

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5) .....	3	1	3	1	3
314.80(c)(1)(iii) .....	5	1	5	1	5
314.80(c)(2) .....	810	17.19	13,923.90	60	835,434
Reports of serious adverse drug events (21 U.S.C. 379aa(b) and (c)) .....	283	687.099	194,449	6	1,166,694
<b>Total</b> .....					<b>2,002,136</b>

<sup>1</sup> The reporting burden for § 310.305(c)(1), (2), and (3), and § 314.80(c)(1)(i) and (ii) is covered under OMB control number 0910–0645.

<sup>2</sup> The capital costs or operating and maintenance costs associated with this collection of information are approximately \$25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1 2</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305(g) .....	25	1	25	16	400
314.80(j) .....	352	1,870	658,240	16	10,531,840
Recordkeeping (21 U.S.C. 379aa(e)(1)) .....	300	885.6667	265,700	8	2,125,600
<b>Total</b> .....					<b>12,657,840</b>

<sup>1</sup> There are no capital costs or operating costs associated with this collection of information.

<sup>2</sup> There are maintenance costs of approximately \$22,000 annually.

Based on submissions received we have increased our burden estimate for reporting under part 314.80(c)(2) and recordkeeping under part 314.80(j). Additionally, and as previously stated, we are consolidating burden associated with reporting and recordkeeping under section 760 of the FD&C Act. Based on our records, we received 194,449 total annual reports from approximately 283 respondents for nonprescription drugs marketed without an approved application. We estimate each submission takes approximately 6 hours to prepare and submit. We estimate that there are 265,700 records per year maintained by approximately 300 respondents, and that it takes 8 hours to maintain each record.

Dated: November 2, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–24442 Filed 11–7–18; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Drug Abuse; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review.

*Date:* November 14, 2018.

*Time:* 12:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, [ramadanir@mail.nih.gov](mailto:ramadanir@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.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Multi-site Clinical Trials.

*Date:* November 16, 2018.

*Time:* 12:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, [ramadanir@mail.nih.gov](mailto:ramadanir@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.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 2, 2018.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Mental Health; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the