples)</u>

- The disposable equipment and materials (implements, paper, petrie dishes, slides, etc.) used during the procedure should be placed in a red biohazard bag for incineration. This bag should be sealed when not being filled. Once filled, it should be placed in a secure location for collection by a biohazard/medical waste disposal company (for example: Stericyle : 800-355-8773) which will send it for incineration. Paperwork showing collection and disposal information should be kept on file.
- All non-disposable equipment and surfaces (unprotected lab bench tops, mortar and pestle, metal sieves, test tubes, metal spatulas) which have come into contact with a violative feed sample must be decontaminated by one of the following methods:

    1) Soak equipment for 30 minutes with 5.25% hypochlorite (full strength commercial bleach) for 30 minutes. Rinse well with water. The bleach solution is sink disposable. This method is preferred since it does not generate a hazardous waste.
    2) Soak equipment for 30 minutes with 1.0 N NaOH. Dispose of solution in chemical hazardous waste container, which is specifically labeled to receive NaOH. Rinse equipment well with water. Place rinse in hazardous waste container or check rinse pH as required by your hazardous waste program to determine if neutralization and/or sink disposal is acceptable. Do not dilute to lower the pH for sink disposal.

Attachment F

Import Alert #99-25
(http://www.accessdata.fda.gov/cms_ia/importalert_381.html**)**

Detention Without Physical Examination
of Animal Feed, Animal Feed Ingredients and Other Products for Animal Use
Consisting or Containing Ingredients of Animal Origin
and Not the Subject of a Valid USDA Import Permit

Type of Alert: Detention Without Physical Examination

(Note: This Import Alert contains the agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for, or on any person, and does not operate to bind FDA or the public.)

PRODUCT: ALL ANIMAL FEED (INCLUDING PET FOOD), ANIMAL FEED INGREDIENTS,AND OTHER PRODUCTS FOR ANIMAL USE CONSISTING OF OR CONTAINING INGREDIENTS OF ANIMAL ORIGIN (SEE ATTACHMENT A)

PRODUCT CODES: SEE ATTACHMENT A

PROBLEM: POSSIBLE CONTAMINATION WITH THE INFECTIOUS AGENT FOR BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

PAC: 71R844

PAF: MIC

COUNTRIES: ALBANIA (AL), ANDORRA (AD), AUSTRIA (AT), BELGIUM (BE), BOSNIA-HERZEGOVINA (BA), BULGARIA (BG), CANADA (CA), CROATIA (HR), the CZECH REPUBLIC (CS), DENMARK (DK), the FEDERAL REPUBLIC OF YUGOSLAVIA (YU), FINLAND (FI), FRANCE (FR), GERMANY (DE), GREECE (GR), HUNGARY (HU), IRELAND, REPUBLIC of (IE), ISRAEL (IL), ITALY (IT), JAPAN (JP), LEICHSTENSTEIN (LI), LUXEMBOURG (LU), the former YUGOSLAV REPUBLIC OF MACEDONIA (MK), MONACO (MC), NETHERLANDS (NL), NORWAY (NO), OMAN (OM), POLAND (PL), PORTUGAL (PT), ROMANIA (RO), SAN MARINO (SM), the SLOVAK REPUBLIC (SLOVAKIA) (SK), SLOVENIA (SI), SPAIN (ES), SWEDEN (SE), SWITZERLAND (CH) UNITED KINGDOM (Great Britain & Northern Ireland, and Falkland Islands) (GB)

CHARGE: "The article is subject to refusal of admission pursuant to Section 801(a)(1) in that it appears that such article has been manufactured, processed, or packed under insanitary conditions." (OASIS Charge Code: MFR INSAN)

RECOMMENDING OFFICE: CVM, Division of Compliance (HFV-230)

REASON FOR ALERT: On December 7, 2000, USDA/APHIS enacted an immediate prohibition on the importation into the United States of all meat and bone meal (MBM), meat meal, bone meal, blood meal, tankage, offal, or any product containing such, which originated directly from Europe or was rendered/processed in European plants processing animal materials, regardless of species of origin, including poultry and fish meal. This prohibition was deemed necessary by APHIS because of the possibility of cross contamination with the BSE agent.

BSE is the bovine form of a group of uniformly fatal neurological diseases known as TSEs (Transmissible Spongiform Encephalopathies). BSE appears to be spread in part through feeding of infected material to cattle. At this time, the causative agent is unknown and there is no test for the presence of the agent in animal derived products. There appears to be a link between the bovine TSE, BSE, and a human form of TSE known as vCJD (new variant Creutzfeldt-Jakob Disease).

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) regulates the importation of animals and animal-derived materials to ensure that exotic animal diseases, such as BSE, are not introduced into United States animal populations. More specifically, under 9 CFR 95.4, the USDA does not allow the importation of animal feeds or feed ingredients that contain or consist of processed animal protein (e.g. meat and bone meal) and other animal waste and by product materials that have been derived from animals that have been in specified BSE-affected and BSE-at-risk countries. The USDA may, however, allow for the importation of specific non-ruminant animal-derived products, provided the product is the subject of a valid USDA import permit (VS Form 16-6).

GUIDANCE: Districts may detain without physical examination shipments of animal feeds (including pet food), animal feed ingredients, and other products for animal use consisting of, or containing, ingredients of animal origin as listed in Attachment A from the designated countries if the product is not the subject of a valid USDA import permit (VS Form 16-6).

OASIS Screening Criteria have been loaded to ensure that entries of products that contain or may contain animal protein or by-products will be selected for review by the entry reviewer. As part of the review process, the entry reviewer should contact the filer/importer, request paper entry documents ***(USDA import permit, VS Form 16-6)),*** and remind the filer/importer of their requirement to hold the shipment intact pending FDA release. Additionally, the entry reviewer should determine the intended use of the product, the ingredients, and the name and address of

the ultimate consignee.

If the filer/importer does not agree to hold the product intact pending FDA release, contact the local office of US Customs and ask that they detain the product. Products which (from labeling or other documentation) appear to contain animal protein or by-products *** and which are not the subject of a valid USDA import permit (VS Form 16-6)***should either be detained by FDA or recommended to USDA/APHIS for appropriate action. (The location of the APHIS/Plant Protection and Quarantine office can be determined by calling USDA's Veterinary Medical Office at (301) 734-7633).

Products detained and refused under the above reference charge may not be reconditioned or converted to non-FDA regulated use. They must be either destroyed or exported.

Please note that APHIS has received information that shipments of animal-derived products may be offered for entry under descriptions that may be misleading or appear to not be subject to their prohibition, such as fertilizer, adhesive, supplement, nutritional supplement, additive, feed/food additive.

PRIORITIZATION GUIDANCE: I

FOI: No purging is required

PREPARED BY: Gloria J. Dunnavan, CVM, Division of Compliance, HFV-230 (301-827-1168) and Dr. Neal Bataller (301-827-0163) and Linda Wisniowski, DIOP, (301-443-6553)

KEYWORDS: MBM, Feed, Meal, Animal, European Union, EU, BSE, TSE

DATE LOADED INTO FIARS: October 1, 2003

ATTACHMENT A

Products Subject to Detention Without Physical Examination

(NOTE: This list is subject to revision as additional information is received.)

69 - Medicated Animal Feeds
69 [ ][ ][ ][ ][ ] All products

70 - Non-Medicated Animal Feeds
70 [ ][ ][ ][ ][ ] All products

71 - By-products for Animal Food
71 [ ][ ][ ][ ][ ] All products EXCEPT:
71F [ ] [ ] [ ] - Brewery and Distillery
71G [ ] [ ] [ ] - Corn Products
71H [ ] [ ] [ ] - Flour Mill
71I [ ] [ ] [ ] - Rice Mill
71J [ ] [ ] [ ] - Fruit
71K [ ] [ ] [ ] - Vegetable
71L [ ] [ ] [ ] - Oilseed

72 - Pet and Laboratory Animal Food
72 [ ] [ ] [ ] [ ] [ ] All products

Attachment G

9 CFR §94.18

USDA Restrictions on the Importation of Meat and Edible Products from Ruminants

[Code of Federal Regulations]
[Title 9, Volume 1]
[Revised as of January 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 9CFR94.18]

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER I--ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 94--RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS--Table of Contents

Sec. 94.18 Restrictions on importation of meat and edible products from ruminants due to bovine spongiform encephalopathy.

(a) (1) Bovine spongiform encephalopathy exists in the following regions: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, the Republic of Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Oman, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Switzerland, and the United Kingdom.

(3) The following regions, because of import requirements less restrictive than those that would be acceptable for import into the United States and/or because of inadequate surveillance, present an undue risk of introducing bovine spongiform encephalopathy into the United States: Albania, Andorra, Bosnia-Herzegovina, Bulgaria, Croatia, the Federal Republic of Yugoslavia, Hungary, the Former Yugoslav Republic of Macedonia, Monaco, Norway, Romania, San Marino, and Sweden.

(4) A region may request at any time that the Administrator consider its removal from a list set forth in paragraphs (a)(1) or (a)(2) of this section by following the procedures set forth in Secs. 92.2(b) (1) through (4), 92.2(b) (5) through (11), and 92.2(c) of this chapter.

(b) Except as provided in paragraph (d) of this section, the importation of fresh (chilled or

frozen) meat, meat products, and edible products other than meat (excluding gelatin, milk, and milk products), from ruminants that have been in any of the countries listed in paragraph (a) of this section is prohibited.

(c) Gelatin. The importation of gelatin derived from ruminants that have been in any region listed in paragraph (a) of this section is prohibited unless the following conditions have been met:

(1) The gelatin must be imported for use in human food, human pharmaceutical products, photography, or some other use that will not result in the gelatin coming in contact with ruminants in the United States.
(2) The person importing the gelatin must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3.\17\

\17\ VS form 16-3 may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, Maryland 20737-1231.

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(3) The permit application must state the intended use of the gelatin and the name and address of the consignee in the United States.

(d) Transit shipment of articles. Fresh (chilled or frozen) meat, and edible products other than meat, that are prohibited importation into the United States in accordance with this section may transit the United States for immediate export if the following conditions are met:

(1) The person moving the articles must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3.\18\

\18\ VS form 16-3 may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, Maryland 20737-1231.

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(2) The articles must be sealed in leakproof containers bearing serial numbers during transit. Each container must remain sealed during the entire time that it is in the

United States.

(3) The person moving the articles shall notify, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification must include the:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;
(ii) Times and dates of arrival in the United States;
(iii) Times and dates of exportation from the United States;
(iv) Mode of transportation; and
(v) Serial numbers of the sealed containers.

(4) The articles must transit the United States in Customs bond.

(Approved by the Office of Management and Budget under control number 0579-0015)

[56 FR 63868, Dec. 6, 1991, as amended at 58 FR 65104, Dec. 13, 1993; 59 FR 24638, May 12, 1994; 59 FR 67616, Dec. 30, 1994; 62 FR 18264, Apr. 15, 1997; 62 FR 46181, Sept. 2, 1997; 62 FR 56023, Oct. 28, 1997; 62 FR 61434, Nov. 18, 1997; 62 FR 66000, Dec. 17, 1997; 63 FR 408, Jan. 6, 1998; 63 FR 4347, Jan. 28, 1998; 63 FR 71210, Dec. 24, 1998; 64 FR 38550, July 19, 1999; 65 FR 51519, Aug. 24, 2000; 66 FR 22426, May 4, 2001; 66 FR 29900, June 4, 2001; 66 FR 42600, Aug. 14, 2001; 66 FR 52484, Oct. 16, 2001; 66 FR 54643, Oct. 30, 2001; 66 FR 62914, Dec. 4, 2001; 67 FR 4878, Feb. 1, 2002; 67 FR 12832, 12834, Mar. 20, 2002; 67 FR 44018, July 1, 2002; 67 FR 47244, July 18, 2002]

Attachment H

9 CFR §95.4

USDA Restrictions on the Importation of Processed Animal Protein and Other Animal Products

[Code of Federal Regulations]
[Title 9, Volume 1]
[Revised as of January 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 9CFR95.4]

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER I--ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 95--SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES -- Table of Contents

Sec. 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

(a) Except as provided in paragraphs (c) through (f) of this section, the importation of the following is prohibited:

(1) Any of the materials listed in paragraphs (a)(1)(i) through (a)(1)(iv) of this section that have been derived from animals that have been in any region listed in Sec. 94.18(a) of this chapter:

(i) Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless, in the opinion of the Administrator, the tallow cannot be used in feed, regardless of the animal species from which the material was derived;
(ii) Glands and unprocessed fat tissue derived from ruminants;
(iii) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the animal species from which the material was derived; and
(iv) Derivatives of glands from ruminants.

(2) Any of the materials listed in paragraphs (a)(2)(i) through (a)(2)(iv) of this section that have been stored, rendered, or otherwise processed in a region listed in Sec. 94.18(a) of this chapter, or that have otherwise been associated with a facility in a region listed in Sec. 94.18(a) of this chapter or with any material listed in paragraph (a)(1) through (a)(3) of this section:

(i) Processed animal protein, tankage, offal, and tallow other than tallow derivatives, unless, in the opinion of the Administrator, the tallow cannot be used in feed, regardless of the animal species from which the material was derived;
(ii) Glands and unprocessed fat tissue derived from ruminants;
(iii) Processed fats and oils, and derivatives of processed animal protein, tankage, and offal, regardless of the animal species from which the material was derived; and
(iv) Derivatives of glands from ruminants.

(3) Products containing any of the items listed in paragraphs (a)(1) and (a)(2) of this section.

(b) Except as provided in paragraphs (d) and (f) of this section, the importation of serum from ruminants that have been in any region listed in Sec. 94.18(a) of this chapter is prohibited, except that serum from ruminants may be imported for scientific, educational, or research purposes if the Administrator determines that the importation can be made under conditions that will prevent the introduction of bovine spongiform encephalopathy into the United States. Serum from ruminants imported in accordance with this paragraph must be accompanied by a permit issued by APHIS in accordance with Sec. 104.4 of this chapter, and must be moved and handled as specified on the permit.

(c) Materials that are otherwise prohibited importation into the United States under paragraph (a) of this section may be imported into the United States if the following conditions are met prior to importation:

(1) The material is derived from a nonruminant species, or from a ruminant species if the ruminants have never been in any region listed in Sec. 94.18(a) of this chapter.
(2) All steps of processing and storing the material are carried out in a foreign facility that has not been used for the processing and storage of materials derived from ruminants that have been in any region listed in Sec. 94.18(a) of this chapter.
(3) The facility demonstrates to APHIS that the materials intended for exportation to the United States were transported to and from the facility in a manner that would prevent cross-contamination by or commingling with prohibited materials.
(4) If the facility processes or handles any material derived from mammals, the facility has entered into a cooperative service agreement executed by the operator of the facility and APHIS. In accordance with the cooperative service agreement, the facility must be current in paying all costs for a veterinarian of APHIS to inspect the facility

(it is anticipated that such inspections will occur approximately once per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including excess baggage provisions up to 150 pounds). In addition, the facility must have on deposit with APHIS an unobligated amount equal to the cost for APHIS personnel to conduct one inspection. As funds from that amount are obligated, a bill for costs incurred based on official accounting records will be issued to restore the deposit to the original level, revised as necessary to allow for inflation or other changes in estimated costs. To be current, bills must be paid within 14 days of receipt.

(5) The facility allows periodic APHIS inspection of its facilities, records, and operations.

(6) Each shipment to the United States is accompanied by an original certificate signed by a full-time, salaried veterinarian of the government agency responsible for animal health in the region of export certifying that the conditions of paragraphs (c)(1) through (c)(3) of this section have been met.

(7) The person importing the shipment has applied for and obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3. (VS Form 16-3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at http://www.aphis.usda.gov/animal_health/permits/downloads/vs16_3.pdf.)

(d) The importation of serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants that have been in any region listed in Sec. 94.18(a) of this chapter, and of collagen and collagen products that meet any of the conditions listed in paragraphs (a)(1) through (a)(3) of this section, is prohibited unless the following conditions have been met:

(1) The article is imported for use as an ingredient in cosmetics;

(2) The person importing the article has obtained a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3 (VS Form 16-3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at http://www.aphis.usda.gov/animal_health/permits/downloads/vs16_3.pdf.); and

(3) The permit application states the intended use of the article and the name and address of the consignee in the United States. (e) Insulin otherwise prohibited from importation into the United States under paragraph (a) of this section is not prohibited from importation under that paragraph if the insulin is for the personal medical use of the person importing it and if the person importing the shipment has applied for and obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit

application on VS form 16-3. (VS Form 16-3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at http://www.aphis.usda.gov/animal_health/permits/downloads/vs16_3.pdf. Note: Insulin that is not prohibited from importation under this paragraph may be prohibited from importation under other Federal laws, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C, 321 et seq.)

(e) Articles that are prohibited importation into the United States in accordance with this section may transit the United States for immediate export if the following conditions are met:

(1) The person moving the articles has obtained from APHIS a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors by filing a permit application on VS form 16-3. (VS Form 16-3 may be obtained from APHIS, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231, or electronically at http://www.aphis.usda.gov/ncie.)
(2) The articles are sealed in leakproof containers bearing serial numbers during transit. Each container remains sealed during the entire time that it is in the United States.
(3) The person moving the articles notifies, in writing, the Plant Protection and Quarantine Officer at both the place in the United States where the articles will arrive and the port of export prior to such transit. The notification includes the:

(i) United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors permit number;
(ii) Times and dates of arrival in the United States;
(iii) Times and dates of exportation from the United States;
(iv) Mode of transportation; and
(v) Serial numbers of the sealed containers.

(4) The articles transit the United States in Customs bond.

(Approved by the Office of Management and Budget under control numbers 0579-0015 and 0579-0183)

[66 FR 42600, Aug. 14, 2001]

Attachment I

21 CFR §7.40

Recall Policy

[Code of Federal Regulations]
[Title 21, Volume 1]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE**:** 21CFR7**.**40]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 7--ENFORCEMENT POLICY--Table of Contents

Subpart C--Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities

Sec. 7.40 Recall policy.

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and Secs. 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at

the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]