GRIFFIN INDUSTRIES, INC.

Dennis B. Griffin, Chairman

January 28, 2003

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

Dear Sir or Madam:

Griffin Industries Inc., is a family owned and operated business, and a recognized leader in the production of top quality fats and proteins since 1943. The company is likely the most diversified rendering company in the world with over 30 locations throughout the United States serving both the domestic and international markets. As such, the company has a definite interest in any proposed regulatory initiatives that could impact the rendering industry, and takes the opportunity to address Docket No. 02N-0273, an Advance Notice of Proposed Rulemaking (ANPR), in which the agency is soliciting information, comments and opinions on potential changes to its existing rule: "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" with special pertinence to five specific questions posed by the agency.

The agency identified the five issues in a question format as of special relevance to the ANPR:

1. Excluding Brain and Spinal Cord From Rendered Animal Products
2. Use of Poultry Litter in Cattle Feed
3. Use of Pet Food in Ruminant Feed
4. Preventing Cross Contamination
5. Eliminating the Plate Waste Exemption

Griffin Industries has and continues to support the current scientifically based animal feeding regulations that restrict the use of certain animal proteins derived from mammalian tissues (with the current exemptions) for use in ruminant feed. The company has, by tradition, pursued conservative measures to preclude hazards that could contribute to any potential for disease transmission from the production cycle. But, a careful scientific analysis of the facts suggests that **no regulatory changes are warranted at this time.** The following reasons support our recommendations:

02N-0273 C 22

4221 ALEXANDRIA PIKE • COLD SPRING, KY 41076-1897

(859) 781-2010 • FAX (859) 572-2569 • WWW.GRIFFININD.COM

1. The Food and Drug Administration (FDA) in 1997 adopted the current feed restrictions based on a review of industry practices and sound science. Griffin Industries is of the opinion that the existing animal feed regulations are appropriate given the miniscule level of potential risk for an outbreak of BSE.
2. All the current indications, based on the government's own inspection audits and monitoring programs, demonstrate that in spite of extensive testing of over 20,000 brains that exceeds the international standards of 4,000 brains recommended by the Office International des Epizooties (OIE), the world organization for animal health, the United States is still free of bovine spongiform encephalopathy (BSE).
3. FDA's inspection oversight of the BSE feed rule (21 CFR 589.2000) indicates a 99.2 percent compliance rate. This is most likely the best conformance finding for compliance in the agency's history and demonstrates the industry's interest in food safety.
4. The U.S. BSE prevention strategy has been developed to include multiple programs commonly described as a "triple firewall" approach with the major goals of (a) a ban on the importation of cattle and beef products from countries with BSE; (b) a statistically sound program to monitor for the presence of the disease, heightening risk-based epidemiology in the process; and (c) ruminant feeding restrictions that are in place and constitute the core of the feed rule.
5. Prior to the Harvard University Center for Risk Analysis findings that the "U.S. is highly resistant to an introduction of BSE or a similar disease," the agency's own internal risk assessment audits done as early as 1997, parallels the findings of the Harvard scientists. (Many reputable epidemiologists in this country and extern to the country, consider the Harvard BSE risk assessment, contracted by two agencies of the U.S. government, was probably the most comprehensive study of an animal disease and the risk factors associated with it, ever studied.)
6. Griffin Industries is equally convinced that in the absence of any changes in the current risk factors that could contribute to a disease outbreak, **the rigorous enforcement of the existing rule**, including the excellent compliance by the industry, will result in a **far greater reduction of risk** that all of the proposed changes in the ANPR.
7. Change or modification of an existing regulation/rule should only be considered when there is new evidence, validated and affirmed by science, that a change is definitely indicated.

While, as an industry, we commend the government's proactive and preventive approach to control this serious disease, nonetheless, it must be clearly recognized that the success of our country's prevention and control initiatives was a clear demonstration of all involved sectors working together collaboratively to keep this enigmatic disease, with its public health implications, from gaining a foothold in the United States. In reality, we have been doing this for 16 years, and currently, with all the instituted controls, we can safely say that the country has today the lowest level of risk factors since the disease was first reported in 1986. This fact should be celebrated as a success story to counter the constant doubts and lingering concerns.

Griffin Industries fully recognizes that BSE is a complex disease and complements the agency for its continuing examination of options, however, as a company, we feel that approximately 6 years since the rule has been in place, the process is working well based on the agency's own official compliance findings, and the rendering industry's own third party inspection audits. We recommit our resources to work diligently with the agency to ensure continuing compliance, but see absolutely no need for any modifications or changes of the present rule, unless as implied earlier, new risk factors are clearly identified that will dictate otherwise. In fact, we feel that change of the rule will send a wrong message and serve to create unnecessary uncertainty in our country that has no evidence of the disease. In fact, we truly believe it is time for your agency to get proactive and consider development of a U.S./FDA rating system that rates countries as to their efforts in prevention of BSE rather than waiting for the BSE infected E.U. to rate the United States in a negative manner and severely effect both domestic and international trade of our BSE safe products.

In summary, as an active participant in this program, we see no need for changes to the existing rule. Keep it simple and **enforce** the existing rule is the most effective action currently needed and also having the FDA relate its current program achievements in inspections and compliance success rate would be beneficial to all of our society and users of animal proteins both domestically and internationally! BSE is still an E.U. problem and we should not conform to their rules and regulations parameters. E.U.'s continued assaults on U.S. products are not food safety issues, but driven by E.U.'s inability to compete with U.S. products economically.

We appreciate this opportunity to comment and express our convictions, and summarize by stating for emphasis that the instituted controls in our country since 1987, and a rule in place since 1997, there is a time for closure. How long of a precautionary period is necessary to assure the U.S. does not experience BSE?

If our company can be a resource, or serve in any way to assist in the examination of objective options to heighten biosecurity of feed ingredients and feed, please do not hesitate to involve us.

Sincerely,

DENNIS B. GRIFFIN, CHAIRMAN
GRIFFIN INDUSTRIES, INC.