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E-ALERT | Food & Drug

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FDA CONSIDERS APPLICATION FOR GENETICALLY ENGINEERED SALMON

Over the past three days, FDA conducted meetings concerning the approval of AquaBounty Technologies' AquAdvantage salmon. This is the first time FDA is considering an application for a genetically engineered ("GE") animal intended for use as a food. FDA regulates GE animals differently than it regulates GE plants. While GE plants for food use are reviewed informally under the "generally recognized as safe" rubric, the DNA of a genetically-modified animal is treated as a "new animal drug" requiring affirmative approval by FDA's Center for Veterinary Medicine (CVM).

FDA conducted a meeting of CVM's Veterinary Medicine Advisory Committee ("VMAC") on September 19 and 20 to consider the safety and effectiveness of the new animal drug (i.e., the genetically-modified DNA in the AquAdvantage salmon) that is the subject of a new animal drug application ("NADA").[1] On September 21, FDA conducted a public hearing on the labeling of food derived from the GE salmon. Throughout the meetings, FDA stressed that discussions should pertain to the particular product definition at issue—triploid hemizygous, all-female Atlantic salmon bearing a single copy of the rDNA construct at a single, fixed place in the DNA lineage—and not GE animals generally. In addition, FDA emphasized that it has not made a decision on the AquAdvantage salmon application, and that it will carefully consider all of the information it received during the course of these meetings.

Advisory Committee Meeting

The members of the VMAC met on Sunday, September 19 for an orientation on general scientific issues surrounding GE animals and the statutory and regulatory constraints under which FDA must operate. On Monday, September 20, the VMAC received additional background information on the state of world fisheries, Atlantic salmon and risk issues associated with fish, AquaBounty Technologies, and regulation of GE animals at FDA. CVM representatives then made presentations to the VMAC on each of the areas considered in FDA's hierarchical risk-based approach to assessing the GE salmon: molecular and phenotypic characterization, food/feed safety and environmental assessments, claim validation, and durability plan and postmarket requirements. VMAC members had the opportunity to question each of the presenters. Members of the public also provided comments to the VMAC in 16 five-minute presentations. The VMAC members were explicitly asked not to vote on whether the AquAdvantage salmon should be approved, but, rather, were charged with considering the following four questions:

- Do the data and information demonstrate that the rDNA construct is safe to AquAdvantage salmon?

[1] FDA provided background information on its website prior to the meeting. *See* Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage Salmon, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222712.htm; An overview of Atlantic salmon, its natural history, aquaculture, and genetic engineering, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222635.htm.

- Do the data and information demonstrate there is a reasonable certainty of no harm from consumption of foods derived from AquAdvantage salmon?
- Do the data indicate that AquAdvantage salmon grow faster than their conventional counterparts?
- Are any potential environmental impacts from AquAdvantage salmon production adequately mitigated by AquaBounty Technologies' proposed conditions of use?

In response to the first and third questions, the VMAC members generally agreed that the rDNA construct was appropriate and that AquAdvantage salmon grow faster than conventional counterparts. With respect to the second inquiry, members expressed a desire for additional information on certain topics, such as allergenicity. Certain members additionally stated that findings of equivalence to conventional salmon would aid their analysis. Concerning environmental impacts, the members agreed that AquaBounty had planned multiple redundant levels of physical and biological containment. They identified other issues of concern, including the necessity for proper management of SOPs on-site and the potential for theft.

Public Hearing

On Tuesday, September 21, FDA conducted a public hearing on the labeling of food made from AquAdvantage salmon. FDA acknowledged that this discussion would not become relevant until FDA approved the AquAdvantage salmon application. The six-person FDA panel at the hearing consisted of Michael Landa, Acting Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN); Alta Charo, Senior Advisor, Office of the Commissioner; Felicia Billingslea, Director, Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements, CFSAN; Abigail Brandel, Attorney, Office of Chief Counsel; Jason Dietz, Science Policy Analyst, Office of Regulations, Policy, and Social Sciences, CFSAN; and William Jones, Acting Deputy Director, Office of Food Safety, CFSAN.

Twenty public participants, including representatives from biotechnology companies, environmental groups, and consumer groups, testified before the FDA panel. Many of the participants had also presented to the VMAC the previous day. These participants were asked to address the following two questions:

- Which facts about the AquAdvantage salmon seem most pertinent for FDA's consideration of whether there are any "material" differences between foods from this salmon and foods from other Atlantic salmon?
- If FDA determined that there are "material" differences, how would that difference be described on a food label in a way that is truthful and non-misleading?

Several participants testified that AquAdvantage salmon should be labeled as "GE" and that FDA had the authority to require such a label. Others opined that there were no material differences between AquAdvantage salmon and Atlantic salmon and no additional information should be required on the label. Several participants noted that voluntary labeling could be used, particularly voluntary labeling that would cast GE salmon in a positive light.

The docket will remain open until November 22, 2010 for the submission of additional comments on the labeling of food from AquAdvantage salmon.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

Eugene Lambert	202.662.5422	elambert@cov.com
Jeannie Perron	202.662.5687	jperron@cov.com
Miriam Guggenheim	202.662.5235	mguggenheim@cov.com
Melissa Whittingham	202.662.5354	mwhittingham@cov.com