

the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft document entitled “Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry.” The draft guidance provides a brief introduction of the product characteristics, patient-related factors, and the preclinical and clinical data that should be considered when assessing the need for LTFU observations for your GT product. The draft guidance also describes the Agency’s current recommendations for the conduct of LTFU studies, specifically the information/data to support a sponsor’s rationale for the duration and design of a LTFU protocol when clinical trials are initiated. Also included in the draft guidance are GT product-specific clinical considerations for monitoring subjects under a LTFU protocol and recommendations on patient monitoring for licensed GT products. The draft guidance, when finalized, is intended to supersede the guidance entitled “Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events” dated November 2006. The draft guidance, when finalized, is also intended to supplement the guidance entitled “Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-up; Draft Guidance for Industry,” published elsewhere in this issue of the **Federal Register**. Also, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another draft guidance entitled “Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Draft Guidance for Industry.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on long term follow-up after administration of human gene therapy products. 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 draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0755; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910-0119; and the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014.

##### **III. Electronic Access**

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

Dated: July 5, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

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

##### **Health Resources and Services Administration**

##### **Advisory Committee on Heritable Disorders in Newborns and Children**

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

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

**DATES:** Thursday, August 2, 2018, from 9:30 a.m. to 5:00 p.m. Eastern Time (ET).

**ADDRESSES:** This meeting is a webinar only and requires advanced registration. Please register online at <http://www.achdncmeetings.org/> by 12:00 p.m. ET on July 30, 2018.

**FOR FURTHER INFORMATION CONTACT:** Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three ways: (1) Send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; (2) call 301-443-3999; or (3) send an email to [AFerrero@hrsa.gov](mailto:AFerrero@hrsa.gov).

##### **SUPPLEMENTARY INFORMATION:**

**Background:** The ACHDNC provides advice and recommendations to the Secretary of HHS on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC’s recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary’s adoption of the condition for screening.

**Agenda:** During the August 2, 2018, meeting, the ACHDNC will discuss issues related to long-term follow-up, timeliness, education and training, the evidence-based review process, and risk assessment in newborn screening. Information about the ACHDNC, a roster of members, and the meeting agenda, as well as past meeting summaries, is located on the ACHDNC website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

**Public Participation:** Members of the public will have the opportunity to provide comments, which are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on July 27, 2018, at <http://www.achdncmeetings.org>. Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and

present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.*, parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

[FR Doc. 2018-14908 Filed 7-11-18; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Cures Acceleration Network Review Board.

*Date:* September 27, 2018.

*Time:* 8:30 a.m. to 3:00 p.m.

*Agenda:* Report from the Institute Director.

*Place:* National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301-435-0809, [annn.ramseyewing@nih.gov](mailto:annn.ramseyewing@nih.gov).

*Name of Committee:* National Center for Advancing Translational Sciences Advisory Council.

*Date:* September 27, 2018.

*Open:* 8:30 a.m. to 3:00 p.m.

*Agenda:* Report from the Institute Director and other staff.

*Place:* National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

*Closed:* 3:15 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD 20892, 301-435-0809, [anna.ramseyewing@nih.gov](mailto:anna.ramseyewing@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

*Dated:* July 5, 2018.

**David D. Clary,**

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

[FR Doc. 2018-14873 Filed 7-11-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the ZAT1 PJ (02) 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 Center for Complementary and Integrative Health Special Emphasis Panel; Mechanisms of Mind and Body Interventions (MMB).

*Date:* August 1, 2018.

*Time:* 11:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Pamela Eugenia Jeter, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301-435-2591, [pamela.jeter@nih.gov](mailto:pamela.jeter@nih.gov). (Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

*Dated:* July 6, 2018.

**Michelle D. Trout,**

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

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Accreditation and Approval of Saybolt LP (Nederland, TX) as a Commercial Gauger and Laboratory

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of accreditation and approval of Saybolt LP (Nederland, TX) as a commercial gauger and laboratory.

**SUMMARY:** Notice is hereby given, pursuant to CBP regulations, that Saybolt LP (Nederland, TX) has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 8, 2017.

**DATES:** Saybolt LP (Nederland, TX) was approved and accredited as a commercial gauger and laboratory as of August 8, 2017. The next triennial inspection date will be scheduled for August 2020.

**FOR FURTHER INFORMATION CONTACT:** Christopher J. Mocella, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt LP, 4144 N Twin City Hwy., Nederland, TX 77627, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt