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December 15, 2005

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

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

Dear Sir or Madam:

We wish to make comments on the FDA proposed rule that prohibits certain animal proteins from being utilized in non-ruminant animal feed which was published in the Federal Register on October 6, 2005.

Our company, Griffin Industries, Inc., is a 63 year old family owned and operated rendering company based in Kentucky with operations in 18 states in the lower Midwest and Southeast. We provide removal services and processing services to all animal sectors including all species of fallen animal removal service to farms, stockyards, and suburban locations. We have been actively involved with all of the "firewall programs" put in place by the FDA to help guard the U.S. Cattle Industry from the European cattle disease known as BSE.

We strongly oppose any additional restrictions of U.S. produced ruminant animal proteins be placed on the U.S. Feed Industry for the following reasons:

1. We **do not** have BSE risk at any level in our U.S. cattle population to warrant any additional feed restrictions.
2. Existing programs now in existence for over 8 years have clearly been effective in dealing with the apparently very small risk of BSE in the U.S. cattle herd.
3. The BSE Risk Analysis completed by Harvard University clearly shows a very low risk of this European disease entering into our cattle industry.

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4. The strongest evidence against additional feed restrictions is the good news generated with the USDA Surveillance/Testing that began in June of 2004 and continues today. The goal of testing 268,500 "highly suspect" animals was designed to detect one positive cow in 10 million with a 99 percent degree of confidence. The sampling program shows that the Harvard Study's worst case scenario of 10 positive cases gave an overestimate of risk, and even with that overstated risk, the Study showed BSE would not spread in the U.S. under existing controls. The testing program has full participation from all slaughtering facilities that tested animals that arrived for slaughter with neurological concerns and the U.S. Rendering Industry testing fallen animals from animal producers. The Rendering Industry has been responsible for over **70%** of all tests which were collected by USDA personnel and tested at their labs throughout the United States. The results of this far reaching program clearly show that we **do not have a BSE problem in the U.S. cattle population.** With current tests now over 550,000 with only 1 positive case, and that animal not being connected with being fed ruminant animal protein, demonstrates **once and for all** that we do not have BSE risks and that we have more serious risks to deal with so it's time to move on to the next challenge.
5. Proponents of additional feed restrictions, including your agency, that relate an "80% reduction risk" if the proposed rule is implemented is very misleading to consumers. The Harvard Risk Study identified if the proposed items of this proposed rule are restricted, then 6 animals will be saved from BSE in worst case scenario over many years which has nothing to do with humans at all! **BSE IS AN ANIMAL DISEASE.**
6. The FDA has not addressed the true financial and environmental impact of this proposed rule. The numbers being used by the FDA to financially score this proposed rule are not correct. Industry information as to tonnage of the SRM's and the number of fallen animals currently handled have been personally given to the FDA, USDA and OMB weeks before the proposed rule was published. Why were they ignored because they clearly showed the financial impact to be well above the threshold for such financial review? In addition, the environmental disposal issues affecting the SRM's and fallen animals alone would fully exceed such a threshold for financial requirements.
7. Our company will cease handling brains, spinal cords and all fallen ruminant animals as well as other fallen animals such as hogs, goats and horses. In our geographic area, our fallen animals are not as fresh as feedlot fallen animals and would be impossible to handle in the same manner, even if we installed different equipment currently being used.

8. The proposed rule puts all the responsibility and liability on the rendering industry to be "the police" for compliance for this proposed rule. It would be impossible for us to guarantee the age of affected animals with no animal I.D. system in place and no way to insure that our slaughterers, locker plants or custom slaughterers have removed all brains and spinal cords. These negative facts, along with the dramatic increase in administrative requirements and cost, will eliminate us from providing these services as we have for over 63 years.
9. The FDA's proposed action is clearly a serious concern for our State Agriculture, Veterinary, and Environmental Agencies. Their concerns of human health issues and improper alternative disposal problems are real and have no easy solution. They view this action as unwarranted and creating a much higher risk of human diseases. They also have concerns of their increased involvement with disposal issues both from increased personnel requirements with no additional financial support for such involvement. Our State Agencies really support our current efforts in rendering and the services we provide. It is a shame that the FDA doesn't realize the importance our industry provides our society as the only regulated provider for fallen animal removal service with its specialized transportation and highly regulated recycling facilities which helps to lower disposal cost of rather difficult materials.

In summary, we strongly oppose any change in your current programs of controlling the risk of BSE in the United States. We do not have this European disease and current FDA programs in place are working well and the USDA Testing Program is providing the scientific data to prove we do not have a BSE animal disease, let alone a human health threat! The FDA's decisions on such a serious proposed action must be based on science. What more impressive science results are needed than the great results from the testing program. Your agency must resist the political and international trade pressures that it is experiencing on this unwarranted proposed regulation and have the backbone to relate to the media and our society that the BSE issue is winding down and the agency has moved on to much more concerning issues.

Thank you for the opportunity to offer our concerns for your proposed regulation and as always, we stand ready to help as we have for the past 63 years.

Respectively Submitted,

Dennis B. Griffin

**DENNIS B. GRIFFIN, CHAIRMAN
GRIFFIN INDUSTRIES, INC.**