current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions of approval to ensure the device's continuing safety and effectiveness.

In the **Federal Register** of October 19, 2016 (81 FR 72063), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR or FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Research conducted outside the United States (814.15(b))	25	1	25	2	50
PMA application (814.20)	35	1	35	668	23,380
PMA amendments and resubmitted PMAs (814.37(a)–(c) and (e))	1,222	1	1,222	167	204,074
PMA supplements (814.39(a))	695	1	695	60	41,700
Special PMA supplement—changes being affected (814.39(d))	88	1	88	6	528
30-day notice (814.39(f))	1,710	1	1,710	16	27,360
Postapproval requirements (814.82(a)(9))	340	1	340	135	45,900
Periodic reports (814.84(b))	695	1	695	10	6,950
Agreement meeting (520(g)(7))	1	1	1	50	50
Expedited review request (515(d)(5) of the FD&C Act)	6	1	6	10	60
Determination Meeting (513(1)(3)(D) of the FD&C Act)	1	1	1	50	50
Panel meeting (515(c)(3) of the FD&C Act)	9	1	9	30	270
Day 100 meeting (515(d)(3) of the FD&C Act)	19	1	19	10	190
Total					350,562

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual responses	Average burden per response	Total hours
Maintenance of records (814.82(a)(5) and (a)(6))	422	1	422	17	7,174

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

Dated: January 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–01188 Filed 1–19–17; 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 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Virtual Reality Tools to Enhance Evidence-Based Treatment of Substance Use Disorders (5583).

Date: February 1, 2017.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4238, MSC 9550, Bethesda, MD 20892–9550, 301–827–5819, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: January 13, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01253 Filed 1–19–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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