

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that EVRYSDI (risdiplam), manufactured by Genentech Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that EVRYSDI (risdiplam), manufactured by Genentech Inc., meets the criteria for a priority review voucher. EVRYSDI (risdiplam) is indicated for the treatment of spinal muscular atrophy in pediatric and adult patients.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about EVRYSDI (risdiplam), go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: August 20, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Meeting of the Advisory Committee on Infant Mortality

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

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Advisory Committee on Infant Mortality (ACIM or Committee) has scheduled a public meeting. Information about ACIM and the agenda for this meeting can be found on the ACIM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

**DATES:** September 23, 2020, 11 a.m.–6 p.m. Eastern Time (ET) and September 24, 2020, 11 a.m.–3:30 p.m. ET.

**ADDRESSES:** This meeting will be held via webinar.

- *The webinar link will be available at ACIM's website before the meeting: <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.*

- *The conference call-in number will be available at ACIM's website before the meeting: <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.*

**FOR FURTHER INFORMATION CONTACT:**

David S. de la Cruz, Ph.D., MPH, Designated Federal Official, Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Room 18N25, Rockville, Maryland 20857; 301-443-0543; or [SACIM@hrsa.gov](mailto:SACIM@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The ACIM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees.

The ACIM advises the Secretary of HHS on department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. The ACIM represents a public-private partnership at the highest level to provide guidance and focus attention on the policies and resources required to address the reduction of infant mortality and the improvement of the health status of pregnant women and infants. With a focus on life course, the ACIM addresses disparities in maternal health

to improve maternal health outcomes, including preventing and reducing maternal mortality and severe maternal morbidity. The ACIM provides advice on how best to coordinate a myriad of federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality and maternal health, including implementation of the Healthy Start program and maternal and infant health objectives from the National Health Promotion and Disease Prevention Objectives.

The agenda for the September 23–24, 2020, meeting is being finalized and may include the following: Updates from HRSA, MCHB, and other federal agencies, continued discussion of the impact of COVID-19 on infant and maternal health, and updates on priority topic areas for ACIM to address (equity, data, access, and quality of care). Agenda items are subject to change as priorities dictate. Refer to the ACIM website above for any updated information concerning the meeting.

Members of the public will have the opportunity to provide written or oral comments. Requests to submit a written statement or make oral comments to the ACIM should be sent to David S. de la Cruz, using the email address above at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing [SACIM@hrsa.gov](mailto:SACIM@hrsa.gov). Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify David S. de la Cruz at the contact information listed above at least 10 business days prior to the meeting.

**Maria G. Button,**

*Director, Executive Secretariat.*

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be held as a virtual meeting and is open to the public.

Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Cancer Institute Clinical Trials and Translational Research Advisory Committee—Translational Research Strategy Subcommittee (TRSS).

*Date:* October 5, 2020.

*Time:* 1:00 p.m. to 2:30 p.m.

*Agenda:* NCI CTAC Radiation Oncology Working Group Report Discussion.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

*Access to Meeting:* <https://nci.rev.vbrick.com/#/webcasts/ctacmeetings>.

*Contact Person:* Peter Ujhazy, MD, Ph.D., Deputy Associate Director, Translational Research Program, Division of Cancer Treatment and Diagnosis, National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Room 3W106, Rockville, MD 20850, 240-276-5681, [ujhazy@mail.nih.gov](mailto:ujhazy@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 20, 2020.

**Melanie J. Pantoja,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

This meeting will be open to the public and held by videoconference.

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.

*Name of Committee:* Center for Scientific Review Advisory Council.

*Date:* September 21, 2020.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Bruce Reed, Ph.D., Deputy Director, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-9159, [reedbr@mail.nih.gov](mailto:reedbr@mail.nih.gov)

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Any member of the public may submit written comments no later than 15 days after the meeting.

URL for virtual access: <https://videocast.nih.gov>. Information is also available on the Institute's/Center's home page: <https://public.csr.nih.gov/AboutCSR/Organization/CSRAdvisoryCouncil>, where an agenda and any additional information for the meeting will be posted when available. (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: August 19, 2020.

**Ronald J. Livingston, Jr.,**

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

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## DEPARTMENT OF THE INTERIOR

### National Park Service

[NPS-PWRO-TUSK-30346; PPPWTUSK00, PPMSPD1Z.YM0000]

#### Tule Springs Fossil Beds National Monument Advisory Council Notice of Public Meeting

**AGENCY:** National Park Service, Interior.

**ACTION:** Meeting notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act of 1972, the National Park Service is hereby giving notice that the Tule

Springs Fossil Beds National Monument Advisory Council (Council) will meet as indicated below.

**DATES:** The meeting will be held on Monday, September 14, 2020, at 5:00 p.m. until 7:00 p.m. (PACIFIC). A teleconference may substitute for an in-person meeting if public health restrictions are in effect.

**ADDRESSES:** The meeting will be held at Springs Preserve, Preserve Partnership Room, S. Valley View Boulevard, Las Vegas, Nevada 89107.

**FOR FURTHER INFORMATION CONTACT:** Further information concerning the meeting may be obtained from Christie Vanover, Public Affairs Officer, Lake Mead National Recreation Area, 601, Nevada Way, Boulder City, Nevada 89005, via telephone at (702) 293-8691, or email at [christie\\_vanover@nps.gov](mailto:christie_vanover@nps.gov).

**SUPPLEMENTARY INFORMATION:** The Council was established pursuant to Section 3092(a)(6) of Public Law 113-291 and in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. Appendix 1-16). The purpose of the Council is to advise the Secretary of the Interior with respect to the preparation and implementation of the management plan.

*Purpose of the Meeting:* The Council agenda will include:

1. Introduction of New Superintendent
2. Superintendent Update:
  - Final Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Report
  - Update on General Management Plan Pre-Planning
  - Update on Tufa Trail
3. Resource Management Update
4. Discussion of Council Priorities
5. Public Comments

A teleconference may substitute for an in-person meeting if public health restrictions are in effect. In the event of a switch to a teleconference, notification and access information will be posted by September 9, 2020, to the Council's website at <https://www.nps.gov/tusk/index.htm>.

The meeting is open to the public. Interested persons may make oral or written presentations to the Council during the business meeting or file written statements. Such requests should be made to the Acting Superintendent prior to the meeting. Members of the public may submit written comments by mailing them to Christie Vanover, Public Affairs Officer, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, NV 89005, or by email [christie\\_vanover@nps.gov](mailto:christie_vanover@nps.gov). All written comments will be provided to members of the Council.