

average of two TEAs and two submissions of safety and effectiveness data each year. Therefore, we estimated the total annual reporting burden to be 2,560 hours. This number included 960 hours for preparing TEAs (two TEAs per year times 480 hours per TEA) and 1,600 hours (two submissions of safety and effectiveness data times 800 hours per submission).

We received a submission from a manufacturer that filed two TEAs stating that our estimates in the 60-day notice were too low. The submission noted that the time spent on “gathering, compiling, evaluating and preparing” the TEA and safety and effectiveness submissions was “significantly greater” than what FDA had estimated in the 2002 TEA final rule and the more recent 60-day notice. The submission estimates that approximately 1,526 hours are required to prepare a TEA and approximately 2,348 hours to prepare a safety and effectiveness submission.

Because the information provided in the submission is based on actual experience by a TEA applicant, we agree with the submission and are adjusting our estimates in this document accordingly. We continue to estimate that we will receive two TEAs and two safety and effectiveness submissions each year. We now estimate that it will take approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission.

The submission included, as part of the estimated burden of safety and effectiveness data submission, an estimated burden to submit environmental data. We agree with the submission and are including the environmental data in our estimated burden of safety and effectiveness data submission. In February 2010, we published a call-for-data to request data on the environmental impact of amending OTC drug monographs to

include any of 13 active ingredients that were found eligible for potential inclusion in an OTC monograph through the TEA process (75 FR 7606, February 22, 2010). In that document, we explain that a proposed rule that would add an ingredient to an OTC drug monograph would be subject to the National Environmental Policy Act of 1969 (NEPA) (see 21 CFR 25.1). In order to comply with NEPA, an environmental assessment of such an Agency action is required, unless we determine that a categorical exclusion is warranted (21 CFR 25.20(f)). Therefore, in this document, the estimated burden of collection for safety and effectiveness data submission includes the burden to collect environmental data to support the application of any categorical exclusion or to conduct an environmental assessment, if necessary.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
330.14(c) and (d) <sup>2</sup>	2	1	2	1,525	3,050
330.14(f) and (i) <sup>3</sup>	2	1	2	2,350	4,700
Total					7,750

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

<sup>2</sup> TEA.

<sup>3</sup> Safety and effectiveness submission, including environmental data in accordance with 21 CFR 25.1.

Dated: February 2, 2011.

**Leslie Kux,**  
Acting Assistant Commissioner for Policy.

[FR Doc. 2011-2692 Filed 2-7-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0594]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration Regulated 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 and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 10, 2011.

**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 e-mailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0497. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, e-mail: *Jonnalynn.capezzuto@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.

**Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)—(OMB Control Number 0910-0497)—Extension**

FDA conducts focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of consumers’ attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers’ attitudes and emotions in response to topics and concepts, and

• To further explore findings obtained from quantitative studies. FDA will use focus group findings to test and refine their ideas but will generally conduct further research before making important decisions, such

as adopting new policies and allocating or redirecting significant resources to support these policies. In the **Federal Register** of November 30, 2010 (75 FR 74061), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Focus Group Interviews .....	1,440	1	1,440	1.75	2,520

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

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the Agency's ability to gather information on public sentiment of its proposals in its regulatory and communications programs.

Dated: February 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-2665 Filed 2-7-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shriver National Institute Of Child Health & Human Development; 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

*Date:* March 3, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Peter Zelazowski, PhD, Scientific Review Officer, Division Of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5b01, Bethesda, MD 20892, 301-435-6902, PETER.ZELAZOWSKI@NIH.GOV. (Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 2, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-2725 Filed 2-7-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of General Medical Sciences; 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel; Modeling the Scientific Workforce.

*Date:* February 24, 2011.

*Time:* 8:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott, 520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Mona R. Trempe, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301-594-3998, *trempepmo@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 2, 2011.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-2724 Filed 2-7-11; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; 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.