

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section No.	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
<i>Prior notice cancelled through PNSI</i>						
1.282 and 1.283(a)(5)	FDA 3540	214,400	0.31	66,464	0.25	16,616
Prior notice cancellations subtotal						22,044
Prior Notice Requests for Review and Post-hold Submissions						
1.283(d) and 1.285(j)	None	1	1	1	8	8
1.285(i)	None	1	1	1	1	1
Prior notice requests for review and post-hold submissions subtotal						9
Total hours annually						1,738,541

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

²To avoid double-counting, an estimated 396,416 burden hours already accounted for in the importer's entry notice information collection approved under OMB control number 0910-0046 are not included in this total.

³The term "Form FDA 3540" refers to the electronic system known as the FDA PN System Interface, which is available at <http://www.access.fda.gov>.

This estimate is based on FDA's experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years.

FDA received 282,244 prior notices through ABI/ACS during December 2003; 6,865,722 during 2004; and 6,171,939 during 2005. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 949.5 prior notices annually, for a total of 6,171,750 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hours, per notice, for a total burden of 1,030,682 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA's importer's entry notice, as previously discussed in this document.

FDA received 35,308 prior notices through the PN System Interface during December 2003; 1,425,825 during 2004; and 1,786,896 during 2005. Based on this experience, FDA estimates that approximately 214,400 registered users of the PN System Interface will submit an average of 8.33 prior notices annually, for a total of 1,785,952 prior notices received annually through the PN System Interface. FDA estimates the reporting burden for a prior notice submitted through the PN System Interface to be 23 minutes, or 0.384 hours, per notice, for a total burden of 685,806 hours.

FDA received no cancellations of prior notices through ABI/ACS during December 2003; 16,624 during 2004; and 21,720 during 2005. Based on this

experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 3.34 cancellations annually, for a total of 21,710 cancellations received annually through ABI/ACS. FDA estimates the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 5,428 hours.

FDA received 1,539 cancellations of prior notices through the PN System Interface during December 2003; 64,918 during 2004; and 65,491 during 2005. Based on this experience, FDA estimates that approximately 214,400 registered users of the PN System Interface will submit an average of 0.31 cancellations annually, for a total of 66,464 cancellations received annually through the PN System Interface. FDA estimates the reporting burden for a cancellation submitted through the PN System Interface to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 16,616 hours.

FDA has not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (December 2003 through 2005); therefore, the agency estimates that one or fewer requests for review will be submitted annually. FDA estimates that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, FDA has estimated a total reporting burden of 8 hours.

FDA has not received any post-hold submissions under § 1.285(i) in the last 3 years (December 2003 through 2005); therefore, the agency estimates that one or fewer post-hold submissions will be submitted annually. FDA estimates that

it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, FDA has estimated a total reporting burden of 1 hour.

In cases where a regulation implements a statutory information collection requirement, only the additional burden attributable to the regulation, if any, has been included in FDA's burden estimate.

Dated: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-8311 Filed 5-30-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 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 cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement application review, the disclosure of which would

constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee H—Clinical Groups.

Date: July 10–12, 2006.

Time: 6 a.m. to 4 p.m.

Agenda: To review and evaluate cooperative agreement application.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Timothy C. Meeker, PhD, M.D., Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8103, Bethesda, MD 20892. 301–594–1279. meekert@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 23, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–4978 Filed 5–30–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel, Comparative Medicine Training Grants.

Date: June 19, 2006.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy

Boulevard, Conference Room 1087, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Mahadev Murthy, MBA, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Ofc of Review, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1070, Bethesda, MD 20892. (301) 435–0813. mmurthy@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine U42/R01

Date: June 21, 2006.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Conference Room 1087, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Mahadev Murthy, MBA, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Ofc of Review, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1070, Bethesda, MD 20892. (301) 435–0813. mmurthy@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine R24 SEP

Date: June 29, 2006.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Conference Room 1087, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Mahadev Murthy, MBA, Scientific Review Administrator, National Institutes of Health, National Center for Research Resources, Ofc of Review, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1070, Bethesda, MD 20892. (301) 435–0813. mmurthy@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: May 23, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–4980 Filed 5–30–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 553b(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 Mental Health Special Emphasis Panel, NIMH IBSC P50 Review.

Date: June 21, 2006.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Henry J. Haigler, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6150, MSC 9608, Bethesda, MD 20892–9608. 301/443–7216. hhaigler@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Research Training.

Date: June 21, 2006.

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

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Agu Pert, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9608, Bethesda, MD 20892–9608. 301/443–0811. apert@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Autism Research Career Development Review.

Date: June 27, 2006.

Time: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Christopher S. Sarampote, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9608, Bethesda, MD 20892–9608. 301–443–1959. csarampo@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, NIMH K99 Review.

Date: July 6, 2006.

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

Agenda: To review and evaluate grant applications.