



## AMERICAN VETERINARY MEDICAL ASSOCIATION

1931 N. MEACHAM ROAD, SUITE 100 • SCHAUMBURG, ILLINOIS, 60173-4360

PHONE (847) 925-8070 • FAX (847) 925-1329 • www.avma.org

August 5, 2004

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

### RE: DOCKET NUMBER 2004N-0264, RIN 0910-AF46

Dear Sir or Madam:

The American Veterinary Medical Association appreciates the opportunity to provide comments regarding considerations for further federal action to mitigate bovine spongiform encephalopathy. Our comments specifically address question 15 – Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

The short answer to the question is no, there is not scientific evidence that demonstrates that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants. We are aware of the report of Hunter *et al.*<sup>1</sup> of transmission of BSE to a second sheep through transfusion of a large quantity of blood from sheep experimentally infected with BSE. We are also aware of the two suspected human cases of vCJD possibly transmitted through blood transfusion. However, to our knowledge BSE has not been transferred to cattle through transfusion of blood or blood products or through feeding of blood or blood products. This may be related to differences in pathogenesis of the disease in different species. For example, Hunter states, “Sheep infected orally with BSE show widespread deposition of PrP<sup>Sc</sup> in the lymphoreticular system (LRS) (Foster *et al.*, 1996a, 2001b), similar to that seen in human vCJD patients. In contrast, in cases of sporadic human CJD and cattle BSE, peripheral pathogenesis does not appear to involve the LRS (Hill *et al.*, 1999; Wells *et al.*, 1998).”

The possible change in ruminant feeding presaged by this question is of significant interest and concern to the veterinary profession. Specifically there are products that are derived from bovine plasma that veterinarians have successfully utilized to improve animal health and welfare, including in calves as a scientifically recognized alternative to inferior or infected colostrum (e.g., colostrum infected with the causative agent of Johne’s disease). In addition, when colostrum is not available these products are the only products available for newborn calves that provide a full complement of immunoglobulin as a replacement for colostrum.

<sup>1</sup> Hunter N, et al. Transmission of prion diseases by blood transfusion. *Journal of General Virology* (2002): 83; 2897-2905.

2004N-0264

C22

Veterinarians understand the need by the FDA to evaluate all aspects of BSE control. However based on the current scientific evidence, the AVMA believes that, given proper controls on stunning and collection from animals less than 30 months old, bovine blood and blood products represent no measurable risk for BSE transmission. Therefore, we believe that a feed rule change to ban the use of blood or blood products in colostrum replacers or supplements will unnecessarily remove a safe and effective group of animal health and nutrition products.

Sincerely,

A handwritten signature in black ink that reads "Bruce W. Little". The signature is written in a cursive, flowing style.

Bruce W. Little, DVM  
Executive Vice President

BWL/AALC/lpv