

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.

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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.

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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