involved in cancer research in any country. *Frequency of Response:* Once per initial trial registration; four amendments per trial annually; and four accrual updates per trial annually. *Affected Public:* Individuals, business and other for-profits, and not-for-profit institutions. *Type of Respondents:* Clinical research administrators on behalf of clinical investigators. The annual reporting burden is estimated at 38,500 hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

A.12–1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/ hours)	Annual burden hours
Clinical Trials	Initial Registration	5,500	1	120/60	11,000.
	Amendment	5,500	4	60/60	22,000.
	Accrual Updates	5,500	4	15/60	5,500.
Total		16,500			38,500.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact John Speakman, Associate Director for Clinical Trials Products and Programs, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH, DHHS, 2115 E. Jefferson Street, Suite 6000, Rockville, MD 20892 or call non-toll-free number 301–451–8786 or e-mail your request, including your address to: *john.speakman@nih.gov*.

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

Dated: October 30, 2009.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E9–26875 Filed 11–6–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0233]

Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion; 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 to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion,'' dated November 2009. This guidance is intended for establishments that collect Whole Blood and blood components intended for transfusion. The document provides recommendations for testing of donations of Whole Blood and blood components for West Nile Virus (WNV) using an FDA-licensed donor screening assay. FDA believes that the use of a licensed nucleic acid test (NAT) will reduce the risk of transmission of WNV, and therefore recommends use of a licensed NAT to screen donors of Whole Blood and blood components intended for transfusion. The guidance announced in this notice finalizes the recommendations as to Whole Blood and blood components contained in the draft guidance ''Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated April 2008. The recommendations as to HCT/P donor specimens contained in the draft guidance are not being finalized at this time because FDA believes additional public discussion is warranted.

DATES: Submit 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 on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, 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 to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion,'' dated November 2009. The guidance document provides

recommendations for testing donations of Whole Blood and blood components for WNV using an FDA-licensed donor screening assay. The recommendations in section III of the guidance apply to all donations of Whole Blood (as defined in 21 CFR 640.1) and blood components for transfusion.

In the **Federal Register** of April 28, 2008 (73 FR 22958), FDA announced the availability of the draft guidance ''Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated April 2008. The draft guidance provided recommendations for testing donations of Whole Blood and blood components and HCT/P donor specimens for WNV using an FDA-licensed donor screening assay. FDA requested that comments on this draft guidance be submitted within 90 days of publication. The 90-day comment period ended on July 28, 2008. In addition, in the **Federal Register** of July 7, 2008 (73 FR 38460), FDA requested the submission of data from the 2008 WNV season relating to the criteria for converting from minipool NAT (MP–NAT) to individual donation NAT (ID–NAT) by January 31, 2009, and stated that we did not intend to finalize the proposed recommendations on conversion from MP–NAT to ID–NAT until we had obtained the additional data. At this time, there is insufficient data to recommend uniform threshold criteria for switching from MP–NAT screening to ID–NAT screening. Until we have sufficient data to support the development of suitable uniform threshold criteria, we consider it appropriate for each blood establishment to define its own threshold criteria for switching from MP–NAT to ID–NAT screening and for reverting to MP–NAT screening.

Additionally, at this time, FDA is continuing to review public comment on our recommendations for testing HCT/P donor specimens for WNV. We believe additional public discussion is warranted. Therefore, we are not finalizing our recommendations for HCT/Ps in this guidance. We intend to seek additional public input and to issue guidance for testing HCT/P donor specimens for WNV in the future.

FDA received numerous comments on the draft guidance and those comments were considered in finalizing the guidance. A summary of changes follows. The guidance announced in this notice: (1) Finalizes only the recommendations as to testing donations of Whole Blood and blood components intended for transfusion for WNV; (2) allows establishments that collect Whole Blood and blood components intended for transfusion flexibility to define their own threshold criteria for switching from MP–NAT to ID–NAT screening; (3) recommends that establishments that collect Whole Blood and blood components intended for transfusion switch from MP–NAT to ID–NAT screening as soon as feasible with 48 hours of reaching the threshold, instead of 24 hours; (4) recommends that establishments notify a blood donor of his or her deferral and counsel the donor following an ID–NAT reactive donation, rather than after additional testing on the reactive index donation; and (5) removes Table 2 (Recommendations on Additional Testing of Blood and Blood Components).

The guidance is being issued in conformance 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 requirements 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 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.122 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 630.6 have been approved under OMB control number 0910–0116.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26870 Filed 11–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities, Office of Science Policy, Office of the Director; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: December 3, 2009.

Time: 8:30 a.m. to 4 p.m. (Times are approximate and subject to change).

Agenda: Presentations and discussions regarding: (1) Introduction of new NSABB voting members; (2) federal responses to NSABB reports; (3) activities of the Working Groups on Outreach and Education and on International Engagement; (4) synthetic biology and NSABB draft report on biosecurity issues raised by synthetic biology; (5) public comments; and (6) other business of the Board.

Place: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Ronna Hill, NSABB Program Assistant, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 496–9838.

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice, guidance and leadership regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The meeting will be open to the public, however pre-registration is strongly recommended due to space limitations.