BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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Submitted via Federal eRulemaking Portal
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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: [Docket No. FDA-2008-D-0394]; Department of Health and Human Services, Food and Drug Administration; Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs; Availability; 73 Fed. Reg. 54407 (Sept. 19, 2008)

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) is pleased to submit these comments in response to the Notice of Availability of a draft guidance document ("Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs," or the Draft Guidance) published by the U.S. Food and Drug Administration (FDA or the Agency)'s Center for Veterinary Medicine (CVM or the Center) on September 19, 2008 (73 Fed. Reg. 54407). BIO is the world's largest biotechnology trade association representing more than 1,200 members in the United States and 31 nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology.

General Comments

BIO supports FDA's decision to apply the new animal drug (NAD) approval process to genetically engineered (GE) animals. Specifically, under the Federal Food, Drug, and Cosmetic Act (FFDCA), the newly introduced genetic construct in GE animals would be regulated as a new animal drug. In these comments, as FDA does in the Draft Guidance, BIO may sometimes refer to regulation of the genetic construct in GE animals as regulation of the GE animal for shorthand purposes.

BIO has long awaited the release of significant guidance clarifying the process of regulation of GE animals and their products, because such regulation is critical to maintaining the viability of the industry both domestically and internationally. BIO therefore recommends that this Draft Guidance be finalized as soon as possible. BIO lauds FDA for issuing the Draft Guidance to clarify the requirements and recommendations for producers and developers of GE animals and their products. When finalized, the Guidance will serve to facilitate approval and commercialization of

products, improve public transparency, and enhance consumer acceptance and industry credibility. We urge the Center to continue actively reviewing New Animal Drug Applications (NADAs) that ultimately will allow for the commercialization of GE animals and their products. Finalizing the Draft Guidance should not delay those efforts. BIO supports FDA's regulation of GE animals intended for food uses or to produce pharmaceutical or other consumer products because the Agency has the statutory authority, expertise, and experience to ensure the safety and effectiveness of these new animal drugs. The process is science-based and rigorous and will be applied appropriately to the technology as the science advances.

BIO also welcomes FDA's willingness to exercise enforcement discretion for low-risk applications of genetic engineering of animals, specifically for non-food-species regulated by other agencies and non-food-species restricted to laboratories.

BIO appreciates that the food safety assessment outlined in the Draft Guidance is consistent with the Codex Alimentarius Commission's "Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Animals." BIO supports the international harmonization of food safety risk assessment and regulation of GE animals and their products.

BIO urges FDA to finalize the Draft Guidance, taking into account relevant public comment, so that industry and other stakeholders have a clear and consistent understanding of the regulatory process. GE animals will provide compelling benefits and allow the United States to make significant advances in healthcare, nutrition, animal welfare, and environmental issues. These are all important goals that FDA should encourage through its oversight of the animal biotechnology industry.

BIO appreciates that FDA has identified areas where more guidance will be issued in the interest of providing more clarity to developers and the public on the regulatory process. However, these steps should not impede FDA from approving an NADA before additional guidance is issued.

As CVM implements these procedures to oversee the development of GE animals, it should seek to develop a process that will allow for timely approvals of NADAs. BIO appreciates that the Center is accessible to sponsors, and we have encouraged sponsors to contact CVM and to meet with CVM regularly during the product development process. BIO also urges the Center to coordinate with other FDA centers and other federal agencies and departments as much as possible, as recognized in the Draft Guidance.

Finally, BIO supports FDA's long-standing policy regarding the labeling of food developed using biotechnology, which was reiterated in the Draft Guidance. As with food derived from GE plants, any foods derived from GE animals should only be required to bear labeling statements if the food is materially different than its traditional counterpart. For example, as recognized in the Draft Guidance, a biotechnology-derived food that has a different nutritional profile or contains a non-traditional potential allergen

would be materially different from its counterpart, and such information should be conveyed on the label.

Specific Comments

Coordination

BIO appreciates that FDA's Draft Guidance emphasizes coordination of the regulatory process among FDA centers and among different agencies, including the U.S. Department of Agriculture (USDA). BIO supports such coordination to ensure that sponsors do not become subject to duplicative or overly-burdensome requirements. Further, due consideration should be given to developers whose animals are already well under development, such that regulatory review is efficient while still being appropriately rigorous. BIO also supports FDA's intention to issue additional guidance regarding how the NAD provision of the FFDCA will be applied to GE animals that produce products for human pharmaceutical use (biopharm animals), including the division of responsibilities between CVM and the other centers and how the different centers and agencies will work both interactively and simultaneously during an NADA review. We expect that other centers will participate in the development of the guidance document on biopharm animals. In addition, we suggest that the biopharm animal guidance include a reference to the FDA Center for Biologics Evaluation and Research's 1995 document, "Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals," which is the only available guidance on this topic to date.

BIO also supports coordination of the regulatory processes between FDA and USDA. We salute the efforts of the two agencies to work together toward appropriate alignment based on statutory authority and regulations, especially because the technology is being used with animals traditionally intended for food. For example, it may be appropriate for CVM to notify USDA's Food Safety and Inspection Service regarding specific aspects of the regulations.

Transparency

BIO supports transparency and open communication to the public from FDA to the extent permitted by law. Indeed, we welcome the public comment period for this Draft Guidance and any future guidance, because it provides an opportunity for the public to study the technology and its benefits, become educated about the regulatory pathway, and provide suggestions that might be valuable to this science-based and already unquestionably rigorous process. The Final Guidance should clarify that NADA summaries and supporting documents (the environmental assessment, for example) will be made available after approval, as per other NADAs.

FDA should discuss its potential use of advisory committees in the Final Guidance. We believe that FDA should clarify that a decision to convene an advisory committee is based on the need to solicit expert external advice relating to scientific questions and

judgment and potential public health considerations, and that the determination would not be driven by "public interest," controversy, or any other type of sensationalism. FDA should also clarify the statutory limits on its ability to release confidential business information.

Enforcement Discretion

BIO appreciates FDA's willingness to exercise enforcement discretion for low-risk applications of genetic engineering of animals, specifically for non-food-species regulated by other agencies and non-food-species restricted to laboratories. It is important to the public and others that the Final Guidance indicates that for such animals, the Center completes a rigorous case-by-case review of data to determine whether there is any risk to humans, animals, or the environment. It is on the basis of that review that FDA exercises enforcement discretion.

Environmental Assessments

Members of the animal biotechnology industry are committed to responsible and prudent release of GE animals to mitigate any possible impact on the environment. BIO supports the goals of the National Environmental Policy Act (NEPA) as well as the goals of the Endangered Species Act (ESA). NEPA review is a well-established aspect of the NADA process. In addition, we suggest that the Draft Guidance be clarified that the Center may be required to prepare biological assessments under the ESA in association with some NAD approvals.

Guidance Documents

BIO appreciates that FDA has identified specific regulatory areas that will benefit from additional guidance. Such guidance to industry will be useful both for developers and the public to understand the rigorous regulatory process that precedes the commercialization of GE animals and products derived from them. Therefore, BIO supports the issuance of future guidance, and we suggest the following order for development, from highest to lowest priority: biopharm animals; Good Manufacturing Practices/Good Laboratory Practices; post-market monitoring; and non-heritable constructs. As mentioned above, however, FDA should not refuse to approve an NADA simply because relevant guidance has not been finalized in cases where, in FDA's judgment, approval is appropriate.

Conclusion

The draft guidance is a commendable and productive effort by FDA to clarify and articulate its approach to regulating GE animals and protecting the public health. We encourage CVM to coordinate internally among other FDA centers and federal agencies as well as internationally to implement a science-based, rigorous regulatory process. We encourage FDA to finalize the guidance and to work diligently to ensure the NADA approval process is as transparent and timely as possible under the law. We also urge FDA to work to guarantee that the public is well-informed about the benefits of animal

biotechnology as well as the safety of individual GE animal-derived food and drug products, as they enter the marketplace.

Sincerely,

Barbara P. Glenn

Barbara P. Glenn, Ph. D.
Managing Director, Animal Biotechnology
Food & Agriculture Section