but no less than 3 years, as recommended by FDA (table 2).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Awardee activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with partnering entities related to Initial Report	300	2	600	8	4,800
Coordination with partnering entities related to Updated Reports	300	4	1,200	8	9,600
Coordination with partnering entities related to Supplement or Followup Report (if applicable)	100	2	200	8	1,600
Total					16,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For those pilot projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other in a pilot project. We estimate that 300 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. We assume each respondent will spend 8 hours coordinating with each partnering entity on each response for this pilot. We estimate that seven respondents will need to coordinate with an average of two partnering entities to create updated reports and the final report to submit to FDA (table 3).

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13642 Filed 6–24–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. 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 issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application for ULTOMIRIS (ravulizumab-cwvz), approved April 27, 2022, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for ULTOMIRIS (ravulizumab-cwvz), approved April 27, 2022, meets the redemption criteria.

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/RarePediatricDiseasesPriorityVoucherProgram/default.htm.* For further information about ULTOMIRIS (ravulizumab-cwvz), approved April 27, 2022, go to the ''*Drugs@FDA*'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13628 Filed 6–24–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a meeting. The meeting will be open to the public via webcast. For this meeting, the TBDWG will review the first draft of chapters for the report and further discuss plans for developing the next report to the HHS Secretary and Congress on federal tick-borne activities and research, taking into consideration the 2018 and 2020 report. The 2022 report will address a wide range of topics related to tick-borne diseases, such as, surveillance, prevention, diagnosis, diagnostics, and treatment; identify advances made in research, as well as overlap and gaps in tick-borne disease research; and provide recommendations regarding any appropriate changes or improvements to such activities and research.

DATES: The public can view the meeting online via webcast on July 19–20, 2022 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change) each day. The confirmed times and agenda items for the meeting

will be posted on the TBDWG web page at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2022-07-19/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. Email: *tickbornedisease@hhs.gov*. Phone: 202–795–7608.

SUPPLEMENTARY INFORMATION: A link to view the webcast can be found on the meeting website at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2022-07-19/index.html* when it becomes available. The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2022-07-19/index.html* and respond by midnight July 11, 2022 ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30-minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: June 7, 2022.

James J. Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2022–13575 Filed 6–24–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): HHS Initiative To Strengthen Primary Health Care

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of Request for Information.

SUMMARY: U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) requests input from persons, communities, health care providers, purchasers and payers, educators, researchers, and other members of the public about what the federal government could do to strengthen primary health care in the United States. Improving access to health care, advancing health equity, and improving the health of the Nation are top priorities for the Biden-Harris Administration and HHS. Access to high-quality primary health care has been shown to improve health equity and health outcomes, and is essential for addressing key priorities, including: the COVID–19 pandemic; mental and substance use disorder prevention and care, including suicide and overdose prevention; prevention and management of chronic conditions; gender-based violence; and maternal and child health and well-being. However, our nation's primary health care foundation is weakening and in need of support: primary health care is under-resourced; the workforce is shrinking; workforce well-being is in peril; and many practices face reimbursement challenges that may result in financial instability. The HHS Initiative to Strengthen Primary Health Care (the Initiative) aims to establish a federal foundation for the provision of primary health care for all that supports improved health outcomes and advanced health equity. The first task is to develop an initial HHS plan for strengthening primary health care that will delineate specific actions that HHS agencies and offices may take to achieve the aims, within the current legislation and funding environment. In addition, the plan will include actions that establish an infrastructure in HHS to continue its focus on strengthening primary health, developing subsequent HHS plans that build on the initial plan, and monitoring progress and impact. The purpose of this RFI is to provide OASH with diverse perspectives, experiences, and knowledge that may inform the development of the initial plan for HHS, as well as future steps for the Initiative. OASH seeks information about successful approaches and innovations that improve primary health care payment, delivery models, service integration, access, workforce education, training and well-being, digital health and primary care measurement and research. OASH also seeks information about barriers to implementation of such innovations and how they could be overcome, including specific ideas for possible HHS action. OASH encourages respondents to address health equity, and is particularly interested in information from community-based settings, such as public housing, personal homes, group homes, and assisted living facilities where older adults and people with disabilities may live, and about populations traditionally underserved by current primary health care.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than 11:59 p.m. Eastern Time (ET) on August 1, 2022. HHS will not reply individually to responders but will consider all comments submitted by the deadline.

ADDRESSES: Please submit all responses via email to *OASHPrimaryHealthCare@hhs.gov* as a Word document attachment or in the body of an email. Include ''Primary Health Care RFI'' in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: For additional information, direct questions to the OASH Primary Health Care Team at *OASHPrimaryHealthCare@hhs.gov* or Sarah Boateng at (202) 401–7003.

SUPPLEMENTARY INFORMATION:

Instructions: Response to this RFI is voluntary. Each responding entity (person or organization) is requested to submit only one response. OASH welcomes responses to inform policies and actions to strengthen primary health care. Respond to one or as many prompts as you choose. Be concise with your submissions, which must not exceed four pages in 12-point or larger font, with a page number provided on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OASH invites input from members of the public representing all backgrounds and perspectives. In particular, OASH is interested in input from individuals; paid and unpaid caregivers; communities; community-based organizations; health care providers (please state discipline and specialty, as appropriate); professional societies; community health centers and Rural Health Clinics; state, local, tribal, and territorial governments and public