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,

Wm. Robert Irvin  Andrew Kimbrell  Trip Van Noppen  
President  Executive Director  President 
**American Rivers**  **Center for Food Safety**  **Earthjustice**

Erich Pica  Wenonah Hauter  Phil Radford  
President  Executive Director  Executive Director 
**Friends of the Earth**  **Food & Water Watch**  **Greenpeace**

Peter Lehner  Andreas Merkl  Michael Brune  
Executive Director  President and CEO  Executive Director 
**Natural Resources Defense Council (NRDC)**  **Ocean Conservancy**  **Sierra Club**