

considerably less time than manufacturers. The estimates include the time for submitting the content of labeling and other labeling in an electronic format (for drugs subject to an approved marketing application, the electronic submission of the content of labeling under § 314.50(l)(1)(i) is approved under OMB control number 0910-0001). We assume it takes 45 minutes for each June and December review and update. These estimates represent the average amount of time to review and update listing information or to review and certify that no changes have occurred. The estimates include the time for submitting any labeling for each drug, changes to the drug's characteristics submitted for a new NDC, and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

Finally, although we expect most respondents will already have prepared a standard operating procedure (SOP) for the electronic submission of drug establishment registration and drug listing information, we estimate each year additional firms will need to create an SOP as recommended in the guidance. We therefore estimate 1,000 firms will expend approximately 40 hours to prepare, review, and approve an SOP, for a total of 40,000 hours annually.

While we retain the currently approved burden estimates for information collection associated with provisions in part 207, we have adjusted our estimate upward by 72,000 hours and 288,000 responses to account for information collection associated with the new manufacturing amount information element required by the CARES Act.

Dated: May 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-09805 Filed 5-7-21; 8:45 am]

BILLING CODE 4164-01-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, notice is hereby given of meetings of the Board of Scientific Counselors, NHLBI.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section

552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NHLBI.

Date: June 4, 2021.

Time: 9:55 a.m. to 4:00 p.m.

Agenda: To review and evaluate to review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building, 10, 10 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Date: June 7, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate to review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Robert S. Balaban, Ph.D., Scientific Director, Division of Intramural Research, National Institutes of Health, NHLBI, Building 10, CRC, 4th Floor, Room 1581, 10 Center Drive, Bethesda, MD 20892, 301/496-2116.

Any interested person may file written comments with the committee by forwarding the 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. These meetings are closed to the public.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(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 5, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-09839 Filed 5-7-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Institute of Mental Health Initial Review Group; Mental Health Services Study Section.

Date: June 10-11, 2021.

Time: June 10, 2021, 1:00 p.m. to 5:00 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).

Time: June 11, 2021, 11:00 a.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: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6136, MSC 9606, Bethesda, MD 20852 301-443-1225, aschulte@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 5, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-09813 Filed 5-7-21; 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: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: June 7–8, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, ryansj@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: June 9–10, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guoqin Yu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, (301) 435–1276, guoqin.yu@nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

Date: June 10–11, 2021.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, greenbergwa@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Nutrition and Metabolism in Health and Disease Study Section.

Date: June 10–11, 2021.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gregory S. Shelness, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, Bethesda, MD 20892–7892, 301–755–4335, greg.shelness@nih.gov.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Clinical Research and Field Studies of Infectious Diseases Study Section.

Date: June 10–11, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pauline Cupit, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–3275, cupitcunninghpm@mail.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroimmunology and Brain Tumors Study Section.

Date: June 10–11, 2021.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aleksey Gregory Kazantsev, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5201, Bethesda, MD 20817, 301–435–1042, aleksey.kazantsev@nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Maximizing Investigators' Research Award A Study Section.

Date: June 10–11, 2021.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Emily Foley, Ph.D., Scientific Review Officer, Center for Scientific Review, Bethesda, MD 20892, 301–402–3016, emily.foley@nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; Mechanisms of Cancer Therapeutics—2 Study Section.

Date: June 14–15, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, tothct@csr.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Progression and Metastasis Study Section.

Date: June 15–16, 2021.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718, jakobir@mail.nih.gov.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: June 15–16, 2021.

Time: 10:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, sarita.sastry@nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Behavioral Genetics and Epidemiology Study Section.

Date: June 16–17, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Andrew Loudon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3137, Bethesda, MD 20817, 301–435–1985, [loudenan@csr.nih.gov](mailto:louden@csr.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 5, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–09834 Filed 5–7–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

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