Contact Person: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss and provide general advice on the extent to which, if any, the pre-surgical identification of clear cell carcinoma of the kidney using an imaging test provides useful clinical information.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 10, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 29, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 2, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12588 Filed 5–23–12; 8:45 am]

BILLING CODE 4160–01–P

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 2, 2012.

If you need special accommodations due to a disability, please contact Lisa Misevicz at least 7 days in advance.

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12592 Filed 5–23–12; 8:45 am]

BILLING CODE 4160–01–P

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 should a pandemic or epidemic disease or other events 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

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]

BILLING CODE 4160–01–P

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 scientific 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 a 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.

Table A.12.1. ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of responses	Average time per response	Annual hour burden
D/OSMB Chairs	10	1	0.33	3.3
D/OSMB Members	78	1	0.33	25.74