and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Poonam Mishra, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6100, Silver Spring, MD 20993, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs and biologics for the treatment of chronic HBV infection from the initial IND through the NDA/BLA and postmarketing phases. The guidance includes general considerations for nonclinical toxicology and virology studies, early phase clinical development, clinical pharmacology assessments, and phase 3 safety and efficacy trials. The guidance discusses phase 3 trial design considerations and efficacy endpoints for the development of combination therapies for the treatment of chronic HBV infection. Drug development considerations for specific subpopulations such as patients coinfected with hepatitis D virus or human immunodeficiency virus and pediatric HBV-infected patients are also included.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Chronic Hepatitis B Virus Infection: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23951 Filed 11–1–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3693]

Product Development in Hemophilia; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Product Development in Hemophilia.'' The purpose of the public workshop is to discuss issues related to development and regulation of novel hemophilia products.

DATES: The public workshop will be held on December 6, 2018, from 8:30 a.m. to 4:30 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Docket: For access to the docket to read background documents go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joan Ferlo Todd, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Hematology and Oncology Products, 10903 New Hampshire Ave., Bldg. 22, Rm. 2139, Silver Spring, MD 20993–0002, 301–796–6079, *Joan.Todd@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Hemophilia is a bleeding disorder caused by deficiency of coagulation factor VIII (hemophilia A) or coagulation factor IX (hemophilia B). Hemophilia treatment strategies are intended to prevent or control bleeding and the attendant complications. Recently, hemophilia treatment strategies have led to the development of factor concentrates, recombinant DNA technology products, antibodies, and potential curative strategies such as gene therapy. These new emerging technologies raise new considerations about trial design, novel endpoints, patient-reported outcomes, and long-term safety collection.

This public workshop is intended to provide a platform for engaging in a discussion with experts in hemophilia treatment, patients, and caregivers. The purpose of this workshop is to advance further development of patient-experience and patient-reported outcomes for use in clinical trials, facilitate reliable and interpretable measurements of factor VIII/IX activity

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.