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.*

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.

[FR Doc. 2020–18648 Filed 8–24–20; 8:45 am]

BILLING CODE 4164–01–P

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.*

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.* 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.

[FR Doc. 2020–18565 Filed 8–24–20; 8:45 am]

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.