

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In addition, the draft guidance discusses when sponsors may need to report on the status of postmarketing study commitments as part of annual reports submitted under 21 CFR 314.81(b) and 21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although labeling submissions are required under certain PREA provisions (e.g., section 505B(a)(4)(D) of the act), the draft guidance does not provide recommendations on these requirements and therefore FDA has not estimated associated burdens.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.

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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.

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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.