provide information on the effectiveness of FDA guidance on this issue.

(Comment 8) Two comments expressed concern that the time delay conditions were not realistic, stating that a time delay of 6 months to a year might be more realistic.

(Response) We agree that a 6-month exposure delay more closely approximates real-world exposure to original and corrective messaging. In response to concerns about the realism of our approach, we have changed the study design in two ways (see Table 2). First, participants will view the stimuli embedded in a ''clutter reel'' of other ads three times over a 3-week period to approximate multiple exposures in a real-world context. Second, we have added a 6-month delay condition.

(Comment 9) One comment critiqued the references included in the 60-day **Federal Register** notice, stating:

''* * * the references offered in the instant [sic] notice seemed less concerned with presenting corrective advertising in a manner most likely to inform the consumer about the safety and efficacy of a given product and more concerned with determining whether the corrective ad might be bad for sales. Furthermore, the only example of application of a judicial remedy to enforce corrective advertising cited by one of these references distorted the clear intent of the opinion cited.''

(Response) Some of the research on corrective advertising, as the commentator notes, has assessed potential damage to an advertiser's reputation. Darke and colleagues (2008, Ref. 1) note the possibility of reputational damage, for example. Other papers cited in the 60-day notice, though, do not focus primarily on reputational damage. Mazis' work, both in the 1970s and 1980s and then again more recently (e.g., Mazis, 2001, Ref. 6), as we have seen a resurgence of corrective advertising, has been concerned with the efficacy of corrective messages. Mazis and colleagues (1983, Ref. 3), for example, focused attention on the extent to which viewers actually noticed and remembered the corrective message inserted into Listerine ads. Moreover, our study was designed to address a gap in the literature—there is scant work on the specific efficacy of televised corrective ads intended to address claims made regarding prescription drugs—rather than to simply extend and replicate past literature. The primary focus of our study is correction of misperceptions that arise from prescription drug advertising. The dependent variables we describe in the 60-day notice do not include advertiser reputation but rather are comprised of constructs such as belief in advertised claims that overstate efficacy or minimize risk, perceived risk of the advertised drug, and perceived efficacy of the advertised drug.

Please note that in response to all comments received, whether we have adopted the suggestions or not, we will specifically examine the items mentioned in cognitive testing. During this testing, nine respondents will participate in the survey while explaining why and how they have chosen their answers and which questions they find difficult to respond to or to understand.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden response	Total hours
Sample availability (pretests and main survey)	24,635				
Screener completes (60%)	14,891	1	14,891	0.0333	496
Eligible (85%)	12,658				
Pretest (stimuli) completes (65%)	1,450	1	1,450	0.333	483
Pretest (questionnaire) completes (65%)	200	1	200	0.5	100
Phase 1 completes (65%)	1,000	1	1,000	.416	417
Phase 2 completes (45%)	4,000	1	4,000	1	4,000
Pretest/Study completes	6,650				
Total					5,496

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates the total annual estimated burden imposed by this collection of information as 5,496 hours for this one-time collection.

V. References

The following references have been placed on display at the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday (FDA has verified the Web site addresses of the following references, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

1. Darke, P. R., Ashworth, L., and Ritchie, R. J. B. (2008). Damage from corrective advertising: Causes and cures. *Journal of Marketing,* 72, 81–97;
2. Mazis, M. B. & Adkinson, J. E. (1976). An experimental evaluation of a proposed corrective advertising remedy. *Journal of Marketing Research,* 13, 178–183.
3. Mazis, M. B., McNeill, D. L., & Bernhardt, K. L. (1983). Day-after recall of Listerine corrective commercials. *Journal of Public Policy & Marketing,* 2, 29–37.
4. Singer, N. (2009, February 11). A birth control pill that promised too much. *The New York Times,* p. B1.
5. From Guidance for Industry: ''Help-Seeking'' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms. Available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf.* Last accessed November 23, 2012.
6. Mazis, M. B. (2001). *FTC* v. *Novartis:* The return of corrective advertising? *Journal of Public Policy & Marketing,* 20, 114–122.

Dated: *December 20, 2012.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–31028 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–2010–D–0643]

Draft Guidance for Industry on Electronic Source Data in Clinical Investigations; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

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.