

Web site for guidance documents with current enforcement policies related to premarket requirements for tobacco products (<http://www.fda.gov/TobaccoProducts/default.htm>)).

With regard to the comment that the number of section 905(j)(1)(A)(i) substantial equivalence reports which FDA estimated to be submitted (150 per year) was too low, FDA has revised its estimate based on information it now has from initial submissions, interactions with industry, and other information, such as the comment received on the 60-day notice on the information collection. As shown

below, FDA is increasing the annual estimate of the number of reports received from 150 to 1,000.

With regard to the comment that the number of hours to prepare and submit each report is unrealistic, FDA continues to believe that the currently estimated hours (360 hours annually) is appropriate, particularly given that the premarket requirements for new tobacco products (Section 910 of the FD&C Act) are new and manufacturers' experience with preparing a submission is just beginning to develop. As the requirements and program become more familiar to respondents, FDA may be

able to refine these estimates. In addition, as discussed previously, the commenter did not suggest an alternative number of hours. FDA's estimate of 360 hours reflects an amount of time that should provide each submitter enough time to prepare and submit a section 905(j)(1)(A)(i) substantial equivalence report to the Agency.

Estimation of Burden

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FD&C Act sections	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
905(j)(a)(A)(i) and 910(a)	1,000	1	1,000	360	360,000
Total					360,000

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

FDA has based these estimates on information it now has available from interactions with the industry, comments regarding the submission of 905(j)(1)(A)(i) substantial equivalence reports, and comments on the 60-day information collection notice request for comments published in the **Federal Register** on January 24, 2011 (76 FR 4116). Table 1 of this document describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j)(1)(A)(i) and 910(a) of the FD&C Act. FDA estimates that it will receive 1,000 section 905(j) substantial equivalence reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 360,000 hours.

Dated: April 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Cancer Biomedical Informatics Grid® (caBIG®) Support Service Provider (SSP) Program (NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 11, 2011 (76 FR 7867) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: cancer Biomedical Informatics Grid® (caBIG®) Support Service Provider (SSP) Program (NCI). **Type of Information Collection Request:** Existing Collection in Use Without an OMB Number. **Need and Use of Information Collection:** The NCI Center for Biomedical Informatics and

Information Technology (CBIIT) launched the enterprise phase of the caBIG® initiative in early 2007 with an emphasis on widespread institutional adoption of the program and tools. This emphasis on adoption has generated an expanding community with diverse needs for support, which are met through the resources available through the caBIG® Enterprise Support Network (ESN), including the caBIG® Support Service Provider (SSP) Program. The caBIG® SSPs provide caBIG® end-users with the freedom to match what caBIG® has to offer to their unique organizational goals and needs, so having this customized support option available is critically important to advancing the goals of the caBIG® program. caBIG® SSP applicants are evaluated against well-defined criteria published in the SSP Program Announcement and must successfully demonstrate that they have the technical capabilities, staffing and scalability, geographic coverage (when applicable), and the domain expertise in biomedicine to effectively serve caBIG® users. The information submitted by SSP applicants enables NCI to determine whether such applicants are qualified to enter into trademark license negotiations with NCI to use the caBIG® trademarks in connection with their services and become designated as caBIG® SSPs. Thus, the collection of information from SSP applicants is critical to both ensuring that the goals and objectives of the caBIG® program will be maintained and furthered by the

organizations designated as SSPs and facilitating NCI's ability to exercise appropriate stewardship of the caBIG® trademarks. Sections 410 and 411 of the Public Health Service Act (42 U.S.C. 285 and 285a) authorize the collection of the information. *Frequency of Response:*

once for the applicants. caBIG® SSP applications are accepted on a rolling basis and reviewed several times a year. *Affected Public: Private sector including Business or other for-profits and not-for-profit organizations and institutions.* *Type of Respondents:* Technical

representatives of commercial, academic or not-for-profit organizations. The annual reporting burden is estimated at 360 hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

A.12-1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Commercial Organizations	14	1	1440/60 (24 hours)	336
Nonprofit Organizations	1	1	1440/60 (24 hours)	24
Totals	15			360

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at OIRA_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact John Speakman, NCI CBIIT Chief Program Officer, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH, DHHS, 2115 E. Jefferson Street, Suite 6000, Rockville, MD 20892 or call non-toll-free number 301-451-8786 or e-mail your request, including your address to: john.speakman@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 30 days of the date of this publication.

Dated: April 26, 2011.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011-10666 Filed 5-2-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Institute on Aging Initial Review Group, Biological Aging Review Committee.

Date: June 1-2, 2011.

Time: 3 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Bitu Nakhai, PhD, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2c212, 7201 Wisconsin Avenue,

Bethesda, MD 20814, 301-402-7701, nakhaib@nia.nih.gov.

Name of Committee: National Institute on Aging Initial Review Group, Neuroscience of Aging Review Committee.

Date: June 2-3, 2011.

Time: 3 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: William Cruce, PhD, Scientific Review Administrator, National Institute on Aging, Scientific Review Office, Gateway Building 2c-212, 7201 Wisconsin Ave., Bethesda, MD 20814, 301-402-7704, crucew@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 27, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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