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 The document announced the availability of a draft guidance entitled “Electronic Source Data in Clinical Investigations.”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


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.”


Leslie Kux, Assistant Commissioner for Policy.

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


Leslie Kux,
Assistant Commissioner for Policy.
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