

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

| Activity/section of FD&C Act (as amended) or FDASIA | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act | 3 | 1 | 3 | 50 | 150 |
| Request for Determination of Eligibility Criteria—613(b) of FDASIA | 2 | 1 | 2 | 10 | 20 |
| ADN Notification—520(m)(6)(A)(iii) of the FD&C Act | 1 | 1 | 1 | 100 | 100 |
| ADN Modification—520(m)(6)(C) of the FD&C Act | 5 | 1 | 5 | 100 | 500 |
| Total | | | | | 1,370 |

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

FDA’s Center for Devices and Radiological Health receives an estimated average of six HDE applications per year. FDA estimates that three of these applications will be indicated for pediatric use. We estimate that we will receive approximately two requests for determination of eligibility criteria per year. FDA estimates that very few or no HDE holders will notify the Agency that the number of devices distributed in the year has exceeded the ADN. FDA estimates that five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease or condition.

Dated: May 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11532 Filed 5–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on April 7, 2016, for the FY 2016 Tribal Management Grant Program. The notice contained the incorrect Fiscal Year regarding funding availability.

FOR FURTHER INFORMATION CONTACT: Michelle Eagle Hawk, Deputy Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 5600 Fishers Lane, Mail Stop 08E17, Rockville, MD 20857, telephone (301) 443–1104. (This is not a toll-free number.)

Correction

In the **Federal Register** of April 7, 2016, in FR Doc. 2016–07950, on page 20396, in the second column, under the heading “II. Award Information, Estimated Funds Available,” the correct first sentence should read as follows:

The total amount of funding identified for the current fiscal year (FY) 2016 is approximately \$2,412,000.

Dated: May 4, 2016.

Mary Smith,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2016–11545 Filed 5–13–16; 8:45 am]

BILLING CODE 4165–16–P

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. 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Transition to Independence Review Committee.

Date: June 9–10, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, Pintuccig@nhlbi.nih.gov.

(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: May 10, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–11397 Filed 5–13–16; 8:45 am]

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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: Infectious Diseases and Microbiology Integrated Review Group; Virology—B Study Section.

Date: June 6–7, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.