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Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Food and Drug Administration Docket No. FDA-2008-D-0394 – Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs; Availability**

Dear Sir/Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), with comments for the U.S. Food and Drug Administration (FDA) on draft Guidance # 187 titled “Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs” and dated September 19, 2008. As a not-for-profit association established to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession. The association’s more than 76,000 members represent approximately 86% of U.S. veterinarians, who are involved in myriad areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The AVMA applauds the FDA in the development and release of draft guidance on the use of genetically engineered (GE) animals in research and food production. We believe that GE has and can continue to provide potentially great benefits for humans, animals, and society. The development and implementation of appropriate regulation of this technology has widespread applications in advancing our knowledge of diseases, food safety, environmental conservation, and efficient food and fiber production.

The AVMA urges all stakeholders involved in GE to incorporate a thorough science-based review of related technologies and to responsibly address not only improved efficiencies, but also animal welfare concerns. AVMA enthusiastically supports the responsible use of biotechnologies, including GE animals, for the improvement of animal and human health. However, the AVMA also wishes to emphasize that the welfare of animals involved in the development and delivery of these technologies must be protected. Welfare concerns related to GE include, but may not be limited to, abnormalities in embryonic development and death *in utero*; abnormal, variable, unexpected or uncontrolled expression of inserted genes; and the large number of donor, recipient, and breeding animals involved and their ultimate disposition (particularly when offspring result that are not transgenic). Welfare concerns are complicated by the fact that some

problems may not become evident until subsequent generations when homozygosis can be manifested.

We recognize limitations in statutory authority of the FDA with regard to animal welfare oversight. Therefore, we urge all federal agencies with GE oversight including the FDA, to work closely with the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) Animal Care to ensure that regulations and policies used in enforcement of the Animal Welfare Act (AWA) are sufficient to protect the welfare of animals used in the development of GE technologies. This is particularly important given that some types and classes of animals commonly used for GE are exempt from coverage under the AWA. Fortunately, voluntary programs providing internal and third-party oversight at public institutions and within private companies have helped narrow some of these coverage gaps. Furthermore, it appears that certain INAD and NADA requirements described in the FDA's draft guidance (e.g., labeling/identification schemes that include animal care information, providing information about potentially disruptive DNA sequences, requiring consistent and predictable genotypes and phenotypes), while aimed primarily at product safety and effectiveness, also have the potential to positively impact the welfare of GE animals.

Existing AVMA policies pertinent to the draft guidance are as follows:

### ***Use of Biotechnology in Veterinary Medicine and Animal Agriculture***

*Humans have altered animals, plants, and even microbes through selective breeding for millennia, to the great benefit of society. Biotechnology increases our ability to continue this process at an accelerated pace and in a more directed manner. With these powerful tools comes an increased ability to do great good but there are risks and benefits to the technology. Although it is imperative that biotechnology be used responsibly and ethically, it is equally important that these powerful techniques for advancement not be sequestered due to unfounded fear of potential adverse consequences.*

*The AVMA supports the opportunity to use biotechnology for a variety of applications including:*

- *The benefit and protection of public health (human, animal, and environmental) and welfare*
- *Enhancing host resistance to infectious diseases and eliminating genetic-based diseases*
- *Increasing the efficiency of food and fiber production*
- *Improving the utility, nutritional value, and safety of human food and animal feeds*
- *The production of improved animal medicinal products and diagnostic tools*
- *The improvement and protection of the environment, and*
- *The mitigation of the environmental impact of crop and agricultural animal production.*

*The AVMA affirms the responsible use of biotechnology to improve animal and human health.*

*The creation of new genetic-based knowledge through basic genetic research and the practical application of that knowledge is potentially a valuable adjunct to veterinary medicine. Therefore, it should not be restricted so long as it does not negatively impact the integrity of the environment and the health, safety, and well being of the resulting animals, the animals receiving or consuming the resulting products, or the consumers of animal products. The AVMA supports a science-based regulatory policy for the approval of products developed through biotechnology. Current regulations require evaluation of product safety and efficacy by USDA, FDA, EPA, or*

*other appropriate government agencies before they can be marketed for the intended uses. Future evaluations should be solidly based on sound science and meaningful risk assessments.*

**Genetically Modified Animals**  
**AVMA Position Statement on the Creation and Use of Genetically Modified Animals**

*It is the position of the American Veterinary Medical Association that the creation of new genetic-based knowledge through basic genetic research and the practical application of that knowledge should not be needlessly restricted so long as it does not impact the integrity of the environment and the general health and well being of the genetically modified animal remains preferential to human values and needs.*

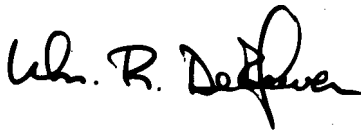
*Since the time when animals were first domesticated, humans have been actively involved in the selection of preferred traits that enhance the functional value and aesthetic appeal of specific animal breeds, while at the same time working to preserve and improve animal health and well being. The ability to select for a specific genetic trait through controlled breeding has resulted in a remarkable variety of animal breeds that are both physically and functionally unique.*

*Advancements made in sequencing the genomes of animals and improved technologies in functional genomics and biotechnology now present the opportunity to accelerate ongoing genetic improvements in animals at a pace and with a precision that is not possible by traditional selective breeding programs.*

*In this regard, having the DNA sequences for animals presents both a remarkable opportunity as well as a profound responsibility to utilize this knowledge and technology in a fashion that will preserve, if not improve, the health and well being of animals, while at the same time enhancing their appeal and value to humans.*

The AVMA commends the FDA's science-based regulatory process and offers its assistance and participation in the development and evaluation of policy governing genetically engineered animals.

Respectfully,



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