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 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. 2012–31044 Filed 12–21–12; 4:15 pm]

BILLING CODE 4160–01–P

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) 443–1984.

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

technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NPDB/HIPDB Users Non-Matched Responses	11,832	1	11,832	0.25	2,958
NPDB/HIPDB Users Matched Responses	1,768	1	1,768	0.25	442
NPDB/HIPDB Self-Query Non-Matched Responses	1,080	1	1,080	0.10	108
NPDB/HIPDB Self-Query Matched Responses	120	1	120	0.10	12
NPDB/HIPDB Non-Users (Hospitals)	1,200	1	1,200	0.10	120
NPDB/HIPDB Non-Users (All Others)	400	1	400	0.10	40
Total	16,400		16,400		3,680

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: December 17, 2012.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2012–30835 Filed 12–21–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Pediatric Palliative Care Campaign Pilot Survey

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Nursing Research (NINR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact Ms. Adrienne Burroughs, Health Communications Specialist, Office of Communications and Public Liaison, NINR, NIH, Building 31, Room 5B10, 31 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 496–0256, or Email your request, including your address to: *adrienne.burroughs@nih.gov*.

Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Proposed Collection: Pediatric Palliative Care Campaign Pilot Survey–0925-New–National Institute of Nursing Research (NINR), National Institutes of Health (NIH).

Need and Use of Information Collection: NINR developed a Pediatric Palliative Care Campaign to address the communications challenges faced by health care providers who recommend and provide palliative care to pediatric populations. NINR is launching this effort to increase the use of palliative care for children living with serious illness or life-limiting conditions. The Pediatric Palliative Care Campaign Pilot Survey will assess the information and materials being disseminated as part of the Pediatric Palliative Care Campaign pilot. Survey findings will help (1) determine if the pilot campaign is effective, relevant, and useful to health care providers who recommend and provide palliative care to pediatric populations; (2) to better understand current perceptions, challenges, and information needs of health care providers when it comes to discussing pediatric palliative care so that information and materials can be refined; and (3) examine how effective the campaign pilot materials are in starting and continuing a pediatric palliative care conversation and addressing the communications needs of health care providers around this topic.

This assessment will deliver strategic and actionable guidance for refining the campaign materials so that they can be used by a wider audience of health care providers. OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 26.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Physicians	25	1	30/60	13