

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]

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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 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>.

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796–2340, email: Christine.Lincoln@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Public Workshop on Minimal Residual Disease 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 plans to explore the potential utility of MRD as a surrogate endpoint in acute lymphoblastic leukemia (ALL) (including the relapsed setting), CLL, and acute myeloid leukemia (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. The CLL and AML workshops are scheduled for February 27, 2013, and March 4, 2013, respectively.

II. Structure and Scope of the Workshop

The workshop's scope will extend to the use of flow cytometry and the molecular methods used to measure minimal residual disease in patients being treated for CLL. The workshop will consist of formal presentations examining the regulatory, scientific, and clinical basis for use of biomarkers as potential clinical trial endpoints in CLL followed by discussions on issues associated with use of an MRD endpoint.

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/WEB22GPA3U95QX> (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

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Dated: December 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443–1884.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's function, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Survey of Eligible Users of the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank (OMB No. 0915–xxxx)—New

Abstract: The Health Resources and Services Administration (HRSA) plans to conduct a survey of the National

Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank (NPDB/HIPDB). The purpose of this survey is to assess the overall satisfaction of the eligible users of the NPDB/HIPDB. This survey will evaluate the effectiveness of the NPDB/HIPDB as flagging systems, sources of information, and use in decision making. Furthermore, this survey will collect information from eligible non-users of the NPDB/HIPDB to understand what can be done to aid the eligible non-users in registering, accessing, and using the information available in the NPDB/HIPDB. This survey is a follow-up to the NPDB/HIPDB users and non-users survey of 2008.

The survey will be administered to eligible users of the NPDB/HIPDB. The survey will also collect information from those that have had matched responses. A matched response occurs when an eligible user queries the NPDB/HIPDB then receives a report. The purpose of collecting the matched response data is to understand what actions or decisions are made when an eligible user receives a matched response.

The survey will be administered to non-users of the NPDB/HIPDB. Non-users of the NPDB/HIPDB are considered eligible users that have (i) never registered, (ii) registered in the past but are not currently registered, or (iii) are registered but are not using the NPDB/HIPDB. The information provided by the non-users will enable understanding of what needs to be done to facilitate and educate non-users on accessing and using the information in the NPDB/HIPDB. Finally, the survey will be administered to those that use the self-query service provided by the NPDB/HIPDB. Understanding self-query user satisfaction and how the information is used is an important component of the survey.

Eligible users of the NPDB/HIPDB will be asked to complete a web-based survey. Eligible non-users that have never registered in the NPDB/HIPDB will be contacted via telephone to obtain email information so that they will be able to complete a web-based survey. Data gathered from the survey will be compared with previous survey results. This survey will provide HRSA with the information necessary to improve the usability and effectiveness of the NPDB/HIPDB.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize