DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

December 6, 2010

Representative Scott Kawasaki
Alaska State Legislature, Interior Delegation
State Capitol, Room 428
Juneau, AK 99801-1182

Dear Representative Kawasaki:

Thank you and Senators Joe Thomas, Albert Kookesh, and Joe Paskvan and Representatives Woodie Salmon, Mike Kelly, and David Guttenberg for the letter dated October 4 concerning AquAdvantage Salmon. We share your view that this product is of particular public interest. The Food and Drug Administration (FDA or the agency) is committed to a thorough review process that is transparent to the public and comprehensive in its attention to safety for humans, for animals, and for the environment.

FDA regulates genetically engineered (GE) animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act. Legally, the genetic material, or rDNA construct, used to engineer the salmon, meets the definition of a drug because it is intended to affect the structure or function of the animal. This regulatory pathway prohibits introducing food from the AquAdvantage Salmon into the United States without specific FDA approval. As part of the approval process, the producer of the GE salmon with the rDNA construct must meet safety standards not only for the animal, but also for the environment and for any food derived from the animal.

Environmental Safety

With regard to the environment, FDA's regulations implement the National Environmental Policy Act (NEPA), and require the agency to assess the environmental impact of an approval. For AquAdvantage Salmon, this requirement has meant evaluating the sponsor's plans for preventing the escape or breeding of the genetically engineered salmon by use of multiple, redundant systems of mechanical, biological, and geographical containment. These include the production of single sex, sterile populations of genetically engineered salmon by AquaBounty, and keeping them contained in inland tanks in areas unsuitable for survival outside the facility. With on-going consultation with sister agencies such as the National Oceanic and Atmospheric Administration, FDA will analyze the possibility of escape, survival, and breeding as part of its determination of the likelihood of any significant impact on the environment, including on populations of wild salmon. The specific conditions of use being considered by the agency are described in our briefing materials were made available to the public before the found at our Web site at:

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf.

If this application were to be approved, it would be approved only for the particular conditions of use specified in the application. If the sponsor wishes to make any changes in location, in containment systems, or in the genetic alteration, then a new application and environmental assessment will be required, and will be subject to the same rigorous safety standards.

Food Safety

In addition to adherence to our statutory and regulatory requirements to demonstrate food safety as outlined in our guidance for industry, (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf), FDA's review is also consistent with internationally-adopted scientific consensus guidelines for the food safety assessment of foods from GE animals as outlined by the Codex Alimentarius, (http://www.codexalimentarius.net/download/standards/11023/CXG_068e.pdf). FDA conducts on-site inspections to ensure (among other things) the accuracy of the data submitted pursuant to these studies. In addition to information from studies conducted by the sponsor, the agency reviews relevant studies from peer-reviewed journals. FDA reviewers use this combination of materials to reach an independent judgment on the safety of any changes caused by the genetic construct.

FDA also considers specific food safety issues, such as allergenicity. Because salmon are finfish, which as a group are among the eight most allergenic foods in the United States, the AquAdvantage Salmon would likely cause allergic reactions in anyone who is already allergic to conventionally bred salmon. FDA is looking closely at the biology of the GE salmon to determine if there is cause to believe the AquAdvantage Salmon would pose additional allergy issues for persons who at present eat salmon safely.

FDA's Review Process

The AquAdvantage Salmon review has followed the procedure described in Guidance for Industry 187, "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs," which was issued in final form in 2009 after public comment.

Key steps to date have included:

- Web publication of background documents on August 25, 2010. These documents contained detailed information on the review process, on the AquAdvantage Salmon, and on the ecology and biology of salmon in general. They presented a summary of all the information and data on which FDA relied for its analyses to date, and an explanation for the preliminary conclusions it would present to an advisory committee for discussion. See http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm224089.htm for these documents.

- FDA held a public Veterinary Medicine Advisory Committee (VMAC) meeting, on September 19-20, 2010. Members of the public were invited to provide written comments for the committee and to make oral presentations.

- FDA had a second meeting, on September 21, 2010, to offer the public a chance to engage in a focused discussion on requirements for food labeling and how they might apply to foods derived from AquAdvantage Salmon in the event that the agency approves AquaBounty's application. Members of the public were invited to speak at the labeling meeting, and to submit written comments both before and after the meeting. Written comments were accepted for 60 days following the labeling meeting (until November 22).

FDA has not made a decision on the AquAdvantage Salmon application. The agency's next steps entail a review of the VMAC meeting discussions and any new information brought to the agency's attention, as well as completion of the environmental review and analysis.

If FDA's environmental review results in a proposed finding of no significant impact (FONSI), the agency will publish a *Federal Register* notice to announce the availability of the environmental assessment and the FONSI, and invite public comment on these documents for 30 days.

If FDA decides to prepare an environmental impact statement (EIS), either initially or after reviewing public comment on a proposed FONSI, the public will have an opportunity to participate in the EIS development process. Either of these actions must be completed before the new animal drug application could be approved.

Food Labeling

If FDA approves the AquAdvantage Salmon, the agency will have to decide on the question of labeling food from the salmon. The September 21 meeting provided a chance for members of the public to learn about the relevant food labeling principles and federal court decisions. These were summarized in a background document available at: http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm.

FDA may require special labeling for "material" differences, such as nutritional content or range of uses (e.g., usability for frying). But as interpreted by the courts to date, the fact that a food comes from a GE source does not trigger mandatory food labeling absent a material change in the food itself. Food labels are geared to informing consumers about the attributes of the product, not about the production method. As a result, it has been held that consumer interest alone is not sufficient for FDA to force a manufacturer to put something on the label.

Manufacturers are free, however, to offer information to consumers provided it is truthful and not misleading. Therefore, if food from this salmon is permitted for sale in the United States, sellers will be free to label the foods as GE or non-GE to meet consumer demand, provided it is truthful and not misleading. This is similar to the system used for other foods, in which terms such as "natural" are used on voluntary basis to meet a growing consumer interest in the

information, whether or not the foods have attributes that could trigger a mandatory labeling requirement.

Thank you again for your interest in this matter. If you have any further questions or concerns, please let us know.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Cc: Senator Joe Thomas, Alaska State Legislature, Interior Delegation
Senator Albert Kookesh, Alaska State Legislature, Interior Delegation
Senator Joe Paskvan, Alaska State Legislature, Interior Delegation
Representative Woodie Salmon, Alaska State Legislature, Interior Delegation
Representative Mike Kelly, Alaska State Legislature, Interior Delegation
Representative David Guttenberg, Alaska State Legislature, Interior Delegation