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.

Persons interested in becoming observers or in presenting 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 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.

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 Friday, July 13, 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.

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