In the **Federal Register** of March 22, 2010, (75 FR 13547), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Submission to Docket No. FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	30	2.33	70	4	280
Total					290

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

Dated: June 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15859 Filed 6–29–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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 meeting.

The meeting 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 Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Fellowship & Training Member Conflict Applications.

Date: July 8, 2010.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, PhD, Chief, Extramural Project Review Branch, EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS).

Dated: June 17 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15610 Filed 6–29–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

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 meeting.

The meeting 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 Institute of Neurological Disorders and Stroke Special Emphasis Panel; SHINE.

Date: July 15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/ Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–594–0635, *Rc218u@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 24, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–15899 Filed 6–29–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Issues in the Design and Conduct of Clinical Trials for Antibacterial Drug Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding scientific issues in the design and conduct of clinical trials for antibacterial drug development. The public workshop is intended to provide information for and gain perspectives from health care providers, researchers, academia, industry, and regulators on various aspects of design and conduct of clinical trials for antibacterial drugs. The workshop will focus on the design and conduct of non-inferiority (NI) clinical

trials, which are often used in the evaluation of the safety and efficacy of a new antibacterial drug. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on August 2, 2010, from 8:30 a.m. to 5:30 p.m. and on August 3, 2010, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993–0002, 301–796–1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone and fax numbers) to *abtrialworkshop@fda.hhs.gov*. Persons without access to the Internet can call Chris Moser or Lori Benner at 301–796–1300 to register (see *Contact Persons*). Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding scientific issues in the design and conduct of clinical trials for antibacterial drug development.

Over the past decade, there have been public discussions on NI clinical trial design and the types of infectious disease indications for which the NI clinical trial design is appropriate. This public workshop will provide information on NI trial design, approaches to the justification of NI margins, and the assessment and timing of efficacy endpoints. Challenges in the conduct of clinical trials will be discussed, including good clinical practice and quality system approaches.

The workshop will include presentations and perspectives from FDA and from stakeholders involved in clinical research. The public workshop is intended to provide information for and gain perspective from health care providers, researchers, academia, industry, and regulators on various aspects of the design and conduct of clinical trials for antibacterial drug development. The input from this public workshop will help in developing topics for further discussion.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15814 Filed 6–29–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Proposed Information Quality Guidelines Policy

ACTION: Notice and request for public comment on Proposed Information Quality Guidelines.

SUMMARY: These guidelines should be used to ensure and maximize the quality of disseminated information. The Department's guidelines are based on the guidelines of the Office of Management and Budget (OMB), "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of the Information Disseminated by Federal Agencies" 67 FR 8452 (Feb. 22, 2002). The guidelines are not intended to be, and should not be construed as, legally binding regulations or mandates. These guidelines are intended only to improve the internal management of DHS and, therefore, are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on the agency or the public. Nothing in these guidelines affects any available judicial review of agency action. These guidelines will serve as the minimum standards for quality within the Department. DHS Components may expand upon these guidelines as necessary, and should use these guidelines to develop or improve their processes for ensuring information disseminated by the Components meet the quality standards. DHS Components should implement processes and mechanisms for receiving, reviewing, and responding to information request that are consistent with these guidelines. DHS Components with existing directives, instructions, and correction processes for information quality may continue to use them, provided they are consistent with the standards and processes established in these guidelines.

The guidelines apply to information disseminated to the public in any medium including textual, graphic, narrative, numerical, or audiovisual forms, including information posted on the Internet. The guidelines also apply to DHS Component-sponsored distribution of information—where the DHS Component directs a third party to distribute information or DHS has the authority to review and approve the information before release. If the Department is to rely on information submitted by a third party that information would need to meet appropriate standards of objectivity and utility.

DATES: Comments are encouraged and will be accepted until July 30, 2010.

Comments: Public comments are invited on the information contained in the proposed policy. Comments on the proposed policy should be submitted electronically to *DHS.INFOQUALITY@DHS.GOV*.

Obtaining a Copy of the Policy: To obtain a copy of the policy please submit a request to *DHS.INFOQUALITY@DHS.GOV* (including your address and telephone number).

FOR FURTHER INFORMATION CONTACT: Department of Homeland Security, Information Quality Program Management Office at 202–447–5959.

Richard A. Spires,

Chief Information Officer.

[FR Doc. 2010–15926 Filed 6–29–10; 8:45 am]

BILLING CODE 9110–9B–P