ACF to fulfill the ongoing legislative mandate for program evaluation specified in the Foster Care Independence Act of 1999.

Respondents: Semi-structured interviews will be held with program leaders, partners and stakeholders, and front-line staff as well as young adults being served by the programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Outreach email for discussion with program administrators and staff	16	8	1	8	64
Outreach email for Focus Group Recruiters	12	6	1	8	48
Discussion Guide for program leaders	48	24	4	1	96
Discussion Guide for program partners and stakeholders	60	30	2	1	60
Discussion Guide for program front-line staff	104	52	1	1	52
Focus Group Guide for program participants	160	80	1	2	160
Compilation and Submission of Administrative Data Files	48	24	2	12	576

Estimated Total Annual Burden Hours: 1,056.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–25548 Filed 11–21–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

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 vouchers as well as the approval of products redeeming a voucher. FDA has determined that AJOVY (fremanezumab-vfrm), approved September 14, 2018, meets the redemption criteria.

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: 301–796–9858, email: *althea.cuff@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 AJOVY (fremanezumab-vfrm), approved September 14, 2018, 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 *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about AJOVY (fremanezumab-vfrm) go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: November 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25480 Filed 11–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Request for Information; A Notice by the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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

ACTION: Notice.

SUMMARY: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council) requests information from the general public and stakeholders related to efforts and strategies to combat Antibiotic Resistance (AR). Given the evolution of AR and the long-term nature of the problem, the Secretary of Health and Human Services (HHS) tasked the Advisory Council with identifying significant areas that have emerged since the release of the National Action Plan (NAP) for Combatting Antibiotic-Resistant Bacteria (CARB) in 2015. To aid in the process of developing its response to the Secretary's task, the Advisory Council has posted this Request for Information (RFI) to hear from a wide range of stakeholders and sectors relevant to the overall CARB effort. This RFI offers the opportunity for the public, including interested individuals, organizations, associations, industries, and others, to provide their input on new priority