TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per recordkeeper	Total hours
170.36(c)(v)	50	1	50	15	750
570.36(c)(v)	10	1	10	15	150
Total					900

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

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. In 1998, FDA began receiving notices that were submitted under the terms of the proposed rule. Since it began receiving notices, FDA has received 12 in 1998, 23 in 1999, 30 in 2000, 28 in 2001, 26 in 2002, 23 in 2003, 20 in 2004, and 22 to date in 2005, notices annually. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5088 Filed 4–6–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support a Single-Source Application—The Critical Path Institute: Collaborative Cardiovascular Drug Safety and Biomarker Research Program—ACTION; Availability of Sole Source Cooperative Agreement; Request for Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of the Commissioner (OC) is announcing its intent to accept and consider a single source application (RFA–FDA–OC–2006–1) for the award of a Cooperative Agreement to the Critical Path Institute. FDA anticipates providing up to $750,000 (direct and indirect costs combined) in fiscal year 2006 to support this multiphased research program that will include, but will not be limited to, the development of an infrastructure to support this program and subsequent related studies in cardiovascular disease and genomic/proteomic biomarker research, as stipulated by Congress.

Subject to the availability of Federal funds and successful performance, an additional 2 years of support up to $750,000(direct and indirect costs combined) per year may be available.

FDA will support the research covered by this notice under the authority of section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The cooperative agreement ensures FDA's continued participation in the Collaborative Cardiovascular Drug Safety and Biomarker Research Program, as proposed by Congress and to be conducted under FDA's Critical Path Initiative. A goal of the Critical Path Initiative is to foster the development of new tools to both promote drug safety and accelerate the development of innovative new therapies, through appropriate collaboration with multiple parties. This collaborative research program is expected to be conducted in a multiphase process, leveraging resources and expertise from the awardee, other collaborators, and FDA to address public health needs involving cardiovascular disease and biomarker research.

II. Eligibility Information

Competition is limited because of Congressional mandate, the mission of the Critical Path Institute, its established collaboration with the University of Utah, and the combined ability of these parties to leverage existing databases, specimen repositories, clinical and other technical expertise in support of this program.

III. Application and Submission

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Officer, Division of Contracts and Grants Management

(HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.hhs.gov*. This RFA can be viewed on *Grants.gov* under ''Grant Find.'' A copy of the complete RFA can also be viewed on the FDA Web site at *http://www.fda.gov/oc/initiatives/criticalpath/*. For issues regarding the programmatic and scientific aspects of this notice contact Wendy Sanhai, Ph. D., Senior Scientific Advisor, Office of the Commissioner (HF–1), Food and Drug Administration, 5600 Fishers Lane, rm. 1471, Rockville, MD 20857, 301–827–7867, e-mail: *wendy.sanhai@fda.hhs.gov*.

Dated: March 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–3408 Filed 4–5–06; 2:33 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Loan Repayment Program for Clinical Researchers (L30s).

Date: April 14, 2006.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Deborah P. Beebe, PhD, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, NIH, Two Rockledge Center, Room 7100, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435–0260, *beebed@nhlbi.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 Heart, Lung, and Blood Institute Special Emphasis Panel, Conference Grants (R13s).

Date: April 14, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Deborah P Beebe, PhD, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, NIH, Two Rockledge Center, Room 7100, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435–0260, *beebed@nhlbi.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 Heart, Lung, and Blood Institute Special Emphasis Panel, Research Project (R01).

Date: April 21, 2006.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Valerie L. Prenger, PhD, Health Scientist Administrator, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, MSC 7924, Room 7214, Bethesda, MD 20892–7924, (301) 435–0270, *prengerv@nhlbi.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 Heart, Lung, and Blood Institute Special Emphasis Panel, Research Demonstration and Dissemination Projects (R18s).

Date: April 27, 2006.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Patricia A. Haggerty, PhD, Scientific Review Administrator, National Heart, Lung, and Blood Institute/NIH, Clinical Studies & Training Studies Rev. Grp., Division of Extramural Affairs/Section Chief, 6701 Rockledge Drive, Room 7194, Bethesda, MD 20892, 301/435–0288, *haggertp@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research: 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 31, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–3328 Filed 4–6–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 562b(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 Allergy and Infectious Diseases Special Emphasis Panel, Central Tolerance and Autoimmune Disease.

Date: April 18, 2006.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Thames E. Pickett, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *pickettte@niaid.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 Institute of Allergy and Infectious Diseases Special Emphasis Panel, Host Mechanisms of Viral Resistance.

Date: April 24, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Room 3258, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Stefani T. Rudnick, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *srudnick@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)