TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	0.12	228,459
1002.40 and 1002.41	2,950	49.2	145,140	0.05	7,257
1020.30(g)	22	1	22	0.5	11
1040.10(a)(3)(ii)	40	1	40	1.0	40
Totals					235,767

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

The burden estimates were derived by consultation with FDA and industry personnel, and are based on actual data collected from industry. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); 1005.21(a) through (c); and 1005.22(b). These requirements apply to the collection of information during the conduct of general investigations or audits (5 CFR 1320.4(b)).

The following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: May 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–11396 Filed 5–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0236]

Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory." This guidance is intended to advise food manufacturers that once a boil-water advisory has been issued they should stop using the water subject to the advisory until the water again meets the applicable Federal and State drinking water quality standards. Further, this guidance is intended to assist food manufacturers in evaluating food that already was produced with water subject to the advisory. The guidance is in response to the recent major water pipe break in Massachusetts that interrupted service to 30 Massachusetts Water Resources Authority (MWRA) customer communities (serving approximately 2 million residents).

DATES: Submit electronic or written comments on the guidance at any time.

ADDRESSES: 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. Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1700

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory." This guidance is intended to advise food manufacturers that once a boil-water advisory has been issued they should stop using the water subject to the advisory until the water again meets the applicable Federal and State drinking water quality standards. Further, this guidance is intended to assist food manufacturers in evaluating food that already was produced with water subject the advisory.

FDA is issuing this guidance as Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document immediately in accordance with 21 CFR 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the recent major water pipe break in Massachusetts that interrupted service to 30 MWRA customer communities (serving approximately 2 million residents). The guidance represents the agency's current thinking on the use of water by food manufacturers in areas subject to a "Boil-Water Advisory." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be

used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*.

Dated: May 10, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–11450 Filed 5–10–10; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Loan Repayment Grants.

Date: May 18–19, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 5635 Fishers Lane, Bethesda, MD (Virtual Meeting).

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Officer, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892, 301–451–2020, *kenshalod@nei.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel; SBIR Grant Application.

Date: May 20, 2010.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892.

Contact Person: Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division Of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300 MSC 9300, Bethesda, MD 20892–9300, 301–451–2020, *rawlings@nei.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

May 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–11307 Filed 5–12–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Adult Brain Tumor Consortium.

Date: May 20, 2010.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6116 Executive Boulevard, Room 6006, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892–8329, 301/496–7987, *lovingeg@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Name of Committee: National Cancer Institute Special Emphasis Panel; Small Grants Program for Cancer Epidemiology.

Date: June 17–18, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Joyce C. Pegues, B.S., B.A., PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 7149, Bethesda, MD 20892–8329, 301–594–1286, *peguesj@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Innovative Technology Development.

Date: June 23–24, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jeffrey E. DeClue, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8059, Bethesda, MD 20892–8329, 301–496–7904, *decluej@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Comprehensive Minority Institution Cancer Center Partnership.

Date: June 29–30, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Lalita D. Palekar, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7141, Bethesda, MD 20892, 301–496–7575, *palekarl@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Nanotechnology Imaging and Sensing Platforms.

Date: June 29, 2010.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Conference Room 707, Rockville, MD 20852 (Telephone Conference Call).