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## CVM Update

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March 17, 2005

### **MARCH 2005 UPDATE ON FEED ENFORCEMENT ACTIVITIES TO LIMIT THE SPREAD OF BSE**

To help prevent the establishment and amplification of BSE through feed in the United States, FDA implemented a final rule that prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, Title 21 Part 589.2000 of the *Code of Federal Regulations*, here called the [Ruminant Feed Ban](#), became effective on August 4, 1997.

This is an update on FDA enforcement activities regarding the ruminant feed regulation. FDA's CVM has assembled data from the inspections that have been conducted AND whose final inspection report has been recorded in the FDA's inspection database as of **March 5, 2005**. As of March 5, 2005, FDA had received over 35,000 inspection reports. The majority of these inspections (around 70%) were conducted by State officials under contract to FDA, with the remainder conducted by FDA officials.

Inspections conducted by FDA or State investigators are classified to reflect the compliance status at the time of the inspection based upon the objectionable conditions documented. These inspection conclusions are reported as Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI).

An OAI inspection classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented.

A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the Ruminant Feed Ban. These include provisions such as minor recordkeeping lapses and conditions involving non-ruminant feeds.

An NAI inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further actions.

The results to date are reported here both by "segment of industry" and "in total". **NOTE** – A single firm can operate as more than one firm type. As a result, the categories of the different industry segments are not mutually exclusive.

### **RENDERERS**

These firms are the first to handle and process (i.e., render) animal proteins and to send these processed materials to feed mills and/or protein blenders for use as a feed ingredient.

- Number of active firms whose initial inspection has been reported to FDA – 255
- Number of active firms handling materials prohibited from use in ruminant feed – 169 (66% of those active firms inspected)
- Of the 169 active firms handling prohibited materials, their most recent inspection revealed that:
  - 1 firm (0.6%) was classified as OAI
  - 6 firms (3.5%) were classified as VAI

### **LICENSED FEED MILLS**

FDA licenses these feed mills to produce medicated feed products. The license is required to manufacture and distribute feed using certain potent drug products, usually those requiring some pre-slaughter withdrawal time. This licensing has nothing to do with handling prohibited materials under the feed ban regulation. A medicated feed license from FDA is not required to handle materials prohibited under the Ruminant Feed Ban.

- Number of active firms whose initial inspection has been reported to FDA – 1,066
- Number of active firms handling materials prohibited from use in ruminant feed – 402 (38% of those active firms inspected)
- Of the 402 active firms handling prohibited materials, their most recent inspection revealed that:
  - 1 firm (0.2%) was classified as OAI
  - 9 firms (2.2%) were classified as VAI

### **FEED MILLS NOT LICENSED BY FDA**

These feed mills are not licensed by the FDA to produce medicated feeds.

- Number of active firms whose initial inspection has been reported to FDA – 5,133
- Number of active firms handling materials prohibited from use in ruminant feed – 1,785 (35% of those active firms inspected)
- Of the 1,785 active firms handling prohibited materials, their most recent inspection revealed that:
  - 4 firms (0.2%) were classified as OAI
  - 30 firms (1.7%) were classified as VAI

## **PROTEIN BLENDERS**

These firms blend rendered animal protein for the purpose of producing quality feed ingredients that will be used by feed mills.

- Number of active firms whose initial inspection has been reported to FDA -- 302
- Number of active firms handling materials prohibited from use in ruminant feed – 86 (28% of those active firms inspected)
- Of the 86 active firms handling prohibited materials, their most recent inspection revealed that:
  - 0 firms (0%) were classified as OAI
  - 3 firms (3.5%) were classified as VAI

## **RENDERERS, FEED MILLS, AND PROTEIN BLENDERS**

This category includes only those firms in the above four categories any firm that actually use prohibited material to is represented by any of the above four categories, but includes only those firms that manufacture, process, or blend animal feed or feed ingredients utilizing prohibited materials.

- Number of active renderers, feed mills, and protein blenders whose initial inspection has been reported to FDA – 6,526
- Number of active renderers, feed mills, and protein blenders processing with prohibited materials – 568 (8.7% of those active firms inspected)
- Of the 568 of active renderers, feed mills, and protein blenders processing with prohibited materials, their most recent inspection revealed that:
  - 6 firms (1.1%) were classified as OAI
  - 22 firms (3.9%) were classified as VAI

## **OTHER FIRMS INSPECTED**

Examples of such firms include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters.

- Number of active firms whose initial inspection has been reported to FDA – 12,009
- Number of active firms handling materials prohibited from use in ruminant feed – 3,001 (30% of those active firms inspected)
- Of the 3,001 active firms handling prohibited materials, their most recent inspection revealed that:
  - 11 firms (0.4%) were classified as OAI
  - 89 firms (3.0%) were classified as VA

**TOTAL FIRMS**

**Note** that a single firm can be reported under more than one firm category; therefore, the summation of the individual OAI/VAI firm categories will be more than the actual total number of OAI/VAI firms, as presented below.

- Number of active firms whose initial inspection has been reported to FDA – 15,249
- Number of active firms handling materials prohibited from use in ruminant feed – 3,804 (25% of those active firms inspected)
- Of the 3,804 active firms handling prohibited materials, their most recent inspection revealed that:
  - 13 firms (0.3%) were classified as OAI
  - 95 firms (2.5%) were classified as VAI

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