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 The document announced the availability of a draft guidance entitled “Electronic Source Data in Clinical Investigations.”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

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.