improves the management and functionality of public health laboratories in partner countries by supporting laboratory systems quality improvement, biosafety, and implementation of international laboratory standards and guidelines; (5) develops models for continuous tracking and improvement of critical outputs and outcomes from the programs around the world that the division supports (monitoring and evaluating function); (6) implements and coordinates CDC's support to WHO'S Integrated Disease Surveillance and Response strategy and directly supports the implementation of the International Health Regulations at the country level; (7) enhances the skills, knowledge, and capacity of the human resources for surveillance by merging those efforts with IT solutions that allow the surveillance workforce to function at a high level of timeliness and reliability; (8) works with partner countries to establish human resource information systems to better track the public health workforce within ministries of health; (9) mobilizes expertise from across the agency and from partners throughout the USG and internationally to provide technical assistance for countries interested in building their own dedicated public health institutions ("national CDCs"); (10) plans, directs, supports, implements, and coordinates public health leadership and management development and organizational excellence efforts; (11) provides leadership and technical assistance for reconstruction and stabilization efforts aimed at rebuilding or strengthening severely disrupted public health systems in countries in crisis or emerging from crisis ("fragile states"); and (12) coordinates and works closely with the Field and Applied Epidemiology Training Programs Branch in areas of assessments and workforce development to meet system needs and overall strategies.

Delete in its entirety the function statement for the Office of the Director (CWJ1), Division of Global Disease Detection and Emergency Response (CWJ), and insert the following:

Office of the Director (CWJ1). (1) Provides leadership, oversight, evaluation and overall direction and management for the activities of the division; (2) develops the division overall strategy and the division policies on planning, evaluation, management, and operations; (3) plans, allocates, and monitors resources; (4) provides liaison with other CDC organizations, other Federal agencies, national ministries of health, international organizations, non-governmental organizations, private sector, and others that CDC cooperates with in global health programs and activities; (5) promotes high standards in science and ethics among CDC's international activities; (6) maintains staff in the CDC Emergency Operations Center to manage, direct, coordinate and evaluate biosurveillance data from domestic and international networks and serve as a central focus for global outbreak and incident response activities; and (7) maintains and supports the Health Systems Reconstruction Office in its efforts to coordinate the implementation of training/capacity building initiatives within Haiti and other impacted countries.

Delete in its entirety item (8) of the functional statement for the Global Disease Detection Branch (CWJB). Delete item (2) and insert the following: (2) provides program support, resources and technical assistance to the Global Disease Detection (GDD) Centers around the world;

Delete items (3), (4), (6), and (7) of the functional statement for the Global Health Security Branch (CWJC) and insert the following accordingly: (3) provides support and coordination at HHS/OGHA regarding the development of policies and priorities on international influenza; (4) serves as liaison with HHS and technical agency (CDC, NIH, FDA) representatives for international pandemic preparedness related to budget formulation, program development, strategic planning, and global health security policy development; (6) provides technical assistance through training, and capacity building in supporting efforts to reduce the public health threat from chemical, biological, and nuclear disasters that are either natural or man-made; (7) provides liaison with the DoS Biosecurity Engagement Program and DoD Defense Threat Reduction Agency to coordinate on global biological threat reduction;

Dated: April 19, 2011.

James D. Seligman,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–10639 Filed 5–2–11; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Project LAUNCH Cross-Site Evaluation.

OMB No.: 0970–0373.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is planning to collect data as part of a cross-site evaluation of a new initiative called Project LAUNCH (Linking Actions for Unmet Needs in Children's Health). Project LAUNCH is intended to promote the healthy development and wellness of children ages birth to eight years. A total of 24 Project LAUNCH grantees are funded to improve coordination among child-serving systems, build infrastructure, and improve methods for providing services. Grantees will also implement a range of public health strategies to support young child wellness in a designated locality.

Data for the cross-site evaluation of Project LAUNCH will be collected through: (1) interviews conducted either via telephone or during site-visits to Project LAUNCH grantees, and (2) semi-annual reports that will be submitted electronically on a web-based data-entry system. Information will be collected from all Project LAUNCH grantees.

During either telephone interviews or the site visits, researchers will conduct interviews with Project LAUNCH service providers and collaborators in States/Tribes and local communities of focus. Interviewers will ask program administrators questions about all Project LAUNCH activities, including: infrastructure development; collaboration and coordination among partner agencies, organizations, and service providers; and development, implementation, and refinement of service strategies.

As part of the proposed data collection, Project LAUNCH staff will be asked to submit semi-annual electronic reports on State/Tribal and local systems development and on services that children and families receive. The electronic data reports also will collect data about other Project LAUNCH-funded service enhancements, such as trainings, Project LAUNCH systems change activities, and changes in provider settings. Information provided in these reports will be aggregated on a quarterly basis, and reported semi-annually.

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