

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]

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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]

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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.

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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