oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0654. 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, *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.

Tobacco Health Document Submission—(OMB Control Number 0910–0654)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act granted 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. Among its many provisions, the Tobacco Control Act added section 904(a)(4) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d(a)(4)), requiring submission of documents related to certain effects of tobacco products.

Section 904(a)(4) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009.

FDA issued a draft guidance document entitled "Tobacco Health Document Submission'" on December 28, 2009 (74 FR 68629) to assist persons making certain document submissions to FDA under section 904(a)(4) of the act. The guidance document was finalized on April 20, 2010 (75 FR 20606). While electronic submission of tobacco health documents is not required, FDA designed the eSubmitter application as an alternative for mailing documents. This electronic tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed a paper form (FDA Form 3743) as an alternative submission tool. Both the eSubmitter application and the paper form can be accessed at *http://www.fda.gov/tobacco*.

On September 1, 2009 (74 FR 45219), FDA published notice in the **Federal Register** announcing that a proposed collection of information had been submitted to OMB for emergency processing under the PRA. On September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. On October 13, 2009 (74 FR 52495), FDA published a notice reopening the comment period until October 26, 2009. On January 7, 2010, FDA received emergency approval for this information collection. Based on comments indicating that the burden estimate was too low, FDA has adjusted its original burden estimate from 1.0 hour per response to 200 hours per response. FDA also increased the annual frequency per response from 1 to 4 (quarterly).

FDA is maintaining the original estimate of the number of respondents at 10. FDA is basing its estimates on the total number of tobacco firms it is aware of, its experience with document production, and comments received in response to the draft guidance document published on December 28, 2009.

In the **Federal Register** of April 20, 2010 (75 FR 20603), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection. The comment stated that the classification/coding recommendations will impose burdens that significantly exceed the burden estimate of 200 hours and will likely inundate FDA with information with little incremental value. The estimated 200 hours per response burden is based on the average burden estimate among all 10 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 200 hours estimate since it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health Document Submission and Form FDA 3743	10	4	40	200	8,000

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

Dated: July 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17230 Filed 7–14–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, Office of Federal Advisory Committee Policy, National Institutes of Health (NIH), announces the establishment of the Interagency Pain Research Coordinating Committee.

Public Law 111–148 ("Patient Protection and Affordable Care Act"), Title IV, as it amends Part B of Title IV of the Public Health Service Act (42 USC 284 *et seq*.) requires the committee to: (a) Develop a summary of advances in pain care research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and

treatment of pain and diseases and disorders associated with pain; (b) identify critical gaps in research on the symptoms and causes of pain; (c) make recommendations to ensure that the activities of the NIH and other Federal agencies are free of unnecessary duplication of effort; (d) make recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand partnerships between public and private entities to expand collaborative, cross-cutting research.

Duration of this committee is two years from the date the Charter is filed.

Dated: July 9, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17261 Filed 7–14–10; 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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Vaccines Against Microbial Diseases.

Date: July 23, 2010.

Time: 5:30 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.

Contact Person: Stephen M. Nigida, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4212, MSC 7812, Bethesda, MD 20892, 301–435–1222, *nigidas@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel. Member Conflict: Topics in Bioengineering.

Date: July 28, 2010.

Time: 1 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark Caprara, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17258 Filed 7–14–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

Date: August 2–5, 2010.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brandt R. Burgess, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2584, *bburgess@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; "Ancillary Studies in Immunomodulation Clinical Trails".

Date: August 12, 2010.

Time: 10:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Paul A. Amstad, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–7098, *pamstad@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 9, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17259 Filed 7–14–10; 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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pharmacology, Plasticity and Mental Disorders.

Date: July 20–21, 2010.

Time: 9 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).