

product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) 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 ZOKINVY (lonafarnib), manufactured by Eiger BioPharmaceuticals, 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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that ZOKINVY (lonafarnib), manufactured by Eiger BioPharmaceuticals, Inc., meets the criteria for a priority review voucher.

ZOKINVY (lonafarnib) is indicated in patients 12 months of age and older with a body surface area of 0.39 m² and above:

- To reduce the risk of mortality in Hutchinson-Gilford progeria syndrome
- For the treatment of processing-deficient progeroid laminopathies with either:
 - Heterozygous *LMNA* mutation with progerin-like protein accumulation or
 - Homozygous or compound heterozygous *ZMPSTE24* mutations

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/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ZOKINVY (lonafarnib), go to the "Drugs@FDA" website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-27778 Filed 12-16-20; 8:45 am]

BILLING CODE 4164-01-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 (PACCARB). The meeting will be open to the public via webex and teleconference; a pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting via webex/teleconference. Individuals who wish to send in their pre-recorded or written public comments should send an email to CARB@hhs.gov. Registration information is available on the website <http://www.hhs.gov/paccarb> and must be completed by February 8, 2021. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/paccarb> on the Meetings page.

DATES: The meeting is scheduled to be held on February 10, 2021, from 10:00 a.m. to 4:00 p.m. and February 11, 2021, from 10:00 a.m. to 3:30 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 PACCARB at <http://www.hhs.gov/paccarb> when this information becomes available. Pre-registration for attending the meeting is required to be completed no later than February 8, 2021.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: <http://www.hhs.gov/paccarb>.

FOR FURTHER INFORMATION CONTACT:

Jomana Musmar, M.S., Ph.D., 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 L616, Switzer Building, 330 C St. SW, Washington, DC 20201. Phone: 202-746-1512; Email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116-22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the Advisory Council are governed by the provisions of the Federal Advisory Committee Act (FACA), 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 PACCARB shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: The effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The February 10-11, 2021, public meeting will be dedicated to presentations from two new working groups of the PACCARB, one on Inter-Professional Education and another on Antibiotics Access and Use, which were formed in response to a task letter from the Assistant Secretary for Health. The two-day virtual public meeting will also include an update on the impact of COVID-19 on antimicrobial resistance. The meeting agenda will be posted on the PACCARB website at <http://www.hhs.gov/paccarb>.

www.hhs.gov/paccarb when it has been finalized. All agenda items are tentative and subject to change.

Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: <http://www.hhs.gov/paccarb>.

Members of the public will have the opportunity to provide comments prior to the public meeting by emailing CARB@hhs.gov. Public comments should be sent in by midnight February 7, 2021 and should be limited to no more than one page. All public comments received prior to February 7, 2021, will be provided to Advisory Council members and will be acknowledged during the public teleconference.

Dated: December 4, 2020.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2020-27769 Filed 12-16-20; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of Organization, Functions, and Delegations of Authority

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is updating the organizational structure of the Office of Grants in the Office of the Assistant Secretary for Financial Resources (ASFR), which is located within the Office of the Secretary. ASFR is modifying the Office of Grants organizational structure to further improve and streamline its operation and to assume responsibility for maintaining and operating the GrantSolutions System currently aligned to the National Grant Center of Excellence (COE) in the Administration for Children and Families (ACF). The changes proposed affect HHS organizational Chapter AM Section AMU1 and AMU2 and Chapter KP Section KPA.

ADDRESSES: 200 Independence Ave. SW, Washington, DC 20201, (202) 619-0142.

FOR FURTHER INFORMATION CONTACT: Alice Bettencourt, Deputy Assistant Secretary for Grants, Alice.Bettencourt@hhs.gov or (202) 619-0142.

SUPPLEMENTARY INFORMATION:

Chapter AMU, the Office of Grants Section AMU1 and AMU2

The Office of Grants (AMU) organizational structure and responsibilities remain as described in **Federal Register** Document 2019-09459, with two divisional modifications.

1. The Division of Systems (AMU2) is renamed the Division of Information and Solutions. The Division of Information and Solutions is headed by a Director and develops, manages, and operates major, grant-shared services and solution offerings for HHS, as directed by the Secretary of HHS or delegated authority. Organizational units within AMU2 may be adjusted from time to time and as necessary to accommodate new, changing, or discontinued shared services or solution offerings. The Division of Information and Solutions assumes responsibility for operating and maintaining the GrantSolutions system in its current form as well as for future GrantSolutions development efforts. The Division of Information and Solutions will also manage GrantSolutions-related customer relationships and agreements, formerly managed by the National Grant COE in ACF.

2. The Division of Grant Policy, Oversight, and Evaluation (AMU1) is renamed the Division of Policy, Oversight, and Evaluation.

Chapter KP, the Office of the Deputy Associate Secretary for Administration (ODASA) in ACF, Section KPA, National Grants Center of Excellence

ODASA dissolves the National Grant COE, in compliance with OMB Memo Memorandum M-18-24, *Strategies to Reduce Grant Recipient Reporting Burden*, which rescinded all Center of Excellence designations. Responsibility for operating and managing the GrantSolutions system moves to The Office of Grants, Division of Information and Solutions (AMU2).

Dated: December 10, 2020.

Alex M. Azar II,

Secretary, Department of Health & Human Services.

[FR Doc. 2020-27814 Filed 12-16-20; 8:45 am]

BILLING CODE 4150-24-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19).

Date: January 14-15, 2021.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E61, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E61, Rockville, MD 20852, 301-761-3100, ann-marie.brighenti@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 11, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-27780 Filed 12-16-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as