Comments from the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

January 13, 2005

Robert A. Robinson
Managing Director, Natural Resources and Environment
Natural Resources and Environment Team
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Robinson:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, *MAD COW DISEASE, FDA's Management of the Feed Ban Has Improved But Oversight Weaknesses Continue to Limit Program Effectiveness, GAO-05-101).* The agency provided technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in developing this report.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Enclosure

General Comments by the Department of Health and Human Services' Food and Drug Administration on the Government Accountability Office's Draft Report, *MAD COW DISEASE: FDA's Management of the Feed Ban Has Improved But Oversight Weaknesses Continue to Limit Program Effectiveness, (GAO-05-101)*

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. While GAO has raised a few areas to further strengthen the feed ban program, FDA does not believe that material weaknesses were identified that support GAO's position that "various oversight weaknesses continue to limit program effectiveness of the ban and place U.S. cattle at risk of spreading BSE."

FDA commends GAO for conducting such a thorough and diligent study on such an important program and we appreciate the recognition of the enhancements put into place as we have expanded our activities. We note that this work was conducted in October 2003 through November 2004, and involved visits to 17 of 19 FDA district offices, visits to many states conducting inspections under the ruminant feed ban, a significant review of our data systems and multiple meetings with headquarters personnel. A considerable amount of FDA resource time has been devoted to responding to the information requests of this GAO study. While FDA has endeavored to provide both timely and complete responses, we note that FDA field offices alone expended approximately 1500 hours nationwide to provide the 413 inspection reports and to respond to questions from GAO during their visits. This does not include the ongoing information collection requested by GAO after the exit conference, of follow-up information on approximately two hundred feed samples.

FDA's ruminant feed ban regulation, our implementation of which uses a risk-based approach, potentially involves a wide variety of firms involved in the animal feed industry. Every firm that manufactures, transports, distributes or sells animal feed or feed ingredients for any animal species is subject to inspection under the FDA ruminant feed ban compliance program, regardless of whether prohibited material is utilized. Even swine and poultry farms that mix their own feed and grocery stores that sell pet food are potentially subject to inspection under this rule. All operations feeding ruminants, such as dairy and beef cattle, are also subject to the rule. In consideration of the limited resources for inspecting this large population of firms, FDA is obligated to set priorities for inspecting a meaningful subpopulation of these regulated firms.

FDA provides inspection priority direction to FDA and state investigators through publication of an inspection priority document as part of the BSE/Ruminant Feed Inspection Compliance Program guidance document. The highest priority for inspection is directed towards firms that are manufacturing or processing animal feeds or feed ingredients that contain prohibited material. This industry segment, which includes renderers, protein blenders, and feed mills, represents the most important industry segment to ensure that ruminant feeds do not contain prohibited material. This industry group is inspected on an annual basis.

Generally, firms outside of these segments collectively have a lower priority for inspection since the operations of the firms in the high priority segment of the industry pose the greatest risk of resulting in contaminated feed. Other segments, such as cattle feeders, are of interest to the FDA, but there are estimated to be over one million ruminant feeders in the U.S. While FDA does not have the resources to fully inspect certain industry segments, the agency continues to develop and utilize educational tools to compliment inspections and to promote voluntary compliance in these large industry segments. FDA will additionally implement inspectional initiatives to increase its presence in some of these less inspected segments, such as

See comment 1.

See comment 2.

transporters and animal feed salvagers, based on our assessment of compliance and risk in these industry sectors.

We also do not agree with the assertion by GAO concerning the format with which FDA summarizes ruminant feed ban reporting of inspection results. FDA has provided a degree of transparency related to these inspections that is unprecedented, compared to any other inspection program. All data related to BSE inspections are posted on an Internet site that is available to Congress, industry and the public. FDA took this action because of the visibility of this inspection program and because of the recognition that one of the best tools to obtain compliance with the feed ban was public disclosure of our findings. While GAO may disagree with the context provided by any summary documents, our web site allows the user to analyze the data, in a multitude of ways, to provide their own contextual reference.

RECOMMENDATIONS FOR EXECUTIVE ACTION

To further strengthen oversight and enforcement of the animal feed ban and to better protect U.S. cattle and American consumers, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following 9 actions:

1) Develop uniform procedures for identifying all firms subject to the feed ban.

FDA Comment

FDA has already identified the merits of using a consistent procedure for identifying additional firms subject to its jurisdiction and has revised the Investigational Operations Manual (IOM).

As noted in the report, FDA acknowledges that more firms are subject to the feed ban than the over 14,800 that have been inspected to date. However, FDA's current inspectional strategy has been to focus on renderers, protein blenders, and feed mills, which we believe are the primary means of controlling feed and feed ingredients that may contain prohibited material. FDA believes that it has uniform procedures for identifying and inspecting these higher risk firms and that we have been successful in covering this inventory. The survey data collected by GAO from the states supports that, to a great extent, this inventory of firms has been both identified and inspected.

The issue that GAO raises in the draft report is related only to the lower risk firms that are purchasing feed ingredients from one of the higher risk establishments. FDA does not have the resources to inspect all ruminant feeders, transporters/haulers of feed, feed retailers and feed distributors that may be subject to this regulation. This total inventory is massive and for most of these firms there is either no commercial handling of prohibited material since they are handling only packaged product (like pet food), or there is limited manipulation of the product that would allow for contamination. Therefore, the FDA approach has been to selectively inspect sample firms in this lower risk category to assess their level of compliance with the regulations, and to assist in determining additional educational efforts that may be needed. FDA has inspected all firm types in these lower risk industry segments and continues to expand the number of inspections conducted both by FDA and the states in these lower risk categories. When FDA identifies a specific segment that may need additional inspectional coverage, the agency will issue specific assignments to broaden our coverage. This is the situation with the transporters/haulers and pet food salvagers for which the FDA's Center for Veterinary Medicine (CVM) is currently drafting an assignment to FDA's field operations.

GAO identified a process used by some FDA investigators, on some of the observed inspections, to help FDA identify additional firms. This process entails investigators writing down the names of the suppliers and customers of firms during inspections to check against the inventory of active firms. While there is value to GAO's suggestion, the recording of the supplier and customer names and later checking them against an inventory of active firms after all inspections would take additional resource time and is not resource neutral as suggested by GAO. The current BSE inspection module is 7.5 hours. Such inventory improvement would utilize time that would have to be diverted from conducting additional inspections. Nevertheless, FDA has already identified the merits of consistently using this approach. Earlier this year, as part of FDA's ongoing improvements in our security awareness program, we recently changed our 2005 Investigations Operations Manual (IOM) regarding the standard narrative report. IOM Chapter 593.03, Individual Narrative Headings, has been revised to advise the FDA Investigator to verify, during the initial inspection, distribution patterns for the firm's products, raw materials, and components to firms which warehouse or further process products which may be subject to FDA regulations. The 2005 IOM revision also reminds FDA District Offices that any new information should be incorporated into their Official Establishment Inventory (OEI) improvement activities. Lastly, this revised section also provides a cross-reference to the necessary section of the IOM that describes how to add firms to a District OEI. Once the 2005 IOM has been finalized, ORA will alert Districts through our various mechanisms to this change, which affects all ORA Inspection programs, including the BSE Inspection Program. We will also discuss this recommendation with the Field Veterinary Committee for incorporation into the next Compliance Program Guidance revision of the BSE Inspection program.

See comment 3.

2) Require that firms that process with prohibited material notify FDA. If FDA believes it does not have legislative authority to require this, it should seek that authority from the Congress.

FDA Comment

FDA's current regulations do not require that firms handling prohibited material notify FDA and the Federal Food, Drug, and Cosmetic Act (FFDCA) does not currently require such notification. If such a notification program were implemented, FDA would need significant additional resources to develop the notification regulation, develop collection and monitoring tools, collect the information, monitor the information and compliance with the requirement, and conduct follow-ups. FDA believes that our current approach of working collaboratively with our state counterparts does give us a good opportunity to keep abreast of changes firms may make in the use of prohibited material and to use our resources to focus on high risk firms. We continue to enhance our working relationships with our state counterparts to facilitate the exchange of such information.

In support of identifying all firms of higher risk, FDA has already initiated the process of reviewing records for food facilities that have registered with FDA under section 415 of the FFDCA, and determining whether there are any facilities that may potentially handle prohibited material that have registered but that we have not previously inspected. Under section 415 of the FFDCA, facilities that manufacture, process, pack, or hold food for consumption in the United States must register with FDA. When the facility registers, it must indicate if it manufactures, processes, or packs certain categories of food. The facility may voluntarily indicate if it manufactures, processes, or packs other categories of food. All categories of animal food are among those that facilities may voluntarily report to FDA. While the registration system has certain limitations, including an exemption for farms that process feed for their own

See comment 4.

animals, we believe that the registration information could still lead us to identify additional facilities that handle prohibited material.

3) Develop guidance for inspectors to systematically use feed microscopy and/or polymerase chain reaction (PCR) to verify the safety of cattle feed and to confirm the adequacy of firms' procedures for ridding equipment and vehicles of prohibited material before they are used for cattle feed or feed ingredients.

FDA Comment

Since no test currently exists for the detection of the infectious prion agent that causes BSE in feed, analysis of feed is not by itself a means of verifying the safety of cattle feed. Additionally, feed microscopy and/or PCR are not adequate methods to make compliance decisions based on test results alone about the presence of prohibited material with respect to the ruminant feed ban rule. The feed microscopy method has limitations and the rule has exemptions. Feed microscopy generally can only detect the presence of mammalian tissue, through the identification of either bone or hair. In certain situations, feed microscopy can only detect the presence of animal tissue when blood is detected. The present ruminant feed ban allows for certain exemptions to the mammalian protein prohibition. Exempted materials include pure porcine meat and bone meal, blood (from any animal species, including ruminants), gelatin, and milk protein. Further, there is no prohibition on the use of non-mammalian proteins (e.g., poultry meal). The detection of certain non-specific materials, such as bone or muscle, may be the result of exempt ingredients, such as ruminant blood meal, pure porcine meat and bone meal, or poultry meal. PCR has similar limitations since the test cannot differentiate between prohibited material ingredients and certain ruminant-containing exempt ingredients, such as ruminant blood, ruminant milk products, and plate waste. Since feed microscopy and PCR cannot differentiate prohibited material from other acceptable materials, the analytical results cannot be used to verify the presence [or absence] of prohibited material, nor used for confirming the adequacy of clean-out measures.

On August 18, 2003, FDA/CVM issued a sampling assignment to the FDA field staff for the collection of 600 domestic samples [increased to 900 samples for the current fiscal year]. The characteristics of the ruminant feed ban sampling assignment are unique when compared to other FDA sampling programs. Other programs are more simply based on methodology that can definitively detect the presence of the objectionable contaminant or pathogen. Further, the nature of the contaminants in some of the other programs allow for the establishment of tolerance levels. The mere detection of a pathogen or some of these contaminants, possibly with respect to an established tolerance, is sufficient to result in the finding of a violation in these other programs. In contrast to these other programs, analytical findings alone under the ruminant feed ban program cannot establish the occurrence of a violation to the rule. As the ruminant feed ban assignment notes, positive analytical findings necessitates follow-up evaluations in determining whether the findings were indeed the result of ruminant feed ban violations.

The fairly recent implementation of this unique ruminant feed ban sampling program has involved efforts to educate laboratory personnel as to the limitations of the methodology, and the approach in categorizing the lab results. Laboratory personnel have been educated through conference calls, training, and individual telephone conversations in classifying these samples. Further, field investigators have been instructed that regulatory action should not be taken on the basis of sample analysis alone. (See the Enforcement and Regulatory follow-up sections in the BSE/Ruminant Feed Ban Inspections Compliance Program Guidance and the

See comment 5.

Domestic Feed Sampling Assignment, respectively.) In the next fiscal year, FDA intends to provide additional guidance to describe the variety of situations where animal, mammal and/or ruminant tissue may be present in an animal feed or feed ingredients. Through an analysis of the experience derived from the first year of the sampling assignment, FDA will revise overall sampling instructions in the sampling assignment, with these sampling procedures eventually being incorporated into the BSE/Ruminant Feed Ban Inspections Compliance Program guidance document.

4) Collect feed test results from states that sample feed to help verify compliance with the feed ban.

2002 GAO BSE Study

Recommendation to track enforcement actions taken by states.

2002 FDA Comment

FDA thanks the GAO for this recommendation. FDA needs to more fully evaluate the impact of this recommendation. FDA does not have the authority to require that all states track and report to FDA enforcement actions taken. Currently, state laws differ on what inspection and enforcement authorities each state has and the ability of each state to provide such information to FDA. We do strongly support the concept of voluntarily sharing inspection and enforcement actions taken by FDA and our state partners. This was one of the primary motivators for our quarterly FDA-State regulator BSE meetings to provide a forum to share such potentially confidential information.

2004 GAO BSE Study

Recommendation to collect feed test results from states that sample feed to help verify compliance with the feed ban.

FDA Comment

We have included the comment from GAO's 2002 recommendation on tracking enforcement actions by states as these two recommendations present some of the same difficulties for the agency. First is the fact that each state agency may enforce different state laws and regulations regarding feed manufacturers and these laws and regulations may not be the same as the federal rules. The collection of enforcement actions and sample results could, therefore, actually confuse the enforcement and compliance national picture rather than enhance it. Second, concerning both enforcement and collection of samples, until FDA and the states have developed a standard for sampling procedures, analytical techniques, and enforcement strategies, the shared data would be considered skewed and potentially misleading. While enforcement could be equalized through adoption of equivalent regulations by the states, FDA would have to evaluate each state enforcement program through our audits, which would require field inspection resources. Accepting sample results would also require not only the use of equivalent testing protocols, e.g. using acceptable ELISA test kits, but also may involve the evaluation of the laboratory and laboratory personnel. Performing this type of evaluation would require resources currently not available to FDA. With the current test and with the implementation of the very sensitive PCR test, the test could be positive for exempt ingredients or for non-ruminant material such as mice, rats, etc.

To enhance our sampling/analytical aspects of this program, FDA is incorporating collection of samples under the Feed Manufacturing/BSE state contracts. States will submit these samples to FDA laboratories to support FDA's own efforts in surveying the animal feed industry. FDA is also considering expanding, as funding permits, the Electronic Laboratory Exchange Network (eLEXNET) to include animal feeds. eLexnet is a nationwide laboratory data network that allows member laboratories the ability to detect, compare and communicate findings. Also with proper funding, FDA will add the state contract feed manufacturer programs into eSAF (electronic state access to FACTS) in FY05/06. Once the programming is funded and completed, the states will be able to enter their contract data (or other inspections) into the system and both FDA and the state will be able to review all the entered inspections for that particular state. This will improve the timeliness of information collected by states during feed establishment inspections.

5) Develop a sample design for FDA's inspectors to use for sampling finished feed and feed ingredients that will allow FDA to more accurately generalize about compliance with the feed ban from the test results.

FDA Comment

Sampling of finished feed and feed ingredients cannot serve as a basis to generalize compliance with the feed ban. As explained in the above responses, the current tests available and in use today are not definitive for prohibited material. Feed microscopy has limitations, including that it can demonstrate animal tissue and can sometimes determine if the tissue is mammalian, but cannot distinguish between prohibited mammalian protein, non-prohibited protein, and exempt mammalian protein. The test being used today [feed microscopy] provides information that there may be a potential problem. The only way to determine compliance with the feed ban is to conduct an inspection of the firm. The feed sampling assignment is designed to be an additional way to review products in the marketplace. Finding a positive result from feed microscopy provides information for us to conduct targeted follow-up inspections but does not by itself prove the presence of prohibited material and a violation of the ruminant feed ban.

See comment 6.

The August 18, 2003 domestic assignment directs ORA Field personnel to routinely sample and analyze feed to verify compliance with the feed ban. (See excerpt below.)

Sampling Information:

A. Sample Selection

Products should be selected for sampling using the following criteria:

1. Animal feed, feed ingredients, and other animal feed products as identified in Attachment B to this assignment.

2. Products intended for ruminant animals. These products should be given the highest priority for collection. At least one half (½) of the samples should be selected from these products if possible.

3. Animal feed, feed ingredients, and other animal feed products that are labeled as containing animal protein but do not bear the caution statement "Do not feed to cattle or other ruminants" on the label.

4. Animal feed, feed ingredients, and other animal feed products that do not list mammalian protein in the product name or ingredient list.

5. Each sample should represent a different source, processor, or manufacturer if possible.

Attachment B
Products/ Product Codes Covered by this Assignment:

69 – Medicated Animal Feeds

69 [ ] [ ] [ ] [ ] [ ] All Products

70 – Non-Medicated Animal Feeds

70 [ ] [ ] [ ] [ ] [ ] All Products

71 – By-product for Animal Food

71 [ ] [ ] [ ] [ ] [ ] All Products

6) Seek authority from the Congress to require the cautionary statement on feed or feed ingredients that are intended for export and that contain prohibited material. In the meantime, FDA should encourage firms to include such cautionary statement on these exports.

FDA Comment

The Federal Food, Drug, and Cosmetic Act currently does not include a provision that directly requires feed or feed ingredients intended for export to bear the cautionary statement. We note that, if FDA determined that it would be appropriate for the agency to adopt a policy encouraging exporting firms to voluntarily include a cautionary statement on feed labels, the agency would first need to determine whether such a policy must be issued under FDA's Good Guidance Practice regulations at 21 CFR 10.115. Under those regulations, a guidance document is a document that includes the agency's "interpretation of or policy on a regulatory issue." For the most part, FDA focuses its policies on matters under its regulatory authority. In addition, before FDA could adopt a policy to encourage the use of the cautionary statement on exports, it would need to determine that such a statement would not be inconsistent with the laws of other countries in light of the requirement in section 801(e) of the Federal Food, Drug, and Cosmetic Act that the product is not in conflict with the laws of the country to which it is intended for export.

FDA has a comprehensive program that reviews the entry of all feed commodities that either are ingredients or may end up as ingredients in ruminant feed. FDA detains animal feeds or feed ingredients that contain ingredients of animal origin and that are imported from countries identified as having BSE or being at risk for having BSE. This system does not rely upon other countries to enforce FDA labeling requirements for feed with prohibited material. Other countries have similar programs to refuse entry to imported products that pose a risk of BSE. Each country thus assumes responsibility for enforcing its own laws with respect to BSE.

Even if FDA were to require products for export that contain prohibited material to include the cautionary statement, this statement might not make the product acceptable to the importing

See comment 7.

country and may conflict with the country's own label requirements. FDA refuses import of products into the U.S. with such material from BSE risk countries regardless of whether they have such a warning because of the risk of diversion.

Currently FDA's guidance for exports, as excerpted below, focuses on clearly labeling the product for export and providing guidance on material that may be brought back into the U.S.

PRODUCTS FOR EXPORT

* Prohibited protein product destined for export should be marked "FOR EXPORT ONLY" on the shipping containers if appropriate and on documents accompanying the shipment. No other labeling would be required for purposes of this regulation but there may be additional labeling requirements for the country of destination.

* Any prohibited protein product destined for export which is diverted back to domestic commerce for any reason (salvage, quality, etc.), will be subject to all of the requirements of the regulation. This will include the requirement to label the product with the cautionary statement "Do not feed to cattle or other ruminants."

* Responsibility for these prohibited protein products rests with the owner of the goods (holder of the title to the goods). The owner is responsible for assuring that they are not diverted back to domestic commerce unless they meet the requirements of the regulation, including use of the cautionary labeling statement.

See comment 8.

7) Ensure that procedures for alerting USDA and states are followed when inspectors discover that feed or feed ingredients with prohibited material may have been fed to cattle.

FDA Comment

FDA has and continues to coordinate closely with USDA and state officials on issues related to BSE. FDA has notified both States and USDA when the agency assessment was that their involvement was important from a public health perspective. Nevertheless, FDA accepts the GAO recommendation and will consider notifying USDA to allow full information to be exchanged with USDA whenever there has been a recall in which prohibited material from domestic or from an imported source may have been used as an ingredient in feed, or as feed for ruminants.

The GAO draft report states that "...although FDA has procedures for alerting USDA and states when it discovers that cattle may have consumed feed that contains prohibited material, FDA officials told us that they have never given such notification even though they have identified the prohibited material being used in cattle feed in the past. FDA said that notification is not needed because BSE has not been discovered in a cow born in the United States...."

The section referenced by GAO is found in the FDA compliance program guidance entitled BSE/Ruminant Feed Ban Inspections, and pertains to recalls. It provides "generic" scenarios that could be encountered by field personnel and suggests appropriate courses of action. 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 compliance program guidance is not intended to cover all situations, and any new or novel scenarios will require review and evaluation by CVM. The guidance to contact USDA is found in the second scenario on "prohibited material from domestic or from an imported source is used as an ingredient in feed, or as feed to ruminants" and is cited below:

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

FDA believes that it has followed this guidance and considered notification of USDA. While it is true that FDA has not notified USDA of every incident when animal feed was recalled and potentially fed to ruminants, FDA does consider the need to notify USDA based on our assessment of the facts in each unique situation. In each case FDA looks into the source of the prohibited material (imported or domestic source), what species of ruminant is it being fed to

(cattle or other species not known to acquire natural infection by the agent of BSE), the potential level of contamination with prohibited material in the feed, as well as the level of evidence available to determine if ruminant animals may have actually consumed any prohibited material.

Again, FDA will continue to coordinate closely with USDA and state officials on all issues related to BSE.

8) Modify the BSE inspection form to include questions inspectors can use to document whether firms that process or handle cattle feed or feed ingredients have procedures to ensure the cleanliness of vehicles they use to transport that cattle feed and feed ingredients.

FDA Comment

FDA has attempted to limit the number of changes to avoid having multiple versions of the reporting tool in use as well as to enhance the quality of the data. However, we will consider whether modifying the reporting tool would be appropriate. We would emphasize that the checklist is an inspection reporting tool, not the guidance for the inspection. As a reporting tool, it reflects the overall results of the inspection but does not capture every item that is inspected, reviewed, or evaluated during the inspection. The Compliance Program provides comprehensive instructions to the inspectors about inspection methods, areas to look at, records to review, and questions to ask. The following are two excerpts from the Compliance Program which specifically include review of transport conveyances:

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.

Feed Storage. [This section is included in the information on inspection of ruminant feeders]

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)).

See comment 9.

9) Ensure that inspection results are reported in a complete and accurate context.

FDA Comment

FDA believes that it has reported inspection results in a complete and accurate context.

GAO states that FDA has reported that industry is 99 percent in compliance with the feed ban. GAO further states that they do not believe that FDA has enough information or enough current information to cite a rate of compliance. GAO also notes that FDA has not inspected the universe of firms subject to the ban, many inspections are five or more years old, and inspections are largely paperwork review with very little testing to confirm compliance.

We do not agree with GAO's conclusion that FDA is reporting data that is incomplete and not accurate. FDA has made tremendous efforts, and at great cost, to have every inspection posted on FDA's Internet site. This extraordinary level of transparency, which is unique to this program, allows Congress, Industry and the public to view the inspection results, virtually at the same time as it is entered into the agency's FACTS system. The data is available to be searched and sorted by any number of variables to allow the user to ascertain their own perspective on the data. Additionally, FDA publishes CVM Updates on "Ruminant Feed (BSE) Enforcement Activities." These updates have been published on a periodic basis since January 10, 2001. These reports identify inspection results by type of industry using the standard FDA inspection classification criteria. At FDA's exit conference with GAO, GAO advised that these updates were an accurate and complete depiction of BSE inspection results.

While we understand GAO's perception with regard to the one line synopsis of overall inspection results as having a confusing message, this confusion is not due to a lack of candor on the part of the agency. We also do not agree that our "inspections are largely paperwork review with very little testing to confirm compliance." Our BSE inspections are thorough assessments where the inspector spends a considerable amount of their inspection time on the plant floor judging the firm's compliance with the feed ban regulation. Furthermore, review of paperwork, including records of feed ingredient receipt and lists of feed ingredients, are one component of our inspections and are crucial to FDA enforcement of the feed ban. FDA believes that its current regulatory approach, of assuring compliance of FDA's feed rule by the major suppliers and users of cattle feed, is the most effective approach in making sure the public health is protected.

See comment 10.