

September 15, 2010

Dr. Margaret Hamburg, Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
White Oak 32, Room 2346
Silver Springs, MD 20993

Dr. Joshua Sharfstein, Principal Deputy Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
White Oak 1, Room 2220
Silver Springs, MD 20993

Dear Commissioner Hamburg and Deputy Commissioner Sharfstein:

Consumers Union (CU), the non-profit publisher of *Consumer Reports* magazine, writes to you regarding concerns about the Food and Drug Administration's (FDA) process regarding review of Aquavantage's application for approval of genetically engineered (GE) salmon. We have concerns both about the safety assessment review period and about the composition of the Veterinary Medicine Advisory Committee (VMAC) that will be reviewing the application.

First, we feel that the current fourteen-day review period on the safety assessment of the Aquavantage genetically GE salmon is far too short, and we respectfully request that it be extended to the standard sixty days.

We also respectfully request that you postpone the meeting of the VMAC, now scheduled for September 19-20, in order to add members to the committee with the appropriate expertise to address critical safety questions. The VMAC currently lacks any scientists whose primary expertise is in food allergies, endocrinology or fish ecology, the main topics on which the VMAC will have to render judgments in order to conclude that the salmon is safe. We strongly urge you not to make a decision on the safety of the first GE animal to be approved for human consumption without the input of scientists in these fields or without wide public input.

When CU, the Center for Food Safety, and the Union of Concerned Scientists met with FDA officials in May, we were assured that even though approval of a veterinary drug is not normally a matter on which FDA solicits public input, the agency would allow for public input in this matter given that a decision on GE salmon is an important and unusual use of FDA's authority on veterinary drugs, and because of the widespread public interest in this landmark decision.

While we appreciate the release of a summary of the scientific data underlying the FDA's review, we have strong concerns about giving the public only two weeks to review the data on the human and environmental safety of the GE salmon, contained in 255 pages of technical information. We are especially concerned about trying to undertake this review in such a constrained time period when there are serious issues of food safety involved. The FDA review discusses the presence of proteins to which some people are acutely allergic, and which may be elevated in the transgenic fish, as well as presence of increased levels of the growth hormone iGF-1. This material raises serious health concerns. Fourteen days are not sufficient to review this material in proper depth.

Given that FDA has had eleven years to review the application of Aquabounty for approval, we question the extremely brief period allowed for public review and input. Since GE salmon is not in any way a lifesaving product such as certain pharmaceuticals or medical devices, we must question why the agency believes it is necessary to move forward so quickly, in a way that does not allow for the standard 60 to 90 days of public review.

We must also object to the current composition of the VMAC, announced last week. Even with four new temporary voting members, the Committee is not constituted so as to provide scientifically sound advice to FDA on this topic. The topic of GE salmon is very different from the veterinary medicine topics this Committee normally addresses. There is, at present, not one single food safety scientist specializing in food allergies on the Committee despite the relative frequency of acute allergies to fish in the US population. Nor is there an endocrinologist knowledgeable about growth hormones - which are at issue here - on the Committee. There is also not one single fish ecologist. Nine of the 13 members are veterinarians or hold doctorates in animal science. Two more have been involved in developing genetically engineered animals themselves, including one who has worked for Monsanto. The consumer representative, though knowledgeable, is a lawyer rather than a scientist. We question

how the Committee can accurately assess the safety of this salmon for humans and the environment when it lacks the essential expertise to do so. We believe that three fish ecologists, four food safety experts (including specialists in food allergies and in the effects of hormones on human health), and scientists from the consumer and environmental community must be added to the Committee, to provide appropriate balance and expertise.

We believe that without the extension of the review period, and the addition of certain scientific experts to the VMAC, the Committee's findings will not have the needed credibility with the public. We also believe that without these experts, FDA will fail to get the sound scientific advice it needs and deserves. For these reasons, we urge you to delay next week's VMAC meeting for two months, to allow a standard 60-day public review period of the data that has been released, and to allow FDA to add the necessary and appropriate expertise to the VMAC.

Thank you for considering our request.

Jean Halloran
Director, Food Policy Initiatives

Michael Hansen, Ph.D.
Senior Scientist