ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| LIHEAP Quarterly Allocation Estimates, Form ACF–535 | 52 | 1 | .25 | 13 |

*Estimated Total Annual Burden Hours:* 13.

*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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2015–17030 Filed 7–10–15; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0001]**

### Science Board to the Food and Drug Administration; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Science Board to the Food and Drug Administration (Science Board).

*General Function of the Committee:* The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda, and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

*Date and Time:* The meeting will be held on July 29, 2015, from 8:30 a.m. to 4 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 B and C), Silver Spring, MD 20993–0002. For those unable to attend in person, the meeting will also be Webcast. The link for the Webcast is available at: *https://collaboration.fda.gov/scienceboard2015/.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

*Contact Person:* Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, Bldg. 1, Rm. 3309, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4769, *rakesh.raghuwanshi@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* The Science Board will be provided with a report from the Commissioner's Fellowship Program Evaluation subcommittee and will be provided with a progress report from the Science Looking Forward subcommittee. The Board will hear an overview of two scientific activities from the Center for Veterinary Medicine and will be asked to provide input on strategies to implement targeted directives contained in the National Strategy for Combating Antibiotic-Resistant Bacteria, designed to guide action by public health, health care, and veterinary partners in a common effort to address urgent and serious drug-resistant threats that affect people in the United States and around the world. A recipient of one of the Fiscal Year 2014 Scientific Achievement Awards (selected by the Board) will provide an overview of the activities for which the award was given. A status update on the 21st Century Cures Act will be presented, and the Deputy Commissioner for Medical Products and Tobacco will discuss his vision for the Office of Medical Products and Tobacco.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 22, 2015. Oral presentations from the public will be scheduled between approximately 2:45 and 3:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or

arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 14, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 15, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Mr. Rakesh Raghuwanshi at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–16957 Filed 7–10–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0147]**

### 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 and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

**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 and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 12, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed 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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

### Guidance for Industry and Food and Drug Administration 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 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) of the FD&C Act (*21 U.S.C. 387e(j)*) authorizes FDA to establish the manner and form for the submission of information related to substantial equivalence (SE). In guidance documents 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.

In the **Federal Register** of March 5, 2015 (80 FR 11989), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. The commenter expressed a concern that small manufacturers have the burden of conducting testing without a definitive guide on what will constitute substantial equivalence. FDA has carefully considered the burden associated with the submission of an SE report. The information needed to demonstrate substantial equivalence is dependent on the new product and the predicate product that the manufacturer identifies. Nevertheless, to assist manufacturers in preparing SE reports, FDA has issued guidance documents and participated in outreach such as webinars to provide manufacturers with information. Moreover, manufacturers seeking to demonstrate substantial equivalence may also contact FDA to seek the Agency's input on the specific types of information that the Agency believes will be necessary to support the manufacturer's section 905(j) report. The commenter also supported FDA's development of more streamlined SE Reports but challenged ''new requirements on label changes,'' and requested that FDA promulgate a rule on categorical exclusions (environmental assessments). Although these comments are outside of the scope of this PRA collection, FDA intends to consider them as part of the Agency's other regulatory efforts as appropriate.

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