DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

June 21, 2013

Representative Geran Tarr
Alaska State Legislature
716 W. 4th Avenue
Anchorage, Alaska 99501

Dear Representative Tarr:

Thank you for your letter dated June 12, 2013 to Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration (Fda) concerning AquaBounty genetically engineered (GE) salmon and a recent study from McGill University concerning reproduction in a laboratory of diploid (non-sterile) GE salmon with brown trout. You ask that FDA take these study results into account in its review of the application concerning AquaBounty GE salmon. We appreciate the concerns you have raised and note that the FDA has not yet made a decision with respect to the application related to AquAdvantage Atlantic Salmon.

Under the National Environmental Policy Act (NEPA), FDA is required to evaluate the effects of any "major actions" it takes, such as approval of an application, on the quality of the human environment of the United States. Under NEPA, we first conduct an environmental assessment (EA) to determine whether the action may result in a significant impact on the environment of the United States. If not, the agency issues a Finding of No Significant Impact (FONSI). If, on the other hand, we discover that there is a significant likelihood of an impact on the environment of the United States, the agency would prepare an Environmental Impact Statement (EIS).

Although FDA ordinarily issues its environmental review of applications for approval at the time it approves the application, in this case, to increase the transparency of our actions, we released a draft Environmental Assessment and our preliminary findings for public comment. The extended comment period, in which we asked the public to comment on the substance of the draft Environmental Assessment and preliminary findings closed on April 26, 2013. There are many comments in the docket, and we will go through each comment carefully to determine whether there is additional scientific information that can help inform us as to whether we will proceed with a final EA and FONSI or move on to prepare an EIS.

Although the study you reference was published after the closing of the public comment period on the EA, FDA is reviewing the study and will take it into careful consideration in deciding whether to issue a final EA and FONSI or prepare an EIS.

Thank you for sharing your concerns.

Sincerely yours,

Tracey H. Forfa, J.D.
Deputy Director
Center for Veterinary Medicine