

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](mailto: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](mailto: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]

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#### 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](mailto: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/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about AJOVY (fremanezumab-vfrm) go to the “Drugs@FDA” website at <https://www.fda.gov/drugs>.

[www.accessdata.fda.gov/scripts/cder/daf/](http://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

areas within each of the five goals of the NAP that should be considered by the United States Government (USG) for 2020–2025.

Responses to the RFI must be received by 11:59 p.m. on January 7, 2019 to be considered. The questions in the RFI are available through an online form on the Advisory Council's web page at [www.hhs.gov/ash/carb](http://www.hhs.gov/ash/carb). Individuals unable to submit their answers using the online platform should send an email to [CARB@hhs.gov](mailto:CARB@hhs.gov), indicating "RFI Response" in the subject line, along with the corresponding goal number(s) for which they are responding.

**DATES AND TIMES:** Comments must be received by 11:59 p.m. on January 7, 2019 to be considered.

**ADDRESSES:** Individuals are encouraged to submit their responses through one of the following methods. Utilization of the online form available on [www.hhs.gov/ash/carb](http://www.hhs.gov/ash/carb) is the preferred method of submission. Should you choose to send in your responses via email, please be sure to include "RFI Response" along with the corresponding goal number(s) in the subject line. Responses should not include information of a confidential nature, such as sensitive personal information or proprietary information. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant. Please be aware that your comments will not be posted publicly, however they may be made available to the public, in part or in full, subject to applicable laws and regulations.

- **Online Form:** [www.hhs.gov/ash/carb](http://www.hhs.gov/ash/carb). Online submissions will receive an automatic confirmation acknowledging receipt of your response, but you will not receive individualized feedback on any suggestions.

- **Email:** [CARB@hhs.gov](mailto:CARB@hhs.gov). Please indicate "RFI Response" and the corresponding goal number(s) in the subject line of your email.

- All submissions will receive an electronic confirmation acknowledging receipt of your response, but you will not receive individualized feedback on any suggestions.

**FOR FURTHER INFORMATION CONTACT:** Dr. Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: [CARB@hhs.gov](mailto:CARB@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of Health and Human Services (HHS) to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for CARB and the Action Plan (NAP). The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating AR and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat AR.

**Background:** Antibiotic Resistance (AR) poses a significant threat to our Nation's public health, economy, and national security. The Centers for Disease Control and Prevention (CDC) estimates that every year more than two million people in the United States (U.S.) contract infections that are resistant to antibiotics, and at least 23,000 people die as a result. The United States exceeds \$20 billion in direct health care costs, and loses \$35 billion in indirect costs due to loss of productivity associated with antibiotic-resistant infections. By 2050, drug-resistant bacterial infections worldwide are estimated to result in greater than 10 million deaths yearly and cost up to \$100 trillion in losses to the world economy. Drug-resistant infections also complicate the U.S. medical response to

chemical, biological, radiological, or nuclear emergencies, and the global spread of AR makes our deployed service members particularly vulnerable.

In response to the AR threat, the USG developed the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) in 2014. The Strategy takes a One Health approach to combating antibiotic resistance based on the persistence of AR within our global environment and the recognition that integrated multi-sectoral action is needed to prevent the emergence and spread of AR. In 2015, the U.S. government issued the corresponding National Action Plan (NAP) for CARB, providing a five-year roadmap (2015–2020) to guide the Nation in implementing the following five goals outlined in the Strategy:

1. Slow the emergence of resistant bacteria and prevent the spread of resistant infections;
2. Strengthen national One Health surveillance efforts to combat resistance;
3. Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria;
4. Accelerate basic and applied research and development for new antibiotics and other therapeutics, including vaccines; and
5. Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control and antibiotic research and development.

The U.S. government has made meaningful progress towards these goals; however, since the issuance of the NAP in 2015, the domestic and international landscape has changed with continued unparalleled advancement and innovation in technology and the life sciences. Additional action is needed and opportunities exist to continue this progress beyond 2020. As such, the U.S. Government will issue a second iteration of the NAP that will guide action on AR for the period of 2020–2025. The development of this draft will involve the U.S. Government's careful consideration of progress to date on the current NAP, including barriers to progress in certain areas and new developments across sectors, at home and abroad.

**Request for Information:** To inform the Advisory Council's deliberation on recommended priorities to consider in the USG's process of developing the next NAP (2020–2025), please review the five goals in the current NAP, and provide the following information:

- In the context of the existing five goals, on what new priorities should the

federal government focus in the next NAP for CARB—that are not already included in the current plan—and why are they the most important? Your response can cover a range of priority areas for human, animal, and environmental health, including surveillance, research and development, stewardship practices, infection prevention and control practices, and/or other areas for consideration.

In preparing your response, please be sure to:

- Consider how your response fits into the existing One Health paradigm, and how your proposed priority should be further pursued by the U.S. Government;

- Provide an answer that is feasible and actionable by the U.S. Government;

- Limit your responses to no more than two priorities for each of the five goals (a maximum of 10 can be submitted);

- Summarize your response for each priority area in 250 words or less, including its scientific justification;

- Indicate whether your response is relevant domestically, internationally, or both;

- Indicate the domain(s) to which your response applies—human, animal, and/or environmental health;

- Include citations to support your response (references must be in the form of an active link or citation; we will not accept attachments. Peer-reviewed citations and journal links are highly encouraged).

*Response to this RFI is voluntary. Responders are free to address any or all of the goals listed in the NAP. Please note that the USG will not pay for response preparation or for the use of any information contained in the response. The answers provided in this RFI must not include any confidential or proprietary data. Responses to this notice are not offers and cannot be accepted by the USG to form a binding contract or issue a grant. Please be aware that your comments will not be posted publicly, however, they may be made available to the public, in part or in full, subject to applicable laws and regulations.*

More information can be found at [www.hhs.gov/ash/carb](http://www.hhs.gov/ash/carb).

Dated: November 13, 2018.

**Jomana F. Musmar,**

*Acting Designated Federal Officer,  
Presidential Advisory Council on Combating  
Antibiotic-Resistant Bacteria Committee  
Manager.*

[FR Doc. 2018–25435 Filed 11–21–18; 8:45 am]

**BILLING CODE 4150–44–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of 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:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to [CARB@hhs.gov](mailto:CARB@hhs.gov). Registration information is available on the website <http://www.hhs.gov/ash/carb/> and must be completed by January 23, 2019; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/ash/carb/> on the Meetings page.

**DATES:** The meeting is scheduled to be held on January 30, 2019, from 9:00 a.m. to 5:00 p.m. and January 31, 2019, from 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the Advisory Council at <http://www.hhs.gov/ash/carb/> when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than January 23, 2019; public attendance at the meeting is limited to the available space.

**ADDRESSES:** U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

The meeting can also be accessed through a live webcast on the day of the meeting. For more information, visit <http://www.hhs.gov/ash/carb/>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S.

Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: [CARB@hhs.gov](mailto:CARB@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The public meeting will be dedicated to hosting stakeholders to explore priority areas that have emerged since the original National Action Plan on Combating Antibiotic Resistant Bacteria was launched in 2015. The meeting agenda will be posted on the Advisory Council website at <http://www.hhs.gov/ash/carb/> when it has been finalized. All agenda items are tentative and subject to change.