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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for two draft environmental review documents for which a notice of availability appeared in the Federal Register of December 26, 2012. In that notice, FDA made available for comment 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 and a preliminary finding of no significant impact (FONSI) for those specific conditions of use. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by April 26, 2013.

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:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 26, 2012 (77 FR 76050), FDA published a notice of availability with a 60-day comment period to make available for public comment the Agency's draft EA of the proposed conditions of use specified in materials submitted by AquaBounty Technologies, Inc., in support of an NADA concerning a GE Atlantic salmon and a preliminary FONSI for those specific conditions of use. Comments on the draft EA and FONSI will inform FDA's decision whether to require an environmental impact statement (EIS) or finalize the EA and FONSI for this NADA.

The Agency has received a request for a 60-day extension of the comment period for the draft EA and FONSI. The request conveyed concern that the current 60-day comment period does not allow sufficient time to respond.

FDA has considered the request and is extending the comment period for the draft EA and FONSI for 60 days, until April 26, 2013. The Agency believes that a 60-day extension

allows adequate time for interested persons to submit comments without significantly delaying the Agency's decision on whether to finalize these documents or prepare an EIS.

II. Request for Comments

Interested persons may submit either electronic comments regarding these documents to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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, and will be posted to the docket at http://www.regulations.gov.

Dated: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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