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Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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September 3, 2010

Dr. Joshua Sharfstein
Principal Deputy Commissioner
U.S. Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740- 3835

Docket No. FDA-2010-N-0001
Docket No. FDA-2010-N-0385
The VMAC Meeting and Public Comments on Science-Based Issues Associated with AquaAdvantage Salmon

90-Day Request for Notice and Comment Period; 30-Day Extension Request for Public VMAC and Labeling Meetings

Dear Deputy Commissioner Sharfstein:

I write regarding your recent announcement on the agency's process for reviewing AquaAdvantage (AA) genetically engineered (GE) salmon. Given the magnitude of this decision and its unprecedented nature, I request that you extend the currently-very limited time the public will have to review the environmental, food safety or efficacy data and provide the agency comment. At a minimum, the agency should provide a 90-day period for written public comments, which must include at least a 60-day comment period prior to the Veterinary Medicine Advisory Committee (VMAC) meetings.

FDA's announcement regarding its review process is the first of its kind, for any GE animal, however the public is being given less than one month to prepare for the AA Salmon hearings. The decision-making process announced by FDA fails to provide the public with sufficient time or available data that would allow for informed and meaningful participation both prior to and after the VMAC and labeling meetings. FDA has first released data about the GE salmon only today, a mere fifteen days before the VMAC meeting is scheduled to take place. At bare minimum, meaningful public participation demands at least 60 days for review and comment now that some data supporting the application has finally been released. The absence of a meaningful public comment period prior to and following the VMAC meetings denies stakeholders and the public at large the opportunity to provide additional input as well as

relevant scientific studies and data to the Committee. The exceedingly short timelines for public comment are exacerbated by the lack of transparency. A *New York Times* article on the GE salmon from June indicated that Aqua Bounty Technologies has had their application before the agency for nearly a decade, and that they had then submitted "most or nearly all of the data" to the agency in support of their application. Given the timelines associated with the application until this point, the agency's decision to announce hearings on the matter less than a month before they are to take place, and then to release crucial data on the application for public review only fifteen days before said hearings, contradicts the agency's public commitment to transparency.

The agency has previously recognized the immense public desire for greater transparency in regard to the GE animal review process, as evidenced by the large volume of public comment it received in response to its Guidance as to how the New Animal Drug provisions of the Federal Food Drug and Cosmetic Act apply to GE animals. Given the magnitude of interest and concern expressed by the public on issues of food safety, food labeling and the environmental impact of GE animals, it is clear that serious and irreversible damage will result if public comment is curtailed. Therefore, it is in the public interest that at a minimum FDA provides a 90-day comment period for written public comments on the safety and effectiveness of GE salmon, to include at least a 60-day comment period from the date of the VMAC meetings. Adhering to past precedent, FDA needs to delay the public VMAC and labeling meetings on AA Salmon by at least 30 days to allow for meaningful and informed public participation. These timelines should not begin until and unless the public has had sufficient time to review the raw data supporting the new animal drug application.

The Oversight and Government Reform Committee is the principal oversight committee in the House of Representatives. The Domestic Policy Subcommittee has broad jurisdiction over many federal agencies, including FDA. I hope you will take into consideration the public's interest in open, accountable and transparent government, and that you will act favorably upon this request. I look forward to your response.

Sincerely,

Dennis J. Kucinich

Dennis J. Kucinich
Chairman
Domestic Policy Subcommittee