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August 13, 2004

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

RE: Docket No. 2004N-0264

The Kansas Livestock Association (KLA) has carefully reviewed the Food and Drug Administration (FDA) Advanced Notice of Proposed Rule-Making (ANPRM) published as Docket No. 2004N-0264. KLA is a trade association representing the business interests of nearly 6,000 members. KLA members come from the cow-calf, stocker and feedlot segments of the cattle business, an industry that annually generates over \$5 billion in cash receipts in Kansas.

KLA appreciates the opportunity to provide comments on the FDA proposals designed to evaluate the need for, benefits of and implications of taking additional actions to prevent the amplification and spread of Bovine Spongiform Encephalopathy (BSE) in the United States. In addition to these comments, KLA supports the comments submitted by the National Cattlemen's Beef Association.

KLA members are concerned with the statement, "FDA has reached a preliminary conclusion that it should propose to remove SRMs from all animal feed and is currently working on a proposal to accomplish this goal." We believe the current risk analysis data and the long history of proactive BSE prevention measures do not support the FDA conclusion that additional feed restrictions are necessary.

The United States has a 15-year history of BSE prevention efforts. In 1989, the Animal and Plant Health Inspection Service (APHIS) prohibited the importation of live cattle, other ruminants and most rendered protein products from countries where BSE is known to exist. In 1997, the prohibition was extended to ruminants and ruminant products from all European countries. The prohibition was expanded further in 2000 by restricting imports of rendered protein products from any animal species from BSE-restricted regions.

Beginning in August 1997, the FDA instituted a ruminant feed ban. The ban prohibits the use of most mammalian protein in feeds for ruminant animals.

The United States implemented an active BSE surveillance program in 1990. Since 1993, this surveillance effort has met or exceeded international standards. For the past three

years, the surveillance effort was designed to detect BSE at a rate of one case in one million cattle.

Beginning in June 2004, USDA implemented an expanded BSE surveillance effort to sample and test over 200,000 animals. This sample size is designed to find BSE if it occurs at a rate as low as one case in 10 million head of cattle.

In 1998, USDA contracted with the Harvard Center for Risk Analysis (Harvard) and the Center for Computational Epidemiology at Tuskegee University (Tuskegee) to conduct a comprehensive evaluation of the BSE risk in the United States. The Harvard-Tuskegee study found the U.S. is highly resistant to any proliferation of BSE and that measures taken by U.S. regulatory agencies make the U.S. robust against the spread of BSE to animals or humans should it be introduced into this country.

In January 2004, USDA implemented additional restrictions to enhance BSE prevention in the United States. These measures included further restrictions on the use of specified risk materials, limitations on the use of advanced meat recovery and prohibition of the use of certain stunning devices.

Compliance with the existing FDA ruminant feed ban is very high. FDA reported on July 29, 2004, that from the most recent round of inspections of 2,901 active handlers of restricted materials, only 17 firms (0.6%) were classified as Official Action Indicated (OAI). These firms were required to take corrective action and were subject to re-inspection. This level of compliance with the ruminant feed rule is well within the set of assumptions utilized by the 1998 Harvard Risk Analysis.

These inspection results show firms are achieving an extremely high level of compliance. BSE risks continue to be reduced and no evidence exists to show the disease prevalence exceeds the range determined by the Harvard-Tuskegee study. The feed ban compliance and ongoing surveillance effort demonstrate the effectiveness of U.S. BSE prevention measures and refute the need for additional BSE prevention measures to protect cattle health.

It is imperative that FDA base its decisions to implement additional regulations to prevent the amplification and spread of BSE on science and risk analysis. In this regard, there is no data to suggest the risk of BSE in the United States has changed since FDA developed the 1997 feed regulations. In addition, FDA data on feed ban compliance is exemplary. Thus, our low BSE risk, coupled with a high degree of feed ban compliance, clearly indicates there is no risk-based or scientific justification to expand the BSE prevention measures to include removal of SRMs or other measures as detailed in the ANPRM.

It appears the sole basis for this ANPRM is the International Review Team (IRT) report. It is important to note that the IRT did not provide a single reference or data set to support their assumptions that additional steps likely were necessary in the U.S. to prevent the amplification and spread of BSE. In fact, their assumption that additional actions were warranted based upon “epidemiological evidence in the United Kingdom” is

inconsistent with the principles of risk analysis. These principles include that you must analyze risk within the given context of the country and its systems rather than simply extrapolate from existing data and experiences. This is exactly what the Harvard study accomplished.

It actually seems the IRT predicated its recommendations upon data to be gathered as a result of the large, one-time sample of the high-risk cattle population that is being carried out at this time. Data from this expanded surveillance program must be used within the context of additional analysis using the Harvard model. This process and data utilization must be the foundation of our decision-making process. If the expanded surveillance program were to alter our BSE prevalence assumptions included in the Harvard BSE Risk Analysis, then and only then, would additional BSE prevention measures be appropriate for consideration.

KLA supports following a science and risk-analysis-based BSE prevention program. We support the use of dedicated equipment, facilities and production lines for firms that handle prohibited ruminant feed. KLA members also support limitations on the use of poultry litter in ruminant feed.

KLA cannot support any other additions to the current ruminant feed ban unless and until valid risk analysis determines its necessity. We strongly oppose removing SRMs from all animal feed, including pet food. We also oppose prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

KLA believes in making science-based decisions regarding BSE prevention measures. We do not believe science justifies the additional feed restrictions outlined in the ANPRM. We appreciate the opportunity to provide these comments and stand ready to answer questions and provide additional input when needed.

Sincerely,

A handwritten signature in cursive script that reads "Terry Handke".

Mr. Terry Handke
President