



Doctors' Research, Inc.
Nutrition from food, what a concept!
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Restrictions on SRMs from Dietary Supplements

Dear U.S. Food and Drug Administration:

We at Doctors' Research Inc. have reviewed the expanded "Mad Cow" safeguards that your agency has put in as interim and proposed regulations.

The safeguard that is the most concern to us is the one related to restricting certain bovine tissue from use in human food. It is similar to one that we got from your website today:

"21 CFR Part 589 [Docket No. 02N-0273] RIN 0910-AC37 I. Excluding Brain and Spinal Cord From Rendered Animal Products The Harvard risk assessment identified removal of high risk tissues, such as brain, spinal cord, gut, and eyes, from human food and rendered material for animal feed, as a way to dramatically reduce the potential exposure of cattle and humans to the BSE agent. In response to the Harvard study, USDA's Food Safety Inspection Service is considering rulemaking to ban high risk tissues obtained from certain populations of cattle (also called specified risk materials or SRMs) from use in human food. Should USDA publish such a proposal, FDA may also propose that SRMs be prohibited from going into rendered material. Therefore, FDA is asking for comments on the following questions: [sbull] Should high risk materials, such as brain and spinal cord from ruminants 2 years of age and older, be excluded from all rendered products? [sbull] How feasible would it be for the rendering industry to implement such an exclusion? [sbull] What will be the adverse and positive impacts (economic, environmental, health, etc.) resulting from a brain and spinal cord exclusion?"

We would like to address two questions that were raised within the proposed regulations.

1. *Should high risk materials, such as brain and spinal cord from ruminants 2 years of age and older, be excluded from all rendered products?*

The simply answer to this is no. Your press release dated 1/26/04 titled *Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission* has expanded that period from 2 years to 30 months of age, which we do feel is an improvement. However, we also feel that exceptions should be considered for tissues coming from low-risk countries such as New Zealand which have had stronger protections to prevent BSE. Also, certified cattle raised domestically that did not consume any meat or meat by-products, such as from certified organic farms, should probably also be exempted.

2. *What will be the adverse and positive impacts (economic, environmental, health, etc.) resulting from a brain and spinal cord exclusion?*

The immediate impact of the questioned interim regulation is that many Americans are going to feel worse. One major nutritional supplement company discontinued the sale of a dietary supplement that we have used successfully for about a decade—other suppliers are intending to do the same or at least change their products.

We helped hundreds, if not thousands, of people with those products with a variety of health issues such as depression, Alzheimer's, memory disorders, mood swings, anger control, etc. We also have also used other products with eye tissue that have helped many improve vision (bovine eye tissue appears to have clinical efficacy for certain forms of macular degeneration).

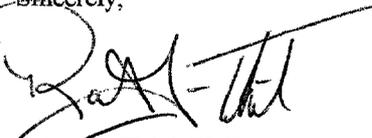
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We, along with Cognitive Enhancement Research Institute, First National University, and the Center for Natural Health Research, are currently conducting research on cognitive decline associated with Down syndrome and Alzheimer's (this is expected to be submitted for peer-review in late Spring). We believe that since bovine brain and spinal tissues contain some small amount of stem cells, as well as naturally occurring substances such as phosphatidyl serine, that any total ban will seriously harm our research. And will have adverse affects on the health of many Americans.

We understand that we are only a small company, but we felt that we should share our position with you as many Americans will not benefit from much of our research if commercially available food sources of the selected substances become less available.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Thiel", written over a horizontal line.

Robert J. Thiel, Ph.D.

President

DOCTORS' RESEARCH INC.