April 26, 2013

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

Re: Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon; Availability, 77 Fed. Reg. 76050 (December 26, 2012), ID No. FDA-2011-N-0899.

Dear Commissioner Hamburg:

We the undersigned national environmental organizations call on the U.S. Food and Drug Administration (FDA or Agency) to immediately suspend consideration of AquaBounty Technologies' new animal drug application for approval of its genetically engineered (GE) salmon product, AquAdvantage Salmon. Given the unprecedented and highly uncertain nature of this GE fish, and the ill-suited statutory process through which it is being considered for approval, FDA must not proceed until the Agency's inadequate May 4, 2012 draft environmental assessment (EA) is replaced with an environmental impact statement (EIS) that thoroughly studies the possible ecological and environmental risks GE salmon pose to our wild fish populations and ocean ecosystems.

Between August 2010 and the present, environmental groups, expert scientists, commercial fisherman, States, members of Congress, and hundreds of thousands of Americans have repeatedly raised the issue of inadequate environmental review under the National Environmental Policy Act (NEPA), and urged FDA to complete a comprehensive EIS before taking action on this first-of-its-kind application. We are disappointed that despite the myriad serious and substantiated concerns we and many others have raised, FDA has instead prepared an overly narrow and incomplete EA.

FDA's draft EA shows that the potential environmental and ecological impacts of this GE salmon on our natural marine environment, including our already imperiled Atlantic salmon populations, are still unknown. Nonetheless, FDA ignores this uncertainty and follows a piecemeal approach to regulation that pushes off full evaluation of potentially significant and irreversible ecological threats posed by AquAdvantage Salmon to some indeterminate later time. The Agency's refusal to conduct a complete and rigorous analysis of the possible risks and consequences now—before determining whether to open regulatory doors to the proliferation of GE fish—contravenes NEPA and the Endangered Species Act.

We remind the Agency that, by exercising authority over AquAdvantage Salmon and all other GE animals, FDA has accepted chief responsibility for protecting our environment and fragile ecosystems when making decisions like this one. To that end, FDA must set a high and rigorous standard for environmental review, to ensure that the full range of potentially significant risks and outcomes associated with each GE food animal application has been carefully and

transparently examined and understood by FDA, other relevant agencies, and the public. The draft EA falls far short of this legally required analysis, and therefore must be replaced by a substantially more extensive EIS.

Respectfully,

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President
American Rivers

Andrew Kimbrell
Executive Director
Center for Food Safety

Trip Van Noppen
President
Earthjustice

Erich Pica
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