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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27724 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0799]

Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, To Reduce the Risk of Transmission of Hepatitis B Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus,'' dated October 2012. The guidance document provides recommendations on the use of FDA-licensed nucleic acid tests (NAT) to screen blood donors for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) and recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling. In addition, the guidance provides notification that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. The guidance is intended for blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes. The guidance announced in this notice finalizes the draft guidance of the same title, dated November 2011. The guidance also supplements previous memoranda and guidance from FDA concerning the testing of donations for hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc) and the management of donors and donations mentioned in those documents.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components, including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus,'' dated October 2012. FDA is providing blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes, with recommendations concerning the use of FDA-licensed NAT to screen blood donors for HBV DNA. FDA is also providing these blood establishments with recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling.

In addition, FDA is notifying those blood establishments that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. FDA-licensed HBV NAT can detect evidence of infection at an earlier stage than is possible using previously approved HBsAg and anti-HBc tests. Therefore, FDA is recommending the use FDA-licensed HBV NAT, in accordance with the requirements under Title 21 Code of Federal Regulations, 610.40(a) and (b) (21 CFR 610.40(a) and (b)).

The guidance supplements previous memoranda and guidance from FDA to blood establishments concerning the testing of donations for HBsAg and anti-HBc, and the management of donors and donations mentioned in those documents. Note that testing Whole Blood and blood components for transfusion and Source Leukocytes for further manufacture for HBsAg and anti-HBc, and Source Plasma for HBsAg, should continue when a blood establishment implements HBV NAT. FDA may consider advancements in technology for testing blood donations, as well as data obtained following the implementation of HBV NAT, to make future recommendations on adequate and appropriate testing for HBV.

In the **Federal Register** of November 28, 2011 (76 FR 72950), FDA announced the availability of the draft guidance of the same title, dated November 2011. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to minor editorial changes made to improve clarity, changes to the draft guidance include revised labeling recommendations and an extension of the time for implementation of the guidance to 6 months after publication of the final guidance. The guidance announced in this notice finalizes the draft guidance dated November 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 601.12 and in §§ 606.121 and 610.40 have been approved under OMB control numbers 0910–0338 and 0910–0116, respectively.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27783 Filed 11–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request (30-day): National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This information collection was previously published in the **Federal Register** on June 29, 2012, page 38840 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Amanda Greene, Office of Science Policy and Public Liaison, NINR, NIH, Democracy One, 6701 Democracy Blvd., Suite 700, Bethesda, MD 20892 or call non-toll-free number (301) 496–9601 or Email your request, including your address to: *amanda.greene@nih.gov.*

Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Proposed Collection: National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey, –0925–New

Need and Use of Information Collection: The NINR Summer Genetics Institute Alumni Survey will obtain information on the long-term outcomes of the NINR Summer Genetics Institute training program for nurse scientists and faculty. Target participants are alumni of this training institute which began in 2000. The survey inquires about career activities, including research, clinical, teaching and educational activities, since completion of the NINR Summer Genetics Institute. This is a 39-item survey that takes an average of 30 minutes to complete. The findings will provide valuable information on the influence of the Institute in developing genetics research capability among Institute alumni, and development and expansion of clinical practice in genetics among alumni who are nurse clinicians.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 75.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Total burden hours
Researchers	150	1	30/60	75

Dated: November 2, 2012.

Amanda Greene,

Project Clearance Liaison, NINR, National Institutes of Health.

[FR Doc. 2012–27578 Filed 11–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee (IACC) Subcommittee for Services Research and Policy.

The IACC Subcommittee for Services Research and Policy will be having a webinar/conference call on Tuesday, November 27, 2012. The Subcommittee will discuss and vote on draft Updates for Chapters 5 and 6 of the 2012 IACC Strategic Plan, which include services and lifespan issues. These Updates will describe recent progress that has been made in the autism field as well as any new gap areas in research that have emerged since the previously released 2011 Strategic Plan. The meeting will be open to the public and accessible by webinar and conference call.