levels for gene therapy products, discuss the need for long-term safety assessments in gene therapy clinical trials, and discern when to enroll pediatric patients in gene therapy trials.

II. Topics for Discussion at the Public Workshop

The workshop will feature presentations and panel discussions on hemophilia product development. The presentations will include an overview of product development in hemophilia, and the regulatory challenges in the development of novel hemophilia therapies. Five sessions include presentations to frame panel discussions to cover the following topics:

1. Overview of product development in hemophilia;
2. Efficacy endpoints related to bleeding outcomes and considerations for factor activity as a surrogate endpoint;
3. Patient and caregiver perspectives on developing outcomes for clinical trials;
4. Discrepancies in the factor activity measurements by different assays observed in gene therapy trials and root causes for the discrepancies; and
5. Clinical trial design considerations for follow up on safety, efficacy, enrollment of pediatric patients in gene therapy trials, and the applicability of on-demand treatment as a control group in the evolving landscape of treatment options in hemophilia.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at *https://fdaoce.formstack.com/forms/pdh120618* before 5 p.m. on December 3, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Joan Ferlo Todd at *Joan.Todd@fda.hhs.gov* no later than 5 p.m., on November 21, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be web-streamed on the day of the workshop.

If you have never attended a webcast event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Adobe webcast program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will be available on the internet at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm620602.htm.*

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23947 Filed 11–1–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcement of Supplemental Award.

SUMMARY: HRSA provided supplemental grant funds to a currently funded National Training and Technical Assistance Cooperative Agreement (NCA) award recipient to coordinate and provide training and technical assistance (T/TA) to health centers that serve migrant and seasonal agricultural workers (MSAW) and their families through three regional forums.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: The National Center for Farmworker Health, Inc.

Amount of Non-Competitive Awards: $150,000.

Period of Supplemental Funding: Fiscal years 2018 and 2019 (contingent upon available funding and satisfactory performance).

CFDA Number: 93.129.

Authority: Section 330(l) of the Public Health Service Act, as amended.

JUSTIFICATION: The award recipient will lead the coordination and management of three regional Migrant Stream Forums to provide T/TA addressing the critical health needs of MSAW in alignment with HRSA priorities. T/TA provided at the Migrant Stream Forums is targeted to a broad range of health center staff positions, and covers diverse topics that address the needs of migrant health centers and the patients they serve. Supplemental funds are necessary to support their timely and successful implementation.

This supplemental funding will augment the current NCA investment for these T/TA opportunities through support of enhanced personnel presence, the availability of continuing education unit-bearing educational sessions to meet the diverse needs of multidisciplinary health center staff, and speaker and participant stipends that underscore the unique value these in-person regional T/TA sessions provide.

FOR FURTHER INFORMATION CONTACT: Tracey Orloff, Strategic Partnerships Division Director in the Bureau of Primary Health Care, Office of Quality Improvement, at *TOrloff@hrsa.gov.*

Dated: October 26, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–24008 Filed 11–1–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Special Emphasis Panel.

Date: November 20, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6710B Rockledge Drive, Bethesda, MD 20817.

Contact Person: Kimberly Lynette Houston, MD, Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20817, *Kimberly.houston@nih.gov,* 301–827–4902.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Population Research; 93.865. Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 29, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23938 Filed 11–1–18; 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: Center for Scientific Review Special Emphasis Panel; Small Business: Dermatology, Rheumatology and Inflammation.

Date: November 27, 2018.

Time: 10:30 a.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: Rajiv Kumar, Ph.D., Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4216, MSC 7802, Bethesda, MD 20892, 301–435–1212, *kumarra@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA Applications in Oncological Sciences.

Date: November 28, 2018.

Time: 11:00 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.

Contact Person: Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301–594–7945, *kotliars@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Non-HIV Diagnostics, Food Safety, Sterilization/Disinfection, and Bioremediation.

Date: November 29–30, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20892.

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301–435–1167, *pandyaga@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Clinical Neurophysiology, Devices, Neuroprosthetics, and Biosensors.

Date: November 29–30, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.

Contact Person: Cristina Backman, Ph.D., Scientific Review Officer, ETTN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7846, Bethesda, MD 20892, 301–480–9069, *cbackman@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Integrative Neuroscience.

Date: November 29, 2018.

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: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 4214 MSC 7814, Bethesda, MD 20892–7814, 301–435–1787, *borzanj@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: October 29, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23939 Filed 11–1–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0880]

Notice of Public Meeting in Preparation for the IMO's One Hundred Twenty First Session of IMO's Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The United States Coast Guard will conduct an open meeting in Washington, DC in preparation for the upcoming one hundred twenty first session of IMO Council to be held at the IMO Headquarters, United Kingdom, November 19–23, 2018.

DATES: This meeting will be held on Wednesday, November 13, 2018, beginning at 10:30 a.m., Eastern Time. This meeting is open to the public.

ADDRESSES: The public meeting will be held in Room 5L18–01 of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King, Jr. Avenue SE, Washington, DC 20593. Due to security requirements, each visitor must present two valid, government-issued forms of identification in order to gain entrance to the building. Those desiring to attend the public meeting should contact the Coast Guard ahead of the meeting (see **FOR FURTHER INFORMATION CONTACT**) to facilitate the security process related to building access, or to request reasonable accommodation.

FOR FURTHER INFORMATION CONTACT: For additional information about this public meeting you may contact Lieutenant Commander Staci Weist by telephone at 202–372–1376 or by email at *Eustacia.Y.Weist@uscg.mil.*

SUPPLEMENTARY INFORMATION:

The primary purpose of this meeting is to prepare for the upcoming one hundred twenty first session of IMO Council (C 120). The agenda items for this session include:

- Adoption of the agenda
- Report of the Secretary-General on credentials
- Strategy, planning and reform
- Rules of Procedure of the Assembly
- Resource Management
- IMO Member State Audit Scheme
- Consideration of the report of the Marine Environment Protection Committee
- Consideration of the report of the Technical Cooperation Committee
- Technical Cooperation Fund: Report on activities of the 2017 programme
- Word Maritime University
- IMO International Maritime Law Institute