

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping (21 U.S.C. 379aa(e)(1))	200	100	20,000	5	100,000
Total	100,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: May 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12589 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]

Risk Communication Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 29, 2012, from 8 a.m. to 3 p.m.

Location: FDA White Oak Campus, Building 31 Conference Center, Great Room, 10903 New Hampshire Ave., Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Lee L. Zwanziger, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3278, Silver Spring, MD 20993, 301–796–9151, FAX: 301–847–8611, email: RCAC@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: On June 29, 2011, the Committee will discuss recent research on communicating and understanding uncertainty, and risk perception and information seeking when facing multiple risks.

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, 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 June 21, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on June 29, 2012. 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 18, 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 June 19, 2012. Interested persons can also log on to <https://collaboration.fda.gov/rcac/> to hear and see the proceedings.

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 Lee L. Zwanziger 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. 2012–12587 Filed 5–23–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 25, 2012, from 8 a.m. to 12:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

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.

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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]

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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 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