4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0899]

Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency) is announcing the availability for public comment of the Agency's draft environmental assessment (EA) of the proposed conditions of use specified in materials submitted by AquaBounty Technologies, Inc., in support of a new animal drug application (NADA) concerning a genetically engineered (GE) Atlantic salmon. Also available for comment is the Agency's preliminary finding of no significant impact (FONSI) for those specific conditions of use.

DATES: Submit either electronic or written comments on the Agency's draft EA and preliminary FONSI by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to: http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Eric Silberhorn,

Center for Veterinary Medicine (HFV-162),

Food and Drug Administration,

7500 Standish Pl.,

Rockville, MD 20855,

240-276-8247,

email:abig@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Notice is given that a draft EA prepared by FDA in support of an NADA associated with AQUADVANTAGE Salmon, a GE Atlantic salmon containing the opAFP-GHc2 recombinant DNA construct is being made available for public comment. FDA is also making available for comment the Agency's preliminary FONSI for those specific conditions of use. In the event of an approval of the application, the approval would only allow AQUADVANTAGE Salmon to be produced and grown-out in the physically contained freshwater culture facilities specified in the sponsor's NADA.

To encourage public participation consistent with regulations implementing the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the draft EA and the preliminary FONSI that are the subject of this notice on public display at the Division of Dockets Management (see DATES and ADDRESSES) for public review and comment for 60 days. Given that the substance of this draft EA was made available to the public in advance of the Agency's 2010 Veterinary Medicine Advisory Committee meeting and consistent with the Agency's regulations implementing the National Environmental Policy Act (21 CFR 25.51(b)(3)), FDA believes that a 60-day comment period is appropriate and does not intend to grant requests for extension of the comment period.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of 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. FDA will also place on public display any amendments to, or comments on, the Agency's draft EA and preliminary FONSI without further announcement in the Federal Register.

If, based on its review, the Agency finds that an environmental impact statement is not required and the NADA results in an approval by the Agency, the notice of availability of the Agency's EA and FONSI, as well as any supporting evidence, will be published with the regulation describing the approval in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: December 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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