September 24, 2010

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

I am writing to express my concern regarding the Food and Drug Administration's (FDA) current review of the AquaBounty Technologies (ABT) AquaAdvantage salmon. FDA is nearing a decision on whether to allow the first genetically engineered (GE) animal to be introduced to the public for human consumption. It does not appear that the FDA has considered all human and environmental impacts thoroughly enough and I ask that you suspend the approval and food labeling process until a full examination of the issues has been completed.

At a meeting from September 19-20, the FDA's Veterinary Medicine Advisory Committee (VMAC) considered Aqua Bounty's application. The FDA announced that the VMAC would, "consider issues regarding the safety and effectiveness of the new animal drug that is the subject of new animal drug application concerning AquAdvantage salmon produced by AquaBounty Technologies, Inc." Clearly, this meeting and the consideration it provided did not include a framework in which human consumption and its potential impacts could be fully vetted.

I remain concerned that the existing regulatory framework that FDA is using for the approval process as well as the information provided by the existing studies does not give the tools FDA needs to determine whether AquaAdvantage salmon warrants approval. Approval would represent the first GE animal allowed for human consumption and the safety and protection of consumers and environmental impacts require further study.

Furthermore, the FDA must not use a veterinary medicine approval process for GE animals that would be used for human consumption. The FDA needs to evaluate whether this particular GE salmon and all further GE animals warrant approval through a framework that uses studies and data that support its safety for human consumption. Concerns over human health risks continue to surround the approval of the AquaAdvantage salmon and because documents were recently released these risks have not been available for the scientific community to evaluate.

Furthermore, the FDA's approval of the AquaAdvantage salmon also poses environmental risks that have yet to be fully understood. Although, the current application is for inland tanks and in order to pursue off-shore aquaculture of GE salmon additional FDA approval would be required, I believe this decision could lead to future hazards. The National Oceanographic and Atmospheric Administration (NOAA) is currently developing a new national policy for marine aquaculture in an effort to expand its usage. With the expansion of off-shore aquaculture and the continued development of new species of GE fish there will greater pressure to allow GE fish into areas where they would threaten the marine life and environment. With Aqua Bounty's own data showing about

a five percent fertility rate in their salmon, our wild salmon populations could quickly interbreed leading to devastating results. The unknown potential for the spread of infectious diseases into the natural environment is also of concern.

It is vital that we thoroughly consider all of the human health and environmental impacts before the FDA approves the AquaAdvantage salmon. With the risk that this approval poses to the public we can not use post-market surveillance to guide how we ensure safety. The FDA is setting precedent in allowing human consumption of a GE animal and it can not be rushed.

I strongly encourage you to suspend the decision on AquaAdvantage salmon until the FDA is able to develop a framework in which the human health and environmental impacts can be more thoroughly studied and reviewed.

Thank you for attention and assistance in this matter.

Sincerely,

FRANK PALLONE, JR.
Member of Congress

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