

TABLE 1.—Estimated Annual Reporting Burden¹—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.81	69	6.7	464	1	464
600.90	3	1	3	1	3
Total					33,695

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

Recordkeeping Burden: There are approximately 391 licensed manufacturers of biological products. The number of recordkeepers under § 600.12(a), (c), (d), and (e) is estimated to be 102. That number excludes the 189 manufacturers of blood and blood components whose recordkeeping is conducted under 21 CFR 606.160, which is approved under OMB Control No. 0910–0116. FDA expects that the total number of AER records kept by the respondent will parallel the total number of reports submitted to FDA.

The total number of annual records, therefore, is based on reporting information provided to FDA by manufacturers. Based on FY 1996 data, the total annual records are estimated as follows: Under § 600.12(a), (c), (d), and (e), the number of lots released was 9,027; under § 600.12(b)(2), the number of recalls was 710; and under § 600.80(i), the total number of AER reports received was 2,745. Based on FDA's experience, the agency estimates that the total number of hours per recordkeeper under § 600.12(a), (c), (d),

and (e) would be 32 hours per lot multiplied by 88.5 lot records on the average per recordkeeper, totaling 2,832 hours; the total number of hours per recordkeeper under § 600.12(b)(2) would be 24 hours per recall multiplied by 1.8 recalls on the average per recordkeeper, totaling 43 hours; and the total number of hours per recordkeeper under § 600.80(i) would be 1 hour per report multiplied by 39.8 AER records on the average per recordkeeper, totaling 40 hours.

TABLE 2.—Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
600.12(a), (c), (d) and (e)	102	88.5	9,027	2,832	288,864
600.12(b)(2)	391	1.8	710	43	16,813
600.80(i)	69	39.8	2,745	40	2,760
Total					308,437

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

Dated: March 4, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5904 Filed 3–9–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1771]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including

any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection

Request: Extension of a currently approved collection;

Title of Information Collection:

Attending Physicians Statement and Documentation of Medicare Emergency and Supporting Regulations in 42 CFR Sections 424.101 and 424.103;

Form No.: HCFA–1771 (OMB# 0938–0023);

Use: Payment, by Medicare, may be made for certain Part A inpatient hospital services and Part B outpatient services provided in a nonparticipating U.S. or foreign hospital, when services are necessary to prevent the death or serious impairment to the health of an individual. This form is used to

document the attending physician's statement that the hospitalization was required due to an emergency and give clinical support for the claim;

Frequency: On occasion;

Affected Public: Business or other for profit;

Number of Respondents: 2,000;

Total Annual Responses: 2,000;

Total Annual Hours: 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards

Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 1, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99-5842 Filed 3-9-99; 8:45 am]

BILLING CODE 4120-03-P

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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Phase I Clinical Studies/Phase II Clinical Trials of New Chemopreventive Agents.

Date: March 30, 1999.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Executive Plaza North, Conference Room F, 6130 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gerald G. Lovinger, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard/EPN—Room 630D, Rockville, MD 20892-7405, 301/496-7987.

(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: March 3, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-5914 Filed 3-9-99; 8:45 am]

BILLING CODE 4140-01-M

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 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 Cancer Institute Special Emphasis Panel, Small Grants Program for Behavioral Research in Cancer Control.

Date: April 8-9, 1999.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, EPN, Room 635, Rockville, MD 20852.

Contact Person: Wilna A. Woods, Deputy Chief, Special Review, Referral and Research Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Rockville, MD 20852, (301) 496-7903.

(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: March 3, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-5915 Filed 3-9-99; 8:45 am]

BILLING CODE 4140-01-M

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 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 Cancer Institute Special Emphasis Panel International Phase III IL-21 Study

Date: March 15, 1999.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Olivia T. Preble, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard—Rm. 643B, Rockville, MD 20892-7405, 301/496-7929.

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. 93.392, 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: March 3, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-5916 Filed 3-9-99; 8:45 am]

BILLING CODE 4140-01-M

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