Serologicals® Corporation

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9 December 2005

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

Re: Docket No: 2002N-0273 (formerly Docket No. 02N-0273)

Substances Prohibited From Use in Animal Food and Feed

Dear Sir or Madame:

Serologicals Corporation is a global provider of biological products to life science companies. The Company's products are essential for the research, development and manufacturing of biologically based diagnostic, pharmaceutical and biological products. Our customers include many of the leading research institutions, diagnostic and pharmaceutical companies throughout the world. The Company's products and technologies are used in a wide variety of applications within the areas of neurobiology, cell signaling, oncology, angiogenesis, apoptosis, developmental biology, cellular physiology, hematology, immunology, cardiology, infectious diseases and molecular biology.

A number of our products are derived from bovine blood or other bovine tissues sourced in the United States, hence the overall health of the national herd is extremely important to our company as well as to our customers and their patients. Some of our bovine based products are used in the manufacture of vaccines and drugs for humans, hence it is critical that all measures are taken to assure these are safe and free from disease especially Bovine Spongiform Encephalopathy (BSE). The most effective way to insure this is to create a system which processes cattle that are BSE free. As a company there are a number of precautions that we can take by our strict specifications but many of the needed precautions require the force of federal regulation, hence we appreciate the opportunity to submit comments to this very important proposed rule.

After the identification of bovine spongiform encephalopathy (BSE) in indigenous North American cattle, the U.S. Department of Agriculture (USDA) responded rapidly to implement measures to protect public health in regard to food. Our company recognizes and supports the importance of the current feed ban which went into effect in August 1997. However, given what is known about the epidemiology and characteristically long incubation period of BSE, we urge

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the FDA to act without further delay and implement additional measures which will reduce the risk of BSE recycling in the US cattle herd.

We feel that for the FDA to provide a more comprehensive and protective feed ban, specified risk materials (SRMs) and deadstock must be removed from all animal feed and that legal exemptions which allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued.

SRMs, as defined by the USDA, are tissues which, in a BSE infected animal, are known to either harbor BSE infectivity or to be closely associated with infectivity. If SRMs are not removed, they may introduce BSE infectivity and continue to provide a source of animal feed contamination. Rendering will reduce infectivity but it will not totally eliminate it. This is significant as research in the United Kingdom has shown that a calf may be infected with BSE by the ingestion of as little as .001 gram of untreated brain.

The current proposed rule falls short of this and would still leave a potential source of infectivity in the system. In fact by the FDA's own statement the exempted tissues which are known to have infectivity (such as distal ileum, DRGs, etc) would cumulatively amount to 10% of the infectivity in an infected animal. This proposed rule would still allow for the possibility that cattle could be exposed to BSE through:

1. Feeding of materials currently subject to legal exemptions from the ban (*e.g.*, poultry litter, plate waste)
2. Cross feeding (the feeding of non-ruminant rations to ruminants) on farms; and
3. Cross contamination of ruminant and non-ruminant feed

We are most concerned that the FDA has chosen to include a provision which would allow tissues from deadstock into the feed chain. We do not support the provision to allow the removal of brain and spinal cord from down and deadstock over 30 months of age for several reasons. These are the animals with the highest level of infectivity in tissues which include more than brain and spinal cord. We do not feel that there can be adequate removal and enforcement of this regulation especially during warmer weather. In addition there is emerging information that at end stage disease, infectivity may also be included in additional tissues such as peripheral nerves (Buschmann and Groschup, 2005).

Leaving the tissues from these cattle in the animal feed chain will effectively nullify the intent of this regulation. This point is illustrated by the 2001 Harvard risk assessment model which demonstrated that eliminating dead and downer, 4D cattle, from the feed stream was a disproportionately effective means of reducing the risk of re-infection. *"The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if the disease were introduced." The base case scenario showed that the mean total number of ID50s (i.e., dosage sufficient to infect 50 percent of exposed cattle) from healthy animals at slaughter presented to the food/feed system was 1500. The mean total number of ID50s from adult cattle*

deadstock presented to the feed system was 37,000. This illustrates the risk of "4D cattle" (i.e., deadstock).

From the Harvard Risk Assessment, 2001, Appendix 3A Base Case and Harvard Risk Assessment, 2001 Executive Summary

Serologicals and companies like ours which supply components of drugs and biologicals have a responsibility to the manufacturers of these products, the medical community and their patients as well as regulatory agencies throughout the world to provide the safest products as possible. Since there is no test for BSE in live cattle or for product, the regulatory agencies throughout the world expect us to reduce or eliminate risk via sourcing criteria. These parameters may include but not be limited to country of origin, herd of origin, age of the animal, etc. The United States is no longer a country with negligible risk, hence individual animal criteria has become more important. In fact other Centers of the FDA have stated that more attention should be given to sourcing from herds likely to be a source of BSE free animals. The exemptions in the current ban as well as in the newly proposed rule make this difficult if not impossible as there are still legal avenues for ruminants to consume potentially contaminated ruminant protein. In addition, the USDA still has not implemented a system of identification and traceability.

Serologicals urges agencies of the US government to work with academia and industry on research in the following areas:

- Methods to inactivate TSEs agents which then may allow a product to be used and even fed to animals without risk
- Alternative uses for animal byproducts which would maintain value

Serologicals will continue to work with the FDA and other government agencies to implement a strong BSE risk control program. Serologicals would like to reiterate our opinion that for the FDA to provide a more comprehensive and protective feed ban, specified risk materials (SRMs) and deadstock must be removed from all animal feed and that legal exemptions which allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued. Thank you for the opportunity to submit these comments to the public record.

Respectfully,

SEROLOGICALS CORPORATION

James J. Kramer, Ph.D.

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