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November 18, 2010

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I am writing to express my concern over the Food and Drug Administration's (FDA) approval process for the first genetically engineered (GE) animal for human consumption, the hybrid salmon produced by AquaBounty Technologies. Serious questions have been raised by consumers, environmentalists, fishermen, and science advocacy groups regarding FDA's lack of transparent approval process for considering this hybrid salmon, as well as the scientific rigor of studies that have been conducted on its potential human safety and environmental impacts.

First, regulating the proposed GE salmon as a "New Animal Drug" does not provide the robust evaluation necessary for a comprehensive approval. The Veterinary Medical Advisory Committee (VMAC) tasked with evaluating the scientific risk assessments, although augmented with some additional experts, lacks sufficient expertise on food safety, endocrine disruption, food allergies, and salmon ecology necessary to fully evaluate this request. Second, the science behind the FDA's approval also leaves room for criticism given the small sample size (six fish) used in some of the comparative studies and that data were all taken from fish raised at a facility in Prince Edward Island, which is not the facility where the salmon will ultimately be reared. Most troubling was the 14-day period of public review of AquaBounty's research, which was inadequate for any independent assessment of the science supporting approval before the VMAC made their determination.

There is also concern that documents recently released through a Freedom of Information Act request seem to indicate that the FDA has not adequately fulfilled its requirements under the Endangered Species Act to consult with both U.S. Fish and Wildlife Service and the National Marine Fisheries Service (NMFS) to determine whether approval of AquaBounty's salmon might impact wild, endangered Atlantic salmon. Although it was decided that AquaBounty's closed systems would not affect Altantic salmon, news that the company is considering building a facility to grow the salmon that would discharge water off the Maine coast is troubling.

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I ask that the FDA address this inadequate approval process, and move forward in a transparent and scientifically rigorous manner. Please let me know of the steps the FDA is taking to substantively address the concerns being raised by consumer groups, fishermen, environmentalists and scientists. I look forward to hearing your response and working together to protect the health and interests of the American public.

Sincerely,

Barbara Boxer
United States Senator

CC: Kathleen Sebelius, Secretary of Health and Human Services
Michael, M. Landa, J.D., Acting Director, Center for Food Safety and Applied Nutrition
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research