

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0385]

Food Labeling; Labeling of Food Made From AquAdvantage Salmon; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding the labeling of food derived from AquAdvantage Salmon, a genetically engineered Atlantic salmon. The purpose of the hearing is for FDA to explain the relevant legal principles for food labeling and to solicit information and views from interested persons on the application of these principles to the labeling of food derived from AquAdvantage Salmon. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing that it will hold a public Veterinary Medicine Advisory Committee (VMAC) meeting.

DATES: See "How to Participate in the Hearing" in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See "How to Participate in the Hearing" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registration, to register orally, or to submit a notice of participation by mail, fax, or by e-mail: Syreeta Jones, BL Seamon Corporation, 9001 Edmonston Road, Suite 200, Greenbelt, MD 20770, phone: 301-577-0244 ext. 4900, fax: 301-577-5261, e-mail: sjones@blseamon.com.

For questions about the hearing, if you need special accommodations due to a disability, or to submit the full text, comprehensive outline or summary of an oral presentation: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1731, e-mail: Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing that it will hold a public VMAC meeting. The VMAC will consider issues regarding

the safety and effectiveness of the new animal drug that is the subject of the new animal drug application (NADA) concerning AquAdvantage Salmon produced by AquaBounty Technologies, Inc. In the event that the NADA relating to AquAdvantage salmon is approved, public input from this hearing on the labeling of food from AquAdvantage Salmon will assist FDA in the application of its food labeling principles which will determine if we should require labeling for such food beyond that required for food from other varieties of Atlantic salmon. A background document entitled, "Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon" describing the relevant legal principles and related questions specific to the labeling of foods from AquAdvantage Salmon is available at: <http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/default.htm>. In addition to this background document, approximately 2 weeks (but no later than 2 business days) prior to the hearing, specific technical information on the AquAdvantage Salmon will be posted on FDA's Web site at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>.

The following are five key principles for labeling foods that are applicable to the specific issue of the labeling of foods from genetically engineered animals, such as the AquAdvantage Salmon:

1. The law prohibits food labeling that is false (Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(a)(1)));

2. The law prohibits food labeling that is misleading, particularly in light of material facts about the product (Sections 403(a)(1) and 201(n) of the act (21 U.S.C. 343(a)(1) and 321(n))¹;

3. The law allows voluntary labeling about production methods, so long as the labeling is not false or misleading;

4. The law requires that the label include a name that accurately describes the basic nature of the food (Section 403(i) of the act (21 U.S.C. 343(i))); and

5. FDA cannot require additional labeling about production methods unless it is necessary to ensure that the

¹ Section 201(n) of the act (21 U.S.C. 321(n)) provides information on how labeling can be misleading. It states that labeling is misleading if it fails to reveal facts that are (1) material in light of representations made or suggested in the labeling, or (2) material with respect to consequences that may result from the use of the food to which the labeling or advertising relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual.

labeling is not false or misleading (See e.g., 72 FR 16291 at 16294, April 4, 2007). Another way of stating this point is that FDA cannot require labeling based on differences in the production process if the resulting products are not materially different due solely to the production process.

II. Purpose and Scope of the Hearing

The purpose of the hearing is for FDA to explain the relevant legal principles for food labeling and to solicit information and views from interested persons on the application of this framework to the labeling of food derived from AquAdvantage Salmon. The scope of this hearing is determined by this notice. We invite information and comments on the issues and questions listed in section III of this document as follows.

III. Issue for Discussion

At this hearing, FDA will seek public comment on the application of the principles of food labeling to food from the AquAdvantage Salmon. To facilitate public comment, specific technical information about the AquAdvantage Salmon will be posted on the FDA website approximately 2 weeks (but no later than 2 business days) prior to the public hearing.

At the public hearing, FDA will be inviting the public to share its views on:

1. 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. (Keep in mind that the use of genetic engineering does not, in and of itself, constitute a "material" difference under the law.)

2. If FDA determined there are "material" differences, how would that difference be described on a food label in a way that is truthful and non-misleading. (Keep in mind that it is the difference in composition, or in functional, organoleptic or other material properties that must be described, not the underlying production process.)

Information about changes in the attributes of the food itself, such as its nutritional value, functional properties (e.g., storage), and "organoleptic" qualities (e.g., texture and aroma) could be material (see e.g., 72 FR 16291 at 16293, April 4, 2007). When commenting on these issues, FDA requests that respondents include support for their answers with relevant data, where appropriate, and/or references to the relevant legal principles.

IV. Notice of Hearing Under 21 CFR Part 15

Because this is the first time the Agency is considering an application for a genetically engineered animal intended for use as food, at this hearing FDA invites the public to share its views on the application of the relevant legal principles of food labeling to food from the AquAdvantage Salmon. By delegation from the Commissioner of Food and Drugs (the Commissioner) (Staff Manual Guide 1410.21, section 1(G)(5)), the Assistant Commissioner for Policy finds that because this is the first time the Agency is considering such an application, it is in the public interest to permit persons to present information and views at a public hearing regarding the labeling of food made from AquAdvantage Salmon, and is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or her designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the hearing (either by making an oral presentation or as a member of the audience) must file a notice of participation (see Table 1, **FOR FURTHER INFORMATION CONTACT**, and "How to Participate in the Hearing" in section V of this document). By delegation from the Commissioner (Staff Manual Guide 1410.21, section 1(G)(5)), the Assistant Commissioner for Policy has determined under § 15.20(c) that advance submissions of oral presentations are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e), and that the submission of a comprehensive outline or summary is an acceptable alternative to the submission of the full text of the oral presentation. We request that individuals and organizations with common interests consolidate their requests for oral presentations and request time for a joint presentation through a single representative. After reviewing the notices of participation and accompanying information, we will schedule each oral presentation and notify each participant of the time allotted to the presenter and the approximate time that the presentation is scheduled to begin. If time permits,

we may allow interested persons who attend the hearing but did not submit a notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing.

After the hearing, we will place the hearing schedule and a list of participants on file in the Division of Dockets Management (see Table 1) under the docket number listed in brackets in the heading of this notice.

To ensure timely handling of any mailed notices of participation, presentations, or comments, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement "Food Labeling; Labeling of Food Made From AquAdvantage Salmon; Public Hearing; Request for Comments."

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to our policy and procedures for electronic media coverage of our public administrative proceedings in part 10, subpart C (21 CFR part 10, subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to the procedures and limitations in § 10.206, to videotape, film, or otherwise record our public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b).

Any persons requiring special accommodations to attend the hearing due to a disability, should direct those needs to the contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of these provisions as specified in §§ 10.19 and 15.30(h). In particular, § 15.21(a) states that the notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time. If the public interest requires, e.g., if a hearing is to

be conducted within a short period of time, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given. If the public interest requires, the notice may also provide for submitting notices of participation at the time of the hearing. In this document, the conditions for the hearing specify that notices of participation be submitted electronically to an agency Internet site, to a contact person (outside of FDA) who will accept notices of participation by mail, telephone, fax, or e-mail, or in person on the day of the hearing (as space permits). We are using these procedures for submitting notices of participation, rather than provide for the submission of notices of participation to the Division of Dockets Management, because the hearing is to be conducted within a short period of time and these procedures are more efficient. In addition, these procedures provide more flexibility to persons who wish to participate in the hearing than would be provided if participants were required to submit the notice of participation in writing to the Division of Dockets Management. By delegation from the Commissioner (Staff Manual Guide 1410.21, section 1(G)(5)), the Assistant Commissioner for Policy finds under § 10.19 that no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law if notices of participation are submitted by the procedures listed in this notice rather than to the Division of Dockets Management.

V. How to Participate in the Hearing

Advance registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis. You may submit the notice of participation electronically (see Table 1); we encourage you to use this electronic means of advance registration. You also may submit the notice of participation orally or by mail, fax, or e-mail (see **FOR FURTHER INFORMATION CONTACT**). See Table 1 for the dates by which you must submit your notice of participation. A single copy of any notice of participation is sufficient.

TABLE 1.—INFORMATION ON PARTICIPATION IN THE HEARING AND ON SUBMITTING COMMENTS

	Date	Electronic Address	Address (Non-electronic)	Other Information
Date of Hearing	September 21, 2010, from 9 a.m. to 4:30 p.m.		Hilton Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20850, 301-468-1100	
Advance Registration	By September 13, 2010	http://www.fedmeetings.net/common/registration.cfm?mid=3210	We encourage you to use electronic registration if possible.	Registration to attend the hearing will also be accepted onsite on the day of the hearing, as space permits. Requests made on the day of the hearing to make an oral presentation may be granted as time permits. Registration information and information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Make a request for oral presentation	By September 8, 2010			
Provide a brief description of the oral presentation and any written material for the presentation	By September 13, 2010		Juanita Yates (See FOR FURTHER INFORMATION CONTACT)	Written material associated with an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Request special accommodations due to a disability	By September 13, 2010		Juanita Yates (See FOR FURTHER INFORMATION CONTACT)	
Submit comments	By November 22, 2010	Federal eRulemaking Portal: http://www.regulations.gov . Follow the instructions for submitting comments.	FAX: 301-827-6870 Mail/ Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane rm. 1061, Rockville, MD 20852	All comments must include the agency name and the docket number found in brackets in the heading of this document. All comments received may be posted without change to http://www.regulations.gov , including any personal information provided. We encourage you to continue to submit electronic comments by using the Federal eRulemaking Portal. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

* You may also register or request to make an oral presentation by mail, fax, e-mail, or phone by providing registration information (including name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available)) (see **FOR FURTHER INFORMATION CONTACT**).

The notice of participation must include your name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available). If you wish to request an opportunity to make an oral presentation during the open public comment period of the hearing, your notice of participation also must include the title of your presentation, the sponsor of the oral presentation (e.g.,

the organization paying travel expenses or fees), if any; and the approximate amount of time requested for the presentation. Presentations must be limited to the questions and subject matter identified in section III of this document.

Under § 15.20(c), if you request an opportunity to make an oral presentation you must submit your presentation (either as the full text of the presentation, or as a comprehensive

outline or summary). You may do so by e-mail or in writing. See Table 1 for the dates by which you must submit your presentation. See Table 1 and **FOR FURTHER INFORMATION CONTACT** for information on where to send your presentation.

Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing. Depending on the

number of oral presentations, we may need to limit the time allotted for each oral presentation (e.g., 5 minutes each). Depending on the content of the presentations, the time allotted for oral presentations may vary. We request that interested persons and groups having similar interests consolidate their requests for oral presentation and present them through a single representative. If you need special accommodations due to a disability, please inform us (see Table 1 and **FOR FURTHER INFORMATION CONTACT**).

We will also accept registration onsite; however, space is limited. Onsite registration will be accepted on a first-come, first-served basis and will be closed when the maximum seating capacity is reached. Requests for an opportunity to make a presentation from individuals or organizations that did not register in advance to make an oral presentation may be granted if time permits.

Persons who registered in advance for the hearing should check in at the onsite registration desk between 8:30 and 9 a.m. Persons who wish to register onsite on the day of the hearing should do so at the registration desk between 8:30 and 9 a.m. We encourage all participants to attend the entire day.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see Table 1) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: August 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Veterinary Medicine Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Veterinary Medicine Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19, 2010, from 1 p.m. to 5:30 p.m. and on September 20, 2010, from 8 a.m. until 6 p.m.

Location: Rockville Hilton, 1750 Rockville Pike, Rockville, MD 20852, 301-468-1100.

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, FAX: 240-276-9020, email: aleta.sindelar@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512548. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 19, 2010, the committee will receive an orientation on both general scientific issues surrounding genetically engineered animals and the statutory and regulatory constraints under which the Agency must operate. On September 20, 2010, the committee will consider issues regarding the safety and effectiveness of

the new animal drug that is the subject of a new animal drug application (NADA) concerning AquaAdvantage salmon produced by AquaBounty Technologies, Inc. These genetically engineered Atlantic salmon are intended to grow faster than conventionally bred Atlantic salmon.

Two background documents entitled "An overview of Atlantic salmon, its natural history, aquaculture, and genetic engineering" and "The VMAC Meeting on Science-Based Issues Associated with AquaAdvantage Salmon" can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>.

In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing that it will hold a public hearing on the labeling of food, including naming of the food, from the AquaAdvantage salmon on September 21, 2010. This public hearing will allow the public to comment on the application of food labeling principles to food from the AquaAdvantage Salmon, if the NADA is approved. An overview of the labeling issues to be addressed is described in "Background Document: Public Hearing before the Commissioner on the Labeling of Food Made from the AquaAdvantage Salmon" at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>.

FDA anticipates making the meeting materials available approximately 16 days before this meeting, but in any event no later than 2 business days before the meeting at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting.

Additional information regarding the Center for Veterinary Medicine's (CVM's) regulatory oversight of genetically engineered animals can be found at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm>.

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of