Consumer Federation of America

November 22, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20853

RE: Comments on Food and Drug Administration
Docket No. 2008-D-0394

Consumer Federation of America[1] submits for your consideration comments on the Food and Drug Administration (FDA) "Draft Guidance for Industry #187: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs," announced in the Federal Register, September 19, 2008 (73FR 54407-08). The Draft Guidance provides FDA's current views on how the Agency will regulate genetically engineered (GE) animals under the Federal Food, Drug, and Cosmetic Act and provides recommendations to developers on complying with legal requirements of the Act.

CFA appreciates the lengthy and detailed consideration that the FDA has given to the regulation of GE animals. From the beginning, the Agency has indicated that it viewed the Investigational New Animal Drug (INAD) and the New Animal Drug Application (NADA) provisions of the FDCA as the most appropriate mechanisms for addressing the issues raised by GE animals. These provisions require the Agency to make a finding that each construct is safe and effective when used as intended for both animals and humans and in that regard are more protective of human health than the GRAS provisions of the FDCA used to regulate genetically engineered plants. The public needs to be certain that this technology, which may create risks to public and animal health and to the environment, is subject to rigorous scrutiny before products go to market.

The problem is with the government's decision to be constrained by existing statute. The authors of the FFDCA never conceived that the law would be stretched to cover a technology no one contemplated at the time it was written. The Agency has determined to use the New Animal Drug provisions simply because they are the best solution to a problem that should not exist.

[1] Consumer Federation of America is a 50 year old non-profit association of over 300 organizations, representing a combined membership of over 50 million Americans, which works to advance the interests of American consumers through research, education and advocacy. Member organizations include local, state and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions, and anti-hunger and food safety organizations. CFA's policy positions are determined by vote of member representatives. The Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

The public is not being well served because the FDA and the Department of Health and Human Services have chosen not to ask Congress to amend the law to provide an appropriate legal structure.

The original decision to stay within current law instead of asking Congress to develop an appropriate regulatory vehicle has delayed the development of genetically engineered animals and has led the Agency to decisions that do not meet the public's needs. Treating these constructs as drugs utilizes a totally opaque system in which the public is denied any information about the regulatory process until it is over; and denies consumers the ability to choose whether to use or not use products produced from GE animals.

The Food and Drug Administration should convey to the new Commissioner and Secretary of HHS the limitations of the current policy and suggest that the new Administration propose new legislation to develop a better vehicle for regulating GE and cloned animals. Consumer Federation of America will urge the new Administration and the new Congress to give this new technology the attention it deserves and propose new legislation specifically written to address the problems of regulating genetically engineered animals.

The FDA's decision to issue Draft Guidance as its regulatory tool further complicates the future of GE animals and public acceptance of the technology. The issue has been before the Agency for over a decade. After this long period the Agency has decided not to issue specific regulations for comment. "Draft Guidance" does not constitute mandatory policy. Further, the Agency has, in the past, operated for long periods of time in this shadowy area of "draft" policy. A lengthy period under draft guidance leaves developers and consumers in uncertain territory. There is inadequate legal recourse if a company does not comply and the public may remain unaware of whether the Agency has responded to public comments.

The Draft Guidance in this case should be amended to provide that the FDA will make public all decisions made with regard to products, including decisions to exercise enforcement discretion, determination to allow investigational GE animals into the fuel or feed supply, decisions to approve a GE animal, and decisions regarding compliance with the National Environmental Policy Act.

TRANSPARENCY AND PUBLIC PARTICIPATION

Because the New Animal Drug Act is a licensing procedure, all communication between the Agency and the applicant is confidential. While this may be appropriate for drugs, it is not an acceptable method for handling items that will enter the food supply. The NADA process does not require the Agency to notify the public that developers of a GE animal have applied for a license to sell their product before the product is approved. It does not require that the data basic to the approval be made public at any time. There is no opportunity for the public to raise issues the Agency may not have considered or to express concern about the quality of data. The Draft Guidance does not acknowledge or address these issues.

The public should not have to rely upon the good will of developers to provide that information. It should be a public right, not a grant from the people who will profit from the product. Any data that comes directly from those who hope to make a profit selling the product is likely to

come in the context of attempts to market the product rather than a dispassionate release of critical safety data.

Since the product will already have been approved, the American people will have only one way to express concern about the safety of the product and that is to seek to have it rejected in the marketplace. The Agency should reconsider the Draft Guidance and develop an effective mechanism for providing information to the public and taking public comment and making the comments part of the record before final approval. In the absence of transparency and public participation it is unlikely that this very novel technology will gain market acceptance.

LABELING

The FDA has again chosen to implement its legal authority in a manner that prevents consumers from making effective choices in the market place. The Agency may not be able to consider social, economic, and ethical issues in its decision making, but consumers will want to consider those factors in making decisions whether or not to purchase the products.

By taking the narrowest possible view of a law that has to be stretched to fit the circumstance, the FDA is pursuing a course that enables developers and food processors to sneak their products into the market and eliminate any real opportunity for consumers to avoid use of products created from a process they consider morally unacceptable. CFA's members certainly do believe that the act of creating a transgenic animal is in and of itself a material difference. The vast majority of Americans believe that a GE animal is different. The Agency is imposing undue restrictions on the ability of our members to choose or avoid particular food products.

It is important that the FDA find some way to provide meaningful transparency and public participation in the approval of GE animals and to require that the public be given sufficient information to be able to choose to purchase or avoid these products in the marketplace. Failure to do so will assure heightened consumer opposition to the products and further undermine the public's already tenuous confidence that the FDA as an institution intends to serve the public interest.

Sincerely,

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