

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

PREA Provision	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
505B(a)(3) Deferrals	54	3.0	160	24	3,840
505B(a)(4) Full and partial waivers	80	1.4	110	8	880
505B(e) Meetings	95	1.7	160	16	2,560
Total					12,580

In addition, the draft guidance discusses when sponsors may need to report on the status of postmarketing study commitments as part of annual reports submitted under 21 CFR 314.81(b) and 21 CFR 601.70. The burdens associated with the annual reporting requirements were previously accounted for under OMB number 0910-0001 (expires 5/31/08) (for 21 CFR 314.81(b) and OMB number 0910-0433 (expires 3/31/07) (for 21 CFR 601.70). Furthermore, although labeling submissions are required under certain PREA provisions (e.g., section 505B(a)(4)(D) of the act), the draft guidance does not provide recommendations on these requirements and therefore FDA has not estimated associated burdens.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-17694 Filed 9-6-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council on Drug Abuse.

Date: September 21, 2005.

Closed: 9 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: 1 p.m. to 4 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Teresa Levitin, PhD, Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, (301) 433-2755.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address,

telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's Home page: <http://www.drugabuse.gov/NACDA/NACDAHome.html>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: August 29, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-17682 Filed 9-6-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Heart Study Applications (UO1s).

Date: September 13, 2005.

Time: 1:30 p.m. to 4 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: Valerie L. Prenger, PhD, Health Scientist Administrator, Review Branch, Room 7214, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892-7924, (301) 435-0270, prengerv@nhlbi.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. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 29, 2005.

Anthony M. Coelho, Jr.,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-17681 Filed 9-6-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals,

the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: September 23, 2005.

Open: 8:30 a.m. to 11:55 a.m.

Agenda: Director's Report, Implementation Plan Report, Concept Clearances.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Rm. 6C10, Bethesda, MD 20892.

Closed: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Rm. 6C10, Bethesda, MD 20892.

Contact Person: Norman S. Braveman, PhD, Assistant to the Director, NIH-NIDCR, Building 31, Rm. 5B55, Bethesda, MD 20892, (301) 594-2089, Norman.Braveman@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.nidcr.nih.gov/about>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 29, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-17680 Filed 9-6-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Waiver of Compliance With Navigation and Inspection Laws

AGENCY: Office of the Secretary, DHS.

ACTION: Notice.

Hurricane Katrina is one of the largest natural disasters to ever strike the United States. It has significantly disrupted production of oil and gas in the Gulf of Mexico, has caused many Gulf Coast oil refineries to go out of service because of flooding, lack of electric power or other reasons, and has significantly disrupted the pipeline transportation of oil and refined products from the Gulf Coast States.

These production losses, outages and disruptions have already caused large runups in the price of oil, gasoline and other refined products. The Department of Homeland Security is also now receiving reports of threatened or actual shortages of gasoline, jet fuel, and other refined products, and of the rationing of these fuels, both in the Southeast U.S. and in other locations throughout the country.

Numerous companies that produce and/or ship petroleum and/or refined petroleum products have submitted to the Department requests for waivers of the Merchant Marine Act of 1920 (the "Jones Act"). 46 U.S.C. App. section 1. This and related laws are generally referred to as the "coastwise laws." These laws provide, among other things, that only vessels built and owned by citizens of the United States and flagged in the United States can carry merchandise between U.S. ports.

The Secretary of Homeland Security is vested with the authority and discretion to waive the coastwise laws "to such extent and in such manner and upon such terms as he may prescribe, either upon his own initiative or upon the written recommendation of the head of any other Government agency, whenever he deems that such action is necessary in the interest of national defense." In consultation with and upon the recommendation of the Secretary of Energy, I have determined that such a waiver, in accordance with the terms set forth below, is in the interest of the national defense.

The catastrophic destruction brought about by Hurricane Katrina has dramatically impeded, and in some places in the affected region stopped altogether, production and transportation or transmission of oil, refined petroleum products, natural gas, and electricity. Much of the lost oil production is from producing areas in the Gulf of Mexico which have been leased pursuant to programs of the Department of the Interior. This lost production, refining and transportation capacity has resulted in the threatened rationing and unavailability of gasoline, jet fuel and other refined products, and threatens the Nation's economic and national security. I believe that waiver of the coastwise laws would facilitate the transportation of oil and refined petroleum products in and from portions of the United States devastated by the Hurricane, and to other regions affected by the disruptions that have occurred in the Gulf Coast area.

Therefore, I am exercising my discretion and authority to waive the coastwise laws generally for the transportation of petroleum and refined