TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request					
21 CFR 1107.1(c)—Preparation of additional information for tobacco product exemption from substantial equivalence request	244	1	244	3	732
Total Hours (§ 1107.1(c))					732
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)					
Abbreviated report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	1217	1	1217	3	3,651
Total Hours (section 905(j)(1)(A)(ii)) of the FD&C Act					3,651
Total Hours Exemptions From Substantial Equivalence Requirements					23,871

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

FDA estimates that we will receive 812 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 19,488 hours. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for an SE request for a total of 24 hours per response.

FDA further estimates that we will receive 244 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 732 hours.

FDA estimates that 1,217 respondents will prepare 1,217 responses and each response will take approximately 3 hours to prepare, as required by section 905(j)(1)(A)(ii) of the FD&C Act, for a total of 3,651 hours.

This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all the modifications are covered by exemptions granted by the Secretary under section 905(j)(3). FDA estimates the total hours for exemptions from Substantial Equivalence Requirements will be 23,871 hours.

FDA's estimates are based on full analysis of economic impacts and information gathered from other FDA-regulated products. Based on a review of the currently approved information collection, we have made no adjustments to our burden estimate.

Dated: May 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11658 Filed 6–4–19; 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; HEAL Initiative: Preventing Opioid Use Disorder in Older Adolescents and Young Adults (ages 16–30) (UG3/UH3 Clinical Trial Required).

Date: June 11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: Coordinating Center to Support NIDA Preventing Opioid Use Disorder in Older Adolescents and Young Adults (ages 16–30) Initiative (U24 Clinical Trial Not Allowed).

Date: June 12, 2019.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard,

Room 4238, MSC 9550, Bethesda, MD 20892, 301–827–5820, *hiromi.ono@nih.gov.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review.

Date: June 26, 2019.

Time: 6:00 a.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, (301) 827–5817, *mcguireso@mail.nih.gov.*

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

Date: July 10–11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

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.*

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: America's Startups and Small Businesses Build Technologies to Stop the Opioid Epidemic (R41/R42/R43/R44—Clinical Trial Optional).

Date: July 10–11, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

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 Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 30, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–11667 Filed 6–4–19; 8:45 am]

BILLING CODE 4140–01–P

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, 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: Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.

Date: June 24, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301–806–2765, *larkinja@csr.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: Center for Scientific Review Special Emphasis Panel; PAR Panel: Opioids and HIV at the single cell, single RNA level.

Date: June 27, 2019.

Time: 10:00 a.m. to 6:00 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: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Health Informatics.

Date: July 1, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: AC Hotel by Marriott National Harbor, 156 Waterfront Street, Oxon Hill, MD 20745.

Contact Person: Sheba King Dunston, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, Bethesda, MD 20892, 301–402–4933, *dunstonsk@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Microbiology Research Enhancement Review.

Date: July 1, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crown Plaza River Oaks, 2712 Southwest Freeway, Houston, TX 77098.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301–996–5819, *zhengli@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA Topics in Infectious Disease.

Date: July 1, 2019.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crown Plaza River Oaks, 2712 Southwest Freeway, Houston, TX 77098.

Contact Person: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, *susan.boyle-vavra@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 30, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–11671 Filed 6–4–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the June 27, 2019 meeting of the National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, which was published in the **Federal Register** on May 20, 2019, 84 FR 22870.

Date, Time and Place remain the same. This notice is amended to update contact information—Dr. Kathy Salaita, Chief, Scientific Review Branch, NIAMS/NIH/DHHS, 6701 Democracy Blvd., Rm. 818, Bethesda, MD 20892, *Kathy.Salaita@nih.gov.* The meeting is closed to the public.