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 The document announced the availability of a draft guidance entitled ''Electronic Source Data in Clinical Investigations.''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.

DATES: The public workshop will be held on March 4, 2013, from 8 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

FOR FURTHER INFORMATION CONTACT: Christine Lincoln, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6413, Silver Spring, MD 20993–0002, 301–796–2340, email: *Christine.Lincoln@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Complete remission, relapse-free survival, and overall survival are frequently used as endpoints in clinical trials of new therapeutics for AML. These endpoints have some limitations, especially in the context of minimal residual disease. Use of morphological complete remission may miss individuals with clinically significant residual disease who are not truly in remission. For those being followed after remission induction, new evidence of submorphological disease may prompt therapy before morphological relapse. Additionally, for patients with good prognosis, the length of the clinical trial followup may be very long when survival is the outcome measured, raising logistical and financial challenges for study conduct. More information is needed on whether MRD in AML can be qualified as a response biomarker and then used as a clinical trial endpoint and what the challenges would be to implement use of such an endpoint.

This Public Workshop on Minimal Residual Disease in AML will be one of a series of FDA workshops to establish processes and procedures necessary to qualify a prognostic biomarker, MRD, as a possible response or efficacy biomarker in a group of hematological malignancies. Evaluation of clinical data suggests that MRD can be established as a potential surrogate endpoint for pivotal clinical trials and drug approval given its prominent role as a prognostic indicator in certain subtypes of acute and chronic leukemia. The Office of Hematology and Oncology Products has explored, or plans to explore, the potential utility of MRD as a surrogate endpoint in acute lymphoblastic leukemia (ALL) (including the relapsed setting), chronic lymphocytic leukemia (CLL), and AML. Given the diverse pathophysiology and natural history of these diseases and current practice standards, individualized consideration of MRD as a surrogate endpoint is warranted. The ALL workshop was held on April 18, 2012, and the CLL workshop will be held on February 27, 2013.

II. Structure and Scope of the Workshop

The workshop's scope will include discussions of the use of flow cytometry and molecular methods used to detect and measure minimal residual disease in patients being treated for AML. The workshop will consist of formal presentations examining the regulatory, scientific, and clinical basis for use of biomarkers as potential clinical trial endpoints in AML interspersed with discussions on issues associated with these endpoints.

III. Attendance and Registration

FDA encourages patient advocates, representatives from industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop. There is no registration fee for the public workshop. To register electronically, please use the following Web site: *http://www.zoomerang.com/Survey/WEB22GPAXN9NQB* (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Seats are limited and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference.

Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm.* Under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.''

Dated: December 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31043 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–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 that of an efficacy/response biomarker in evaluating new drugs for the treatment of chronic lymphocytic leukemia (CLL). Our objective for the workshop is to provide a venue for an in-depth discussion of potential surrogate endpoints for trials intended to support the approval of new drugs or biologics for the treatment of CLL. Participants in the workshop will examine the advantages and disadvantages of MRD as a surrogate endpoint for approval, identify the preferred technology platform and performance characteristics for the assay of this biomarker, and discuss any issues regarding methodological standardization for the biomarker. The primary focus will be on the biomarkers that are ready for incorporation into clinical trials and the technical and regulatory challenges for use of these markers.

DATES: The public workshop will be held on February 27, 2013, from 8 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

FOR FURTHER INFORMATION CONTACT: Christine Lincoln, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6413, Silver Spring, MD 20993–0002, 301–