SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Tuesday, November 20, 2012 (77 FR 69632). The document announced the availability of a draft guidance entitled ''Electronic Source Data in Clinical Investigations.'' The document was published with an incorrect date in the **DATES** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Office of Planning & Informatics, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993–0002, 301–796–5333, FAX: 301–847–8443.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–28198, appearing on page 69632 in the **Federal Register** of Tuesday, November 20, 2012, the following correction is made:

1. On page 69632, in the third column, in the **DATES** section, the date ''January 22, 2013'' is corrected to read ''March 26, 2013.''

Dated: December 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31027 Filed 12–21–12; 4:15 pm]

BILLING CODE 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 February 25, 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: 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.

[FR Doc. 2012–31118 Filed 12–21–12; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Public Workshop on Minimal Residual Disease; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the American Society of Clinical Oncology, is announcing a public workshop that will provide a forum for discussion of extending the qualification of minimal residual disease (MRD) detection as a prognostic biomarker to an efficacy/response biomarker in evaluating new drugs for the treatment of acute myeloid leukemia (AML). Our objective is for the workshop to provide a venue for an in-depth discussion of potential endpoints for trials intended to support the approval of new drugs or biologics for treatment of AML. Participants in the workshop will examine if any currently used biomarker can be used as a surrogate endpoint, identify the preferred technology platform and performance characteristics for the assay of the biomarker, discuss any issues regarding ongoing deficiencies in methodological standardization for the biomarker, and determine the need for additional FDA-approved in-vitro diagnostics for AML drug development. The primary focus will be on the biomarkers that are or will soon be ready for incorporation into clinical trials, and the technical and regulatory challenges for use of these markers.