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April 7, 2004

Dr. Karen James-Preston
Director
Technical Trade Services
National Center for Import and Export
VS, APHIS
4700 River Road Unit 38
Riverdale, MD 20737-1231

Re: Docket Number 03-080-1: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities; PhRMA comments on proposed rule.

Dear Dr. James-Preston:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is providing comment to the import rule proposed by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service to amend existing import regulations to allow the import of live ruminants and ruminant products from regions presenting a minimal risk of bovine spongiform encephalopathy (BSE). We provided comments on January 12, 2004, to the original docket proposing the minimal risk rule, Docket Number 03-080-1. In this letter, we reinforce our original comments and update our recommendations based on recent developments.

PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA members invested an estimated \$33.2 billion in 2003 in discovering and developing new medicines. PhRMA companies are

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leading the way in the search for new cures.

As we stated in our original letter, animal-derived materials are ubiquitous in our lives and have many important uses. In pharmaceutical manufacturing, animal-derived materials are often sourced and used according to guidelines issued by regulatory authorities and the specifications outlined by the quality systems of the pharmaceutical company. One important consideration in sourcing bovine-derived materials is the BSE status of the country where the animal lived.

The BSE status of countries has historically been determined by the USDA in a binary fashion: either the country is considered BSE free or it is not. A binary system of BSE categorization is no longer appropriate as there are numerous factors that influence the spread of the disease. This proposed rule recognizes that while a country may have animals diagnosed with BSE, evaluation of the measures put in place to halt the spread of the disease is as crucial as identification of the disease. PhRMA continues to support a science-based approach to identifying minimal risk regions for BSE, as outlined in the proposed rule.

Recent experience in the United States supports this science-based approach. The completed epidemiological investigation into the BSE positive animal identified in Washington State in December 2003 established the animal was born prior to the

implementation of the most important BSE firewall, the ruminant to ruminant feed ban. Now that the epidemiological investigation is complete, PhRMA supports implementation of the proposed rule.

The full benefit of this risk-based approach to categorization will only be realized following international harmonization. Agreement on the designation of minimal risk regions will be invaluable in alleviating regulatory and trade barriers. Efforts must continue to communicate this science-based concept to our trading partners worldwide. On December 30, 2003, Secretary Veneman announced additional safeguards to bolster the US protection systems against BSE. PhRMA applauds the implementation of these safeguards and has encouraged the licensure of an appropriately validated, rapid test for BSE to aid in returning timely results in the ongoing BSE surveillance program. We are pleased that USDA has evaluated and is licensing rapid tests. We fully support preventing tested animals from entering the production stream until negative BSE test results are obtained.

Timely implementation of a mandatory cattle track and trace system will enhance the ability to determine cattle movement within the system from birth to death and facilitate investigation if BSE is again identified. Specifically, PhRMA supports mandatory identification and tracking of bovines from their birth herd to slaughter. In order to facilitate tracing of herd-mates and progeny of a BSE -infected animal, as specified in

the Office International des Epizooties (OIE) classification schemes for the lower risk categories, a new requirement for permanent identification is proposed. Progeny of BSE infected cows born within 2 years of disease onset and herd-mates that consumed the same potentially infected feed must have their movement controlled and be completely destroyed. To avoid a massive, indiscriminate cull that would be inevitable under OIE guidelines if a BSE infected cow is again identified in the United States, mandatory cattle identification and traceability appears to be the only solution.

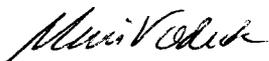
PhRMA supports USDA plans to increase BSE surveillance and target BSE testing to the populations most likely to test positive for BSE. Because PhRMA member companies distribute their products globally, we encourage the adoption of surveillance goals that harmonize with international practice, such as surveillance of a sub-set of apparently healthy animals over 30 months, including older animals born before the ruminant to ruminant feed ban. Thus we applaud the recent announcement by the USDA to include this population in the expanded surveillance program. We also support recent USDA guidelines to test all downer cows and the new safeguard to exclude downer animals from slaughter for human consumption.

We recommend working with other government agencies (e.g., Food and Drug Administration (FDA)) to enhance the ruminant to ruminant feed ban enacted in 1997. The current exemptions in the feed ban must be critically examined in light of the

developments in Canada and Washington State. Serious consideration should be given to prohibiting all specified risk material in rendered product used for non-ruminant feed, due to the potential for “on farm” cross-contamination with feed designated for ruminants. We strongly recommend implementation of measures to ensure that specified risk material is excluded from all animal feed.

We applaud the aggressive efforts of the USDA and the FDA in support of the investigation to determine the source of the infected animal in Washington State and the rapid implementation of the additional safeguards to bolster the US protection systems against BSE. All measures designed to prevent the amplification and spread of BSE should be reevaluated periodically in order to determine their effectiveness and to document any unintended consequences of implementing the safeguards. We appreciate the opportunity to share our comments with respect to USDA’s proposed rule concerning the designation of minimal risk regions for BSE and the importation of commodities. Please do not hesitate to contact me should you have any questions.

Sincerely,



Marie Vodicka, PhD

Cc: Dr. Lester Crawford, FDA