over raw material quality. Risk management enables manufacturers to make proper choices and ensure the continued suitability of these materials and supply chains. The Agency needs to better understand how manufacturers, processors, and packers of drug products approach managing risks related to components, containers, and closures as well as the supply and distribution chains between the producers of raw materials and drug product manufacturers, processors, and packers. Such information will allow FDA to examine the potential economic impact of changes to regulations that govern the manufacturing, processing, and packing of drugs.

This is a one-time information collection, the primary purpose of which is to collect industry-wide data on how facilities that manufacture, process, and pack drug products for use in humans and/or animals ensure the quality of their operations, including their current risk management approaches and practices for ensuring the quality and suitability of the drug components, containers, and closures that they use. FDA intends to use this information to inform its economic analyses of potential updates to CGMPs for human and animal drug product manufacturing, processing, and packing facilities under 21 CFR parts 210 and 211. Survey respondents will be contacted by email or, if necessary, by regular mail. Respondents will be able to take the survey online or, if requested, they can return a hard copy by mail. FDA estimates the maximum burden of this collection of information as follows:

TABLE 1—ESTIMATED BURDEN HOURS FOR ONE-TIME DATA COLLECTION [1]

Type of respondent/facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Group 1: Facilities in United States engaged in drug manufacturing (in addition to other possible activities).	394	1	394	1.1	433
Group 2: Facilities in United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	333	1	333	0.75 (45 minutes)	250
Group 3: Facilities outside United States engaged in drug manufacturing (in addition to other possible activities).	407	1	407	2.20	895
Group 4: Facilities outside United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	261	1	261	1.5	392
Total	1,395		1,395		1,970

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

Burden hours are based on pretests of the survey and interviews with industry representatives and reflect the time required by each type of respondent to read the survey invitation and instructions and complete the survey questions. The total estimated one-time burden hours are 1,970.

Dated: September 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20619 Filed 9–17–20; 8:45 am]

BILLING CODE 4164–01–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: Immunology Integrated Review Group; Innate Immunity and Inflammation Study Section.

Date: October 15–16, 2020.

Time: 8:00 a.m. to 6:30 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: Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, (301) 594–6375, *mcintyrt@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimmunology and Brain Tumors.

Date: October 15, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@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: September 14, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–20578 Filed 9–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel; ZDE1 EP (09) DSR Member-Conflict Special Emphasis Panel.

Date: November 6, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 662, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elizabeth M. Perruccio, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 662, Bethesda, MD 20892, (301) 827–4603, *perruccioem@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 14, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–20586 Filed 9–17–20; 8:45 am]

BILLING CODE 4140–01–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 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; SINGLE–SITE AND PILOT CLINICAL TRIALS REVIEW COMMITTEE.

Date: October 22–23, 2020.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20814 (Virtual Meeting).

Contact Person: Carol (Chang-Sook) Kim, Ph.D., Scientific Review Administrator, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–B, Bethesda, MD 20892–7924, (301) 827–7940, *carolko@mail.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: September 14, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–20582 Filed 9–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 Eye Institute Special Emphasis Panel; NEI Clinical Secondary Data Analysis and Applications.

Date: October 20, 2020.

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

Agenda: To provide concept review of proposed grant applications.

Place: National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeanette Hosseini, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Suite 3400, Bethesda, MD 20892, 301–451–2020, *jeanetteh@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: September 14, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–20577 Filed 9–17–20; 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: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics A Study Section.

Date: October 14–15, 2020.

Time: 9:00 a.m. to 5:00 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: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, *bloomm2@mail.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Language and Communication Study Section.

Date: October 14–16, 2020.

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: Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7770, Bethesda, MD 20892, (301) 455–1761, *kellya2@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Innovative Research in Cancer Nanotechnology.

Date: October 14, 2020.

Time: 10:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.