April 11, 2014

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hamburg,

We are writing today to alert you to erroneous comments being made by AquaBounty Technologies about FDA's pending rulemaking on genetically engineered salmon, currently being reviewed through a New Animal Drug Application (NADA) by the Center for Veterinary Medicine. We request that the FDA take immediate steps to correct the public record and to formally instruct AquaBounty to stop disseminating false information, which confuses and distorts the public debate about FDA's decision making process on the first genetically engineered animal destined for the human food supply.

The seafood trade publication *Fish Farming Xpert* published a news article on March 14, 2014, in which AquaBounty Vice-President Henry Clifford announced that FDA has already made its decision that its genetically engineered salmon will not need to be labeled as such. He is quoted as saying, "We sell to fish farmers and we encourage voluntary labeling but each producer has to operate under the labeling laws of their country. According to the Federal Food, Drug and Cosmetic Act, the FDA does not require labeling in the US of genetically modified foods. They use a product oriented labeling as opposed to process oriented labeling."

Clifford continues, "…under the current laws in the US, this product does not have to be labeled as a genetically modified food. If the producer wishes to label it he can, but Marine Harvest cannot demand in the US, unless they want to change the labeling laws."

Clearly and unambiguously, Clifford is referring to the actual salmon, not to salmon eggs, and we direct your attention to the full article, which is attached.

Henry Clifford has served as Vice-President of AquaBounty for many years, and it is difficult to believe that he could make such patently false statements unknowingly. Whether or not the statements were intentionally deceitful, they call into question, once again, whether AquaBounty is committed to understanding and following a rule-based system.

This is by no means the first time that AquaBounty has been less than accurate, either with the public or the FDA. For the sake of brevity, we offer one example. AquaBounty apparently failed to disclose the existence of a major disease outbreak at its Canadian egg hatchery in 2009. FDA called the facility "disease free" in its 2010 Environmental Assessment (dated September 2010) and in its 2011 draft Environmental Assessment (released via FOIA, dated July 2011).[1] And at the FDA's September 2010 veterinary

medicine advisory committee meeting, the president of AquaBounty, Ron Stotish, stood at the podium in front of invited scientists, members of the public, many media outlets and FDA regulators, enumerating the devastating problems other salmon growers' problems have had with infectious salmon anemia virus, which he said had raised prices of salmon. He never mentioned his own company's problems just the year before.[2]

It wasn't until a public-interest group independently discovered and publicized the truth in December 2011 that the world learned about the outbreak.[3] We later learned that AquaBounty had to depopulate much of its facility and has no idea how the disease entered into the company's purportedly high-tech, biosecure facility.[4] FDA did not address this issue until it issued its December 2012 Environmental Assessment, and even then did not analyze it adequately.

This episode represents AquaBounty's apparent failure to disclose crucial information necessary to FDA's risk assessment, and, like the recent statement from Clifford, strongly suggests AquaBounty's knowing misrepresentation of the facts.

We call on the FDA to finally step up and put an end to this apparent pattern of distorting statements by AquaBounty. This letter represents the third time we have asked the FDA to correct Henry Clifford's erroneous comments on the labeling issue. Food & Water Watch brought this issue to the attention of CVM Director Bernadette Dunham on March 20, asking the agency to take steps to correct the public record and to call on AquaBounty to stop disseminating false information. The agency demurred, then, when pressed a second time to take action on March 24, FDA officer Jason Dietz offered another non-response via email: "As previously noted, FDA has not yet made an approval decision on the application relevant to the AquAdvantage Salmon nor has it made a decision regarding labeling of food derived from AquAdvantage Salmon. This has been our general response to inquiries we have received, and we note that, at this time, we have received no additional media inquiries as a result of this story."

We find it completely unacceptable that FDA would sit on its hands and knowingly allow a drug sponsor to disseminate incorrect information about the agency's administrative process. We, likewise, find it reprehensible that AquaBounty would publicly announce that FDA had made a labeling decision when it has not. It's time that FDA put an end to the unsubstantiated and false claims that AquaBounty has long broadcast surrounding AquAdvantage Salmon, which continue to distort the public process that informs FDA's rulemaking.

Should you have questions, please contact Tim Schwab, Senior Researcher at Food & Water Watch (tschwab@fwwatchorg, 202-683-2517) or George Kimbrell, Senior Attorney for Center for Food Safety (gkimbrell@centerforfoodsafety.org, 971-271-7372).

Sincerely,

Wenonah Hauter, Executive Director of Food & Water Watch
Andrew Kimbrell, Executive Director of Center for Food Safety

[1] Food and Drug Administration Center for Veterinary Medicine. Veterinary Medicine Advisory Committee. "Briefing Packet: AquAdvantage Salmon." September 20, 2010 at 23; Documents released through FOIA request to United States Fish & Wildlife Service.

[2] Transcript of Veterinary Medicine Advisory Committee Meeting on AquAdvantage Salmon. Monday, September 20, 2010 at 101 to 102.

[3] Living Oceans Society. Press Release. "ISA virus confirmed in AquaBounty's genetically-engineered salmon." December 20, 2011.

[4] Food and Drug Administration Center for Veterinary Medicine. "Draft Environmental Assessment for AquAdvantage® Salmon." May 4, 2012 at 43 to 44; Stotish, Ron. Transcript from Testimony before U.S Senate Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard Oversight Hearing on the Environmental Risks of Genetically Engineered Fish." December 15, 2011 at 73.