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.