

**KALUZYNY BROS., INC.**  
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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.

**Reference: Docket No. 2002N-0273, Substances Prohibited From use in Animal Food or Feed**

To Whom It May Concern:

This letter is in reference to FDA's proposed rule and the invitation to comment on substances prohibited from use in animal food or feed.

I disagree with the conclusion that further action proposed in the rule is necessary, urge the FDA to seriously consider comments from the National Renderers Association (NRA) and the 2005 Rendering Industry Study by Informa Economics, and demand the agency to do in-depth economic and environmental impact studies, based on current and representative data, before formalizing any proposed rule.

I continue to support scientifically based animal feeding regulations to restrict the use of certain animal proteins derived from mammalian tissues used in ruminant feeds. I agree that animal feed regulations need to be reviewed from time-to-time if new risks are identified or new, relevant science is brought to light. However, I do not see any new risks and agree with the NRA analysis of the facts and believe FDA's preliminary conclusion to remove cattle brains and spinal cord and rendered dead animals from all animal feed is not warranted. This action aimed at removing a very minute risk from BSE will increase risks from other diseases, cause environmental degradation, and cost much more than can be justified.

The 1997 feed rule is working and compliance is extremely high! No other Federal program has such a high compliance rate. Furthermore, the USDA enhanced surveillance testing program found only one indigenous cow tested positive for BSE out of more than 534,879 surveillance samples from high risk groups over the past 15 months showing the incidence of BSE in the U.S. to be near zero. The National Cattleman's Beef Association estimates an infection rate in the U.S. of one in more than 18 million cattle over 30 months of age—for all practical purposes it is statistically zero.

2002N-0273

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**Docket No. 2002N-0273 Comments**

**Page 2**

Applying the same rules as recommended in Europe is nonsense. The incidence in the U.S. is at least 500 fold lower than in the EU. The U.S. instituted preventive measures long before Europe, and the early action assured the infection was never established here.

Let's remember the EU has no FDA or agency like it. Had they had such an agency and promulgated the same rules as we have the disease would not have spread throughout Europe as it did. It is also worth noting that the rendering industry in Europe is heavily subsidized so that prohibited materials are picked up and processed avoiding a massive disposal problem.

I agree with NRA's statement that the feasibility of removing brains and spinal cords from dead stock is very low except under the best conditions of weather, climate, distance between production and rendering locations, age, size, and condition of cattle, worker skill, and equipment and technology. Renderers will be forced to charge higher collection fees to cover the increased costs of material disposal, processing, and lost product revenues or end the practice of collecting dead cattle altogether. The magnitude of the disposal problem the proposed rule would cause is much larger than FDA estimates.

FDA describes the primary benefit of the proposed rule as "elimination of the vast majority of the risk of spreading BSE to other cattle from intentional or unintentional use of non-ruminant feed for ruminants or cross-contamination of ruminant feed with non-ruminant feed or ingredients intended for non-ruminant feed." Let's be realistic and call it like it is; that vast amount of risk amounts to virtually nothing in the first place! The risks eliminated by the proposal are far smaller than the future risks of burying carcasses and disease agents on the farm in the best case scenario, and even far worse if inappropriate methods are used.

If the FDA requires dedicated facilities, equipment, storage, and transportation equipment to handle prohibited cattle materials, it may not be economically feasible for renderers to continue processing such material. It would be more likely for this material to be deposited in landfills, resulting in increased environmental exposure because of the high biological load of this material in its unprocessed state.

In summary, I believe this action aimed at removing an extremely minute risk from BSE will increase risks from other diseases, cause environmental degradation, and cost much more than can be justified—for renderers, producers, processors, and society.

Let us remember that the FDA's credibility rests with operating in the realm of science based decisions and rule making. To deviate from that core premise of operation is not only wrong but puts the agency careening down that proverbial long and slippery slope

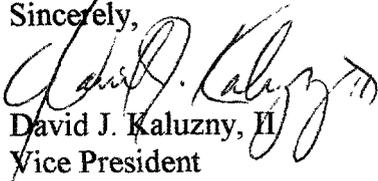
**Docket No. 2002N-0273 Comments**

**Page 3**

which leads to everyone questioning its authority and ability to both legally and ethically operate as a valid entity.

I therefore urge the FDA to take no further action to add restrictions to the 1997 feed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "David J. Kaluzny, II". The signature is written in a cursive style with a large, stylized initial "D".

David J. Kaluzny, II  
Vice President

DJK,II/dmw