EARTHJUSTICE

ALASKA CALIFORNIA FLORIDA MID-PACIFIC NORTHEAST NORTHERN ROCKIES
NORTHWEST ROCKY MOUNTAIN WASHINGTON, DC INTERNATIONAL

June 1, 2012

Via U.S. Certified Mail and E-mail

Bernadette Dunham, D.V.M., Ph.D.
Director, Center for Veterinary Medicine
U.S. Food and Drug Administration
7519 Standish Place
Rockville, MD 20855
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Re: Citizen Petition on Review of AquaBounty Application (Docket No. FDA-2011-P-0448)

Dear Dr. Dunham:

I am writing to ask that the Food and Drug Administration ("FDA") promptly provide its final response to the above-referenced Citizen Petition filed by Earthjustice one year ago on June 1, 2011 on behalf of Ocean Conservancy, Friends of the Earth, Center for Food Safety, Food & Water Watch, Center for International Environmental Law, and Greenpeace. FDA's regulations, 21 CFR § 10.30, require FDA to issue a final substantive ruling on our Petition. However, to date, the only response we have received from FDA is a letter from you on November 21, 2011 merely stating that "the Agency will require additional time to issue a final response because of the complexity and the number of issues raised in your petition." FDA has now had an additional six months to consider our Petition and there is no excuse for the continued delay.

As you know, the subject of our Petition—FDA's review of the AquaBounty new animal drug application for genetically engineered salmon—is a significant and controversial matter that has sparked serious environmental risk concerns from a host of scientists, advocates, public representatives, and citizens. For the reasons detailed in our Petition and in light of more recent information linking AquaBounty's genetically engineered salmon to the Infectious Salmon Anemia virus, FDA must refrain from making a final determination on this application until the agency has completed a comprehensive environmental impact statement that carefully considers the wide range of environmental and ecological risks associated with genetically engineered salmon. Moreover, as also stated in our Petition, prior to taking final action on this application, FDA should revise its existing regulatory framework to specifically account for the unique concerns presented by genetically engineered food animals like AquaBounty's salmon and to provide for a transparent regulatory review process that allows for meaningful public participation.

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The urgency of the agency's full response is heightened by recent representations indicating that FDA approval of AquaBounty's application is imminent. I now ask that FDA issue a final substantive response to our Citizen Petition without further delay and before it takes further action on the AquaBounty application.

Sincerely,

Khushi K. Desai
Attorney