

May 1, 2007

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

RE: Docket No. 2003N-0573

The National Cattlemen's Beef Association (NCBA) has carefully evaluated the United States Department of Health and Human Services Food and Drug Administration, Center for Veterinary Medicine's (FDA, CVM) draft risk assessment, proposed risk management plan and draft guidance documents published in the Federal Register on December 28, 2006 and entitled respectively: "Animal Cloning: A Draft Risk Assessment," "Animal Cloning: Proposed Risk Management Plan For Clones and Their Progeny" and "Guidance for Industry Use of Edible Products From Animal Clones or Their Progeny For Human Food or Animal Feed (Guideline No. 179)."

NCBA's comments are based on a careful analysis of the draft risk assessment, proposed risk management plan, guidance for industry and accompanying documents. NCBA appreciates the opportunity to review and comment on this important topic as part of the ongoing scientific process. Producer-directed and consumer-focused, the National Cattlemen's Beef Association is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

NCBA is supportive of FDA following a science-based process for the risk assessment, management proposal and guidelines.

NCBA is supportive of open channels of communication between Federal Government regulatory agencies and professional and scientific organizations. Additionally, maintaining open and informal communication with animal clone producers and researchers will be important as technologies such as cloning further develop and progress.

NCBA is supportive of innovative science and technology that improve our United States cattle herd, supportive of improving the genetics of cattle, and supportive of using all available responsible approved tools (including technology) to continually enhance our ability to produce safe, healthy, nutritious and affordable cattle and beef.

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NCBA supports the development of cloning technology as another assisted reproduction tool that would be available to producers. U.S. cattle producers have a rich and long history of being innovators and leaders to produce and maintain a healthy U.S. cattle herd. Cattlemen have been responsibly using safe, assisted reproduction methods for many years and cloning is just another one of these methods.

Cloning is one of many breeding technologies (e.g. artificial insemination, embryo transfer) ranchers have available to increase reproduction of the healthiest, highest quality animals.

Cloning could be a tool to help in the effort to continually improve genetics and in saving important genetics of the U.S. cattle herd. The technology would allow breeders to introduce naturally occurring desirable traits, like disease resistance, similar to what is done through other breeding technology, only quicker.

Beef producers use safe and efficient methods to provide wholesome, high-quality beef for consumers and cloning is another method that may be used in the future. Cloning could allow cattle ranchers to select animals which produce the highest quality beef to give consumers an even greater taste and more consistent, beef eating experience.

Cloning is simply assisted reproduction that produces a “twin” (i.e. identical twins of donor animals, just born at different times); it does not add, change or modify genes to produce a new trait. Clones are virtually indistinguishable from their non-cloned counterparts and clones and their progeny are all born naturally.

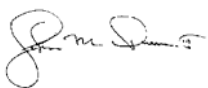
Additionally, extensive study (covering more than thirty years of research of cloning, including several generations of livestock) into all publicly available information about the safety of cloning in regards to both human and animal health have shown that clones and their progeny do not pose any unique risks to the animals involved relative to other assisted reproductive technologies or natural mating, and foods derived from animal clones or their progeny do not pose any unique risks for human consumption. NCBA urges FDA to take a strong stance on labeling in that it is not necessary to label these products unless significant differences are found between these products and their conventional counterparts.

That being said, NCBA is supportive of and urges complete participation by the technology companies and the owners of cloned livestock in the voluntary prohibition of cloned animals and their offspring from entering the food supply until FDA makes its final decision based on science. This is appropriate at this point in the process.

We appreciate the opportunity to review and comment on these important documents. We look forward to working with FDA as this process continues and encourage FDA in their efforts to maintain relationships with researchers, technology groups and industry as they evaluate this technology and it’s potential. NCBA encourages FDA to maintain a science-based process and issue a final risk assessment in as expeditious a manner as possible after reviewing all relevant new science that may be presented during the comment period.

If you have any questions or concerns, please contact Dr. Elizabeth Parker, NCBA’s Chief Veterinarian. She can be reached at (202) 347-0228 or at [eparker@beef.org](mailto:eparker@beef.org).

Sincerely,



John Queen