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December 13, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2002N-0273, Substances Prohibited From Use in Animal Food or Feed

To Whom It May Concern:

I am the President of Baker Commodities, Inc., one of the major rendering companies in the United States. We are extremely concerned about the FDA's proposed changes to the 1997 ruminant to ruminant feed ban. We believe that this change is not necessary as the current feed ban is working and the proposed change would be very costly to cattlemen, dairymen, renderers and consumers with little or no reduction in the risk of bovine spongiform encephalopathy (BSE) or mad cow disease.

On October 5, 2005, FDA published an advance notice of proposed rule making (ANPR) in the Federal Register. The ANPR proposes changes to the existing feed ban that was enacted in 1997, which prohibits the feeding of ruminant-derived proteins back to ruminants. FDA is under constant pressure by so-called consumer groups, animal rights advocates and other special interest groups to make these changes under the guise of reducing the threat of BSE within the United States. Although the enhanced surveillance program instituted by USDA has demonstrated that the risk of BSE in our nation's herd is virtually nonexistent, these groups have chosen to focus on the 2003 BSE case in Washington State involving a cow of Canadian origin, and the 2005 BSE case in Texas, an animal that was approximately twelve years old.

USDA has completed testing on over 555,000 samples submitted for BSE testing. Of these samples, 535,000 were taken from animals that USDA and FDA believe are "at the highest risk of testing positive for BSE." These so-called "high risk animals" are animals that are over 30 months of age, that have died from causes other than slaughter, as well as non-ambulatory and disabled cattle. In other words, these were animals that either died on the farm or were downers. In addition, Senator Tom Harkin (D-Iowa) suggested to the U.S. Dept. of Agriculture that tests on healthy cattle be done because some clinically "normal" cattle over 30 months of age had tested positive for

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BSE in other countries. These tests have been completed. The original goal was 20,000, but the department exceeded that goal, by stopping at 21,216.

Having tested well over one half million head of cattle from what USDA considers to be the "highest risk population," and having found one animal that has tested positive under very questionable circumstances (the Texas case), provides more than enough scientific data to back up the assertion that the livestock and rendering industries have made for years. Our beef is the safest in the world, and BSE poses no risk to human or animal health in this country.

Nevertheless, the Food and Drug Administration (FDA) has chosen to ignore the scientific data that the enhanced surveillance program has afforded us, and chosen to propose further changes to the feed rule that will place a hardship on both industry and the producer. FDA maintains that there is virtually no economic or environmental impact as a result of the proposed rule. This position by FDA is blatantly wrong, and serves only to enable the agency to impose the recommended changes without requiring them to conduct an economic or environmental assessment.

There are several items in the proposed rule that are bothersome. Namely, the requirement in the proposed rule stating that packers remove the brain and spinal cord from all cattle over 30 months of age and the prohibition from using specified risk materials (SRM) in all animal feed. This will require the packer to install separate handling equipment on the kill floor, for this material, so that it can be disposed of properly, where as now, it is commingled with other inedible by-products. If the packer renders his own inedible by products, he will have to add additional equipment to process this material, or dispose it in some other manner. If a render is picking up the packer's inedible by-product, the packer will have to provide a system where the SRM's can be picked up separately, in designated vehicles by the render.

A requirement in the proposed rule mandating the removal of the brain and spinal cord from cattle of any age not inspected and passed for human consumption poses additional problems and costs to renderers. This means that all animals that die, mainly at feed lots and farms, regardless of age, and non-ambulatory disabled cattle, will have to have their brains and spinal cords removed before other parts of the animal can be used for animal feeds.

Removing the brain and spinal cord from dead cattle picked up at the farm or feedlot is not impossible, but it is not an easy task. It is a very labor-intensive process that is further complicated by seasonal changes that greatly affect the condition of the animal and the ability to successfully remove these materials. Our central California dead stock plant processes over 5,000 of such animals each week.

During the winter months, with colder temperatures and wind chill factors, the spinal cord becomes frozen in the vertebral column making it impossible to remove the spinal cord without either splitting the carcass or cutting off the ribcage and disposing of the entire vertebral column. Likewise the brain cavity of the animal freezes requiring disposal of the entire head. In calves, the entire carcass would require disposal as SRM's considering the amount of labor required to separate these materials in comparison to the value of finished product derived from the remaining portion of the carcass.

During the summer months, rapid decomposition of the animal may make removal of SRM's in some animals impossible, requiring the entire carcass to be disposed of. In concentrated dairy areas it is not uncommon for renderers to procure thousands of calves per week that would now have a negative economic value to the renderer at the present pickup fee. Of the 5,000 weekly animals processed at our central California dead stock plant, approximately 3,000 are calves.

Renderers will be required to either construct separate facilities for processing SRM's or take them to a landfill. Constructing additional facilities will be very difficult due to zoning restrictions, grandfathering and plant cost constraints. There will most likely be insufficient SRM's generated by any one renderer to justify the cost of such a facility. Multiple renderers may decide to construct regional facilities to handle SRM material. This raises anti-trust and other concerns.

The least cost method for disposing of SRM's would be land filling. Incineration, composting and chemical digestion have a significantly higher cost than rendering, which may not be available due to the limited quantity of such material.

Why is the FDA worried about animals less than 30 months of age? For human consumption, packers only have to remove the brain and spinal cord from animals over 30 months old. Why should there be a greater standard for animals being used for feed purposes? There is no scientific basis for removing the brain and spinal cord from a calf.

Landfill disposal is generally the least cost option for SRM disposal. This creates several additional problems as a result. First, not all landfills are permitted by EPA to accept raw animal materials. Second, landfills that are permitted may elect to classify this material as special or hazardous waste and charge significantly higher fees for its disposal. Third, but by no means the least significant problem, is that scavengers such as coyotes, dogs, rats and other animals will enter the landfill and scatter raw animal materials throughout the surrounding area. This problem in and of itself creates a far

more significant risk to human and animal health than the threat of BSE under the current feed rule. We believe that an environmental impact study should be required before greatly increasing the amount of raw animal materials being disposed of using non-rendering methodologies.

Transportation of these materials to the landfill will be another significant cost to the renderer and the packer alike. Under the proposed rule, separate dedicated containers must be used to collect these materials once they are separated from the carcass. This would include separate dedicated containers within the packing or rendering plant facility, as well as separate dedicated trucks or trailers for transporting these materials to the landfill.

FDA has cited three main reasons further regulations are needed. These are: Cross contamination during feed manufacturing or transport, unintentional misfeeding on the farm and the concern that poultry litter that is currently allowed in cattle feed may contain spilled poultry feed and would provide a source of contamination in ruminant feed. Comments regarding this concern were submitted to FDA in 2004.

FDA has stated on one hand that it acknowledges that livestock production in the United States is greatly different than livestock production in other countries, particularly in the United Kingdom, where multi-specie farms are commonplace. On the other hand, FDA continually refers to the BSE situation in the UK, where livestock production and rendering practices are greatly different.

And why did the USDA have EU scientists recommend steps that our government should take to prevent the establishment of BSE in the U.S. and prevent exporting contaminated feed, if we did have BSE? It seems that the EU should have paid more attention to their own exports of contaminated feed, at discount prices, all over the world, which resulted in Japan and other nations, having BSE .

The Harvard Study commissioned by USDA states that the existing firewall provided by the current feed rule makes the United States "extremely robust against the establishment of BSE." The Harvard Study also points out that if introduction of BSE had occurred via importation of live animals from the United Kingdom before 1988, that the current feed rule has minimized exposure, and began to eliminate the disease from the cattle population, even assuming less than complete compliance with the feed ban.

If the proposed rule is made final by FDA there may be significant economic, environmental and human and animal health impacts. The costs associated with the proposed rule will certainly lower the market value of animals over 30 months of age sold to packers. Renderers will be forced to increase their fees for the removal of dead

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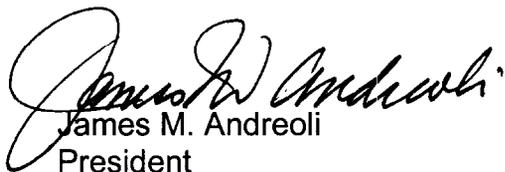
or disabled cattle to offset the labor and disposal costs associated with the rule. Smaller or less conscientious producers may elect to improperly dispose of dead cattle to avoid pickup fees and create further environmental and human and animal health issues, in addition to those imposed by placing raw animal materials in a landfill.

Consumer groups, animal rights activists and special interest groups will be very vocal in their support of further regulation. It is up to the FDA to realize that we DO have the safest and best beef and milk in the world, and that no further action is necessary.

I would like to summarize this letter by saying "ENOUGH IS ENOUGH" and it is not too late to tell Brussels, OIE, and the EU to "KISS OUR ASS".

Very Truly Yours,

BAKER COMMODITIES INC.


James M. Andreoli
President