the previously mentioned items, they should include a statement indicating which information is not being submitted and an explanation of why the information is not being submitted.

FDA also encourages persons who would like to study their new tobacco product to meet with the Office of Science at the Center for Tobacco Products (CTP) to discuss their investigational plan prior to distributing the product for investigational purposes. The request for a meeting should be sent in writing to the Director of CTP's Office of Science and should include adequate information for FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

FDA is required to deny a PMTA and issue an order that the product may not be introduced or delivered for introduction into interstate commerce under section 910(c)(1)(A)(ii) of the FD&C Act if FDA finds that the manufacturer has not shown that the product is appropriate for the protection of the public health, the manufacturing methods, facilities, or controls do not conform to manufacturing regulations issued under section 906(e) (21 U.S.C. 387f(e)) of the FD&C Act, the proposed labeling is false or misleading, or the manufacturer has not shown that the product complies with any tobacco product standard in effect under section 907 of the FD&C Act (21 U.S.C. 387g).

Under section 902(6)(A) (21 U.S.C. 387b(6)(A)), a tobacco product is deemed adulterated if it is a new tobacco product and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act, as necessary under section 910(a) of the FD&C Act. Under section 301(a) of the FD&C Act (21 U.S.C. 331(a)), the introduction or delivery for introduction into interstate commerce of any adulterated tobacco product is a prohibited act. Violations of section 910 are subject to regulatory and enforcement action by FDA, including, but not limited to, seizure and injunction.

Description of respondents: The respondents to this collection of information are applicants who are responsible for creating and submitting new tobacco product premarket applications and who wish to obtain an FDA order to allow them to market their product.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collected and FD&C act section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total burden hours
Obtaining an FDA order authorizing marketing of tobacco product (the application) Section 910(a)(1)(B)	20	1	20	5,000	100,000
Request for Meeting with CTP's Office of Science to discuss Investigational Plan	18	1	18	4	72
21 CFR 25.40 Preparation of an Environmental Assessment	20	1	20	12	240
Total Reporting Burden Hours					100,312

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

FDA estimates that each respondent will take approximately 5,000 hours to complete the information required in table 1 of this document to obtain an order from FDA allowing the marketing of a new tobacco product. FDA's estimate includes anticipated burden for the writing of an application, including intracompany edits and approvals, of approximately 200 hours. In addition, FDA expects that conducting the necessary scientific investigations for a new tobacco product will require, on average, 4,800 hours. FDA also estimates the number of PMTA applications that FDA expects to receive annually will be 20.

FDA anticipates that 18 potential respondents to this collection of information may need to meet with CTP's Office of Science to discuss their investigational plans. To request this meeting, applicants must compile and submit information to FDA for meeting approval. FDA estimates that it will take approximately 4 hours to compile this information, for a total of 72 hours additional burden (18 respondents × 4 burden hours).

FDA also estimates that 20 potential respondents will take approximately 12 hours to prepare and submit an environmental assessment under part 25 (21 CFR part 25) in accordance with the requirements of § 25.40, as referenced in 21 CFR 1107.1(b)(9).

The total burden for this collection of information is estimated to be 100,312 hours ((20 respondents multiplied by 5,000 per response) plus (18 respondents multiplied by 4 hours per response) plus (20 respondents multiplied by 12 hours per response)). These burden estimates were computed using FDA staff expertise and by reviewing comments received from recent FDA information collections for other tobacco-related initiatives.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: September 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24989 Filed 9–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Cognitive Function in Chronic Disease Ancillary Studies.

Date: October 26, 2011.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *ls38z@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 21, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–24826 Filed 9–27–11; 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.

Name of Committee: Vascular and Hematology Integrated Review Group, Molecular and Cellular Hematology.

Date: October 13–14, 2011.

Time: 8 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: Katherine M Malinda, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301–435–0912, *Katherine_Malinda@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cell Biology.

Date: October 19–20, 2011.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: David Balasundaram, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Motor Function, Speech and Rehabilitation Study Section.

Date: October 28, 2011.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Mandarin Oriental, 1330 Maryland Avenue, SW., Washington, DC 20024.

Contact Person: Biao Tian, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301–402–4411, *tianbi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA Panel: Understanding and Promoting Health Literacy.

Date: October 28, 2011.

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

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Rebecca Henry, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301–435–1717, *henryrr@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cancer Etiology Overflow.

Date: October 28, 2011.

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

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Review of Immunology AREA Grant Applications.

Date: October 28, 2011.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaylord National Resort, 201 Waterfront Street, National Harbor, MD 20745.

Contact Person: Calbert A Laing, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4210, MSC 7812, Bethesda, MD 20892, 301–435–1221, *laingc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA–OD–11–004: Strengthening Behavioral and Social Science in Medical School Education (R25).

Date: October 28, 2011.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

(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: September 22, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–24940 Filed 9–27–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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,