

objectives of the Drug X REMS were being met and did not propose any changes to the REMS as a result of the REMS assessment findings.

*FDA conclusion:* FDA concluded that while not all objectives are fully met, the overall goals of the program are being met. Appropriate outreach to likely prescribers was completed via REMS letters and the open rate for email letters is consistent with communications for other REMS. Surveys of a sample of enrolled prescribers showed that they understood the risks of Drug X, the need to monitor following dosing, and how to treat anaphylaxis. Patients surveyed were also aware of the risk and the need to be observed for 30 minutes following each dose. No Drug X was shipped to facilities that were not enrolled. Audits of facilities were in compliance with the need to have access onsite to equipment, emergency medication, and personnel trained to manage anaphylaxis; however, findings did reveal that 25 percent did not have specific policies and procedures in place to ensure that patients are observed 30 minutes following each injection of Drug X. Certified healthcare facility personnel surveyed were also aware of the risk and stated that they ensure all patients are observed for 30 minutes following each injection. Facilities reporting patient non-compliance with the 30-minute observation period were warned and will be followed in subsequent assessment reports. Although patients experiencing anaphylaxis were treated appropriately, three did require transport to a hospital and their outcome was not provided in this report.

#### *E. Next Steps*

Based on our review of the findings in the third REMS Assessment Report, modifications to the Drug X REMS are not warranted.

On May 1, 2019, FDA sent a letter to the applicant to acknowledge our completion of the third REMS assessment report review. In the letter the applicant was instructed to ensure that the audited healthcare settings that were out of compliance are fully compliant within 3 months of the date of issuance of the letter and that the outcome for the three patients that were transferred to a hospital must be provided to FDA as soon as possible. The applicant was also encouraged to use probability random sampling and recruit a larger sample of prescribers in subsequent prescriber surveys.

#### **IV. Additional Issues for Consideration**

FDA is soliciting comment from stakeholders regarding the information that would be posted in the Summary of the REMS Assessment. In addition to any other aspects of or issues concerning FDA's proposal to publicly post a Summary of the REMS Assessment, FDA is interested in comments on the following topics:

- (1) Whether the information contained in the Summary of the REMS Assessment example would be beneficial to the public, and if so, why it would be beneficial
- (2) whether the Summary of the REMS Assessment would be useful to a wide range of stakeholders, including healthcare providers, patients, the pharmaceutical industry, and academics, and if so, why it would be beneficial
- (3) whether any additional information should be included in the Summary of the REMS Assessment
- (4) possible negative impacts of posting the Summary of the REMS Assessment

Dated: October 30, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-24540 Filed 11-4-20; 8:45 am]

**BILLING CODE 4164-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Meeting of the Advisory Committee on Minority Health**

**AGENCY:** Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice of meeting.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS or Department) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for the public to attend the meeting, provide comments, and/or distribute printed material(s) to ACMH members. Information about the meeting is available from the designated contact person and will be posted on the HHS Office of Minority Health (OMH) website: [www.minorityhealth.hhs.gov](http://www.minorityhealth.hhs.gov). Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Workgroups*.

**DATES:** The ACMH meeting will be held on Friday, November 20, 2020, from 3 p.m. to 5:30 p.m. ET. If the Committee completes its work before 5:30 p.m., the meeting will end early.

**ADDRESSES:** The meeting will be held virtually and will be accessible by webcast. Participants must register for the meeting by 5 p.m. ET on November 18, 2020. Registered participants will receive webcast access information prior to the meeting.

**FOR FURTHER INFORMATION CONTACT:** Samuel Wu, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240-453-6173; email: [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with Public Law 105-392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

The purpose of the November 2020 ACMH meeting is to finalize recommendations for improving access to and utilization of clinical preventive services among racial and ethnic minority populations. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts for removing barriers to achieving health equity.

The meeting is open to the public. Any individual who wishes to attend the meeting must register by sending an email to [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) by 5 p.m. ET on November 18, 2020. Each registrant should provide name, affiliation, phone number, and email address. Registrants will receive webcast access information via email. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) and reference this meeting. Requests for special accommodations should be made at least ten (10) business days prior to the meeting.

Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals who would like to submit written statements should email [OMH-ACMH@hhs.gov](mailto:OMH-ACMH@hhs.gov) at least five (5) business days prior to the meeting.

Any members of the public who wish to distribute electronic or printed material(s) related to this meeting's topic to ACMH members should email the Designated Federal Officer at *OMH-ACMH@hhs.gov*. The material should be received by the Designated Federal Officer at least five (5) business days prior to the meeting.

Dated: November 2, 2020.

**Samuel Wu,**

*Designated Federal Officer, Advisory Committee on Minority Health.*

[FR Doc. 2020-24580 Filed 11-4-20; 8:45 am]

**BILLING CODE 4150-29-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; America's Startups and Small Businesses Build Technologies to Stop the Opioid Epidemic (R41/R42/R43/R44—Clinical Trial Optional).

*Date:* December 2–3, 2020.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827-5819, *gm145a@nih.gov*.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; National Institute on Drug Abuse R25s.

*Date:* December 9, 2020.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Drug Abuse, 301 North

Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827-5702, *sindhu.kizhakkemadathil@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 30, 2020.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19).

*Date:* December 11–14, 2020.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room #3G42, Rockville, MD 20892, (Virtual Meeting).

*Contact Person:* Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room #3G42,

Rockville, MD 20852, *sandip.bhattacharyya@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 30, 2020.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19).

*Date:* December 8, 2020.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20892 (Virtual Meeting).

*Contact Person:* Jennifer H. Meyers, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20852, 301-761-6602, *jennifer.meyers@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)