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AVMA 2005 0110 011

December 12, 2005

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

RE: Docket No. 2002N-0273

Dear Sir or Madam:

The American Veterinary Medical Association, on behalf of its more than 73,000 members, provides the following comments on the proposed rule regarding substances prohibited from use in animal food or feed. As the authorized voice for the veterinary profession, the AVMA works to advance the science and art of veterinary medicine, including its relationship to public health, biological science, and agriculture.

The AVMA applauds the decision of FDA to not propose a prohibition on the use of blood and blood products, which include plasma-based therapeutics. The comments of the AVMA in response to the 2004 Advance Notice of Proposed Rulemaking summarized the importance of these products for animal health and welfare. The AVMA comments also summarized the scientific evidence that does not demonstrate a measurable risk of BSE transmission from these products. We note and agree with the conclusion of FDA that is stated in the current proposed rule that, "We did not include this option in this proposed rule because we could not at this time show any BSE risk reduction as a result of such a prohibition, and these products have beneficial effects in ruminant feed."

While we believe that the FDA has achieved a proper balance in this proposed rule between BSE risk reduction and negative impacts on animal disease surveillance activities and the environment, we are concerned that the balance may not be appropriate if the estimates and assumptions in the proposed rule are not accurate.

The proposed rule estimates a 90% risk reduction as a result of the proposed prohibitions of cattle brains and spinal cords from the feed or food of all animals. While that appears to be a large reduction, in absolute terms it is a small reduction because the risk of BSE in the United States is already small. As of December 2, 2005, the United States Department of Agriculture BSE enhanced surveillance program had tested 21,216 clinically normal adult

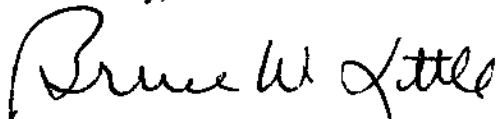
animals and 542,103 higher risk animals since June 1, 2004. Only one animal tested positive.

We are concerned that the FDA may be underestimating the negative effects on the environment and the alternative disposal costs associated with the proposed change. The FDA is transparent in noting, "FDA acknowledges that there is some uncertainty regarding the amount of material that will require alternative disposal as a result of the proposed requirements pertaining to cattle not inspected and passed for human consumption (i.e., dead stock and nonambulatory disabled cattle)" and "FDA seeks comment and further information on the feasibility of removing brain and spinal cord from cattle not inspected and passed for human consumption and on the impact of this proposed rule on the number of these cattle that would be disposed of by rendering". The first statement refers to disposal required as an alternative to rendering for use in animal feed. FDA believes that such increases will be modest but this is based on the assumptions that brains and spinal cords can and will be removed from most animals being rendered and that there will not be a substantial reduction in the number of animals being rendered for use in animal feed. Reportedly, many relatively remote locations have already been excluded from renderer pickups due to price and regulatory changes over the past ten years. FDA concluded that the prohibitions currently proposed would not trigger wider, rippling effects through the renderers' situation. Based on industry information, the FDA estimates an increase of 3.5% in the number of cattle that will require on-farm disposal. If the assumptions are not accurate, the increase in on-farm disposal could be much larger. The FDA is requesting comment on the number and percent of cattle not inspected and passed for human consumption that are currently rendered, as well as the expected number of additional cattle that would be disposed of on farms or elsewhere due to this proposed rule. Hopefully, FDA will be provided with that information by those knowledgeable of the industry.

A related concern of the AVMA is the potential effect on animal disease surveillance activities. Currently, cattle presented to rendering plants are one of the sources of samples for testing for BSE in the high risk population of cattle. If the proposed rule significantly reduces the number of animals shipped to rendering plants, the number of samples tested for BSE could be negatively impacted.

We appreciate the opportunity to comment on this proposed rule.

Sincerely,



Bruce W. Little, DVM
Executive Vice President