***DEPARTMENT OF HEALTH AND HUMAN SERVICES***

**Food and Drug Administration**

[Docket No. FDA–2012–N–0001]

**Requirements for Importing Food and Drug Administration Regulated Products Into the United States**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following meeting: “Requirements for Importing Food and Drug Administration Regulated Products Into the United States.” The topics to be discussed are FDA regulations with respect to importing pharmaceutical products, medical devices, food products, as well as technology which applies to brokers and forwarders.

**Date and Time:** The meeting will be held on July 18, 2012, from 8:30 a.m. to 5 p.m., in Des Plaines, IL.

**Location:** The meeting will be held at the Illinois Department of Transportation Building, 9511 West Harrison St., Des Plaines, IL, 60016.

**Contact:** Lisa Misevicz, Food and Drug Administration, 550 West Jackson Blvd., suite 1500, Chicago, IL 60661; 312–596–4217; email: lisa.misevicz@fda.hhs.gov.

**Registration:** Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by July 10, 2012.

**Contact Person:** Leslie Kux, Assistant Commissioner for Policy.

**BILLING CODE 4160–01–P**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2012–N–0001]

**Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Use of Computer Simulation of the United States Blood Supply in Support of Planning for Emergency Preparedness and Medical Countermeasures.” The purpose of this public workshop is to provide stakeholders a forum for discussion of data needs and to obtain feedback on possible modeling scenarios to explore emergency supply situations that could adversely impact the blood supply in the United States occur.

The public workshop will include presentations and panel discussions with experts from academia, regulated industry, government, and other stakeholders.

**Date and Time:** The public workshop will be held on July 24, 2012, from 8:30 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Ave., Bethesda, MD 20814, 301–657–1234.

**Contact Person:** Mark Walderhaug, Center for Biologics Evaluation and Research (HFM–210), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6028, email: Mark.Walderhaug@fda.hhs.gov.

**Registration:** Mail or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to Mark Walderhaug (see Contact Person) by July 17, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m. If you need special accommodations due to a disability, please contact Mark Walderhaug (see Contact Person) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** The public workshop presentations and panel discussions will:

1. Discuss the role of computer simulation in emergency preparedness and medical countermeasures.
simulation modeling of the U.S. blood supply, including the possible application of an FDA computer simulation model of the U.S. blood supply in support of emergency preparedness and planning for potential disruptions in blood donations; (2) discuss with the blood community the utility of simulation methods as a complementary approach to support planning for daily inventory needs and forecasting for future blood donations and demand; (3) discuss the capabilities and limitations of the U.S. computer simulation model, assumptions used in the model and data gaps for model validation; (4) describe and prioritize future model enhancements to extend the model predictions from red blood cell units to other blood components, such as plasma and platelets; and (5) discuss the level of detail required for a model to characterize the U.S. blood supply and to develop possible scenarios in which shortages may be addressed through countermeasures such as the use of local and interregional transfers of blood and blood components.

Transcripts: Transcripts of the public workshop may be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at: http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.

Dated: May 18, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2012–12593 Filed 5–23–12; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Web-Based Assessment of the Clinical Studies Support Center (CSSC)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on March 12, 2011, Volume 77 No. 44, pages 14531–14533 and allowed 60-days for public comment. One comment was 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 current valid OMB control number.

Proposed Collection: Title: Web-Based Assessment of the Clinical Studies Support Center (CSSC). Type of Information Collection Request: New. Need and Use of Information Collection: Over the past decade Data Safety Monitoring Boards (DSMBs), Observational Safety Monitoring Boards (OSMBs), and Protocol Review Committees (PRCs) have become an important quality standard in clinical trials and research involving human subjects. The National Heart, Lung, and Blood Institute (NHLBI) alone currently has approximately 60 active review Committees. These include DSMBs, OSMBs, and PRCs which are independent groups convened to review study protocols developed under NHLBI funded Clinical Trial Networks. These committees are composed of members with expertise in biostatistics, clinical trials, bioethics, and other specific and research areas. The NHLBI is charged with ensuring the highest quality of each Institute-funded clinical research project and compliance with Department of Health and Human Services (DHHS)/National Institutes of Health (NIH)/NHLBI regulations regarding human subject protections and safety monitoring. To carry out this responsibility, the NHLBI program staff instituted a new methodology for supporting the administration of NHLBI-appointed Committees in 2009. The new methodology included the establishment of the Clinical Studies Support Center (CSSC) under the direction of Westat, Inc. The CSSC is a pilot program to support the operations of NHLBI’s DSMBs, Observational OSMBs, and PRCs for the Division of Blood Diseases and Resources. Utilizing Executive Secretaries to support each NHLBI safety monitoring board, the CSSC is responsible for documenting standardized operating procedures related to the administration of monitoring committees and the support center in a CSSC Manual of Operations and Procedures (MOP); coordinating meeting space and logistics for in-person meetings, Web conferences, and teleconferences; managing distribution of adverse event notifications to DSMB chairs and members, new protocols, and proposed amendments; and providing Executive Secretaries who provide scientific and administrative support to document board recommendations related to the safety and efficacy of trial interventions and the quality and completeness of clinical research study data. To move forward with full knowledge of current Committee operations and to monitor the effect of newly established procedures, Westat is required, as part of this contract, to conduct an assessment of the efficiency and effectiveness of NHLBI CSSC committee operations. As part of this assessment, the NHLBI requires feedback and advice regarding the support provided by the CSSC for monitoring board operations. To this end, a Web-based questionnaire will be administered to Chairs and members of monitoring boards to learn about their opinions about specific CSSC activities and their satisfaction with the performance of CSSC staff.

Frequency of Response: Once.

Affected Public: Individuals. Type of Respondents: Monitoring board members. The annual reporting burden is as follows: Estimated Number of Respondents: 90; Estimated Number of Responses per Respondent: 1; Average Burden of Hours per Response: 0.33 and Estimated Total Annual Burden Hours Requested: 30.36. The annualized cost to respondents is estimated at: $ 3.036 (based on $100 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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Table A.12.1. ESTIMATES OF HOUR BURDEN