

made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical

utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**State Enforcement Notifications—21 CFR 100.2(d)**

*OMB Control Number 0910-0275—Extension*

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d) .....	1	1	1	10	10

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential

future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: December 9, 2020.  
**Lauren K. Roth,**  
*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-27748 Filed 12-16-20; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-N-0026]

**Issuance of Priority Review Voucher; Rare Pediatric Disease Product**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease

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](mailto: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 m<sup>2</sup> 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](mailto: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](mailto: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>.