BIOTECHNOLOGY INDUSTRY ORGANIZATION
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March 13, 2007

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

Re: Docket No. 2005N-0373, Proposed Rule on the Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants.

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) provides the following comments. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) *Proposed Rule on the Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants.*

We recognize that FDA is proposing this new rule with the goal of strengthening defenses against the potential risk of, exposure to, and spread of bovine spongiform encephalopathy (BSE) and related human disease, and we support this goal. However, we offer the following general comment and related specific concerns.

General Comment

The proposed rule does not appear to take into account materials that would be sourced from live, healthy cattle such as transgenic cattle that are not intended for human or animal consumption. Healthy cattle can serve as donor animals (e.g. donors of plasma) as long as they are ambulatory or do not have other signs of disease.

Specific Comments

Section §300.200 (a) Definitions, (1) Prohibited materials

BIO members are engaged in research and development of biologics produced in transgenic cattle. Transgenic cattle used to produce biologics would not necessarily be approved for human food or animal feed, but would be produced in herds where all inputs are controlled to mitigate risk of exposure to BSE. Therefore, BIO supports addition of another category of materials that are not "prohibited materials" (p 118). The following should be added so that these are not prohibited materials: "materials sourced from live, healthy cattle produced under controlled conditions that have been approved for producing biologics but will not be used for human consumption (food)."

Section §300.200 (a) Definitions, (2) Inspected and passed

In the proposed rule, a material such as plasma sourced from healthy, live donor cattle, would be considered a prohibited material, because the animals would continue to live and not be "inspected and passed for human consumption by the appropriate regulatory authority ..." (p 118). BIO supports adding to the definition that "Live cattle inspected and passed through screening by a veterinarian for donation of biological samples (ie. milk, blood, plasma) are also acceptable."

Section §300.200 (c) Records (1) - (5)

As applicants / manufacturers operating under cGMPs, we have internal standards and processes (e.g., Supplier Qualification Programs, Supplier Quality Agreements) to minimize the risk of transmitting BSE. We believe that our current BSE programs meet the "Records" requirements of the proposed rule for our material suppliers and we ask FDA to clarify that biotechnology companies should not be required as applicants / manufacturers to query all intermediaries in the supply chain.

Conclusion

BIO appreciates this opportunity to comment on FDA's *Proposed Rule on the Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants*. We look forward to seeing the final rule, and would be pleased to work with FDA to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Sara Radcliffe
Vice President
Science and Regulatory Affairs