Respondents: State/Tribal Child Wellness Coordinator, State/Tribal Wellness Council Members, State ECCS Project Director, Local Child Wellness Coordinator, Local Wellness Council Members, Local Evaluator, and Local Service Providers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Telephone or Site Visit Interview Guide	240	1	1.25	300
Electronic Data Reporting: Systems Measures	24	2	4	192
Electronic Data Reporting: Services Measures	24	2	8	384

Estimated Total Annual Burden Hours: 876.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, submit comments on or before June 2, 2011. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration, for Children and Families.

Dated: April 25, 2011.

Seth F. Chamberlain,

OPRE Reports Clearance, Officer.

[FR Doc. 2011–10410 Filed 5–2–11; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0044]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 2, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that the written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer. *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0673. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance: *Information Request Regarding Guidance for Industry and FDA Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products—(OMB Control Number 0910–0673)—Extension.*

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(j)(1) of the FD&C Act authorizes FDA to establish the form and manner for the submission of information related to substantial equivalence (21 U.S.C. 387e(j)(1)). In a level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act, and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence (*see* "Guidance for Industry and FDA Staff—Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" (January 6, 2011, 76 FR 789).)

In the **Federal Register** of January 24, 2011 (76 FR 4116), FDA published a 60-day notice requesting public comment on the proposed information collection.

FDA received one comment in response to the 60-day notice. The commenter indicated that the substantial equivalence requirements were "burdensome to industry in the extreme," that FDA's estimation of the number of reports to be received was too low, and that the current burden hours to complete each report was unrealistic. Although the commenter asserted that the burden hours were too low and unrealistic, no alternative estimates were provided.

The recommendations in the "Guidance for Industry and FDA Staff—Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" are the information that FDA suggests a manufacturer include in a report submitted under section 905(j)(1)(A)(i) of the FD&C Act. The recommendations reflect the information FDA believes is necessary for it to make the required findings under section 910(a) of the FD&C Act (21 U.S.C. 387j(a)). FDA has also articulated current enforcement policies in its guidances that are intended to address some of the burden associated with premarket requirements for new tobacco products (manufacturers and interested parties may refer to FDA's

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.

[FR Doc. 2011–10618 Filed 5–2–11; 8:45 am]

BILLING CODE 4160–01–P

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