

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:

Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 240-402-2507, Fax: 301-847-8533, email: PADAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss the new drug application 214070, for a fixed dose combination of budesonide and albuterol sulfate metered dose inhaler, submitted by AstraZeneca and Bond Avillion 2 Development LP. The proposed indication is as-needed treatment or prevention of bronchoconstriction and for the prevention of exacerbations in patients with asthma 4 years of age and older.

FDA intends to make the meeting's background material and pre-recorded presentations available to the public no later than 2 business days before the meeting. The pre-recorded presentations will be viewed by the committee prior to the meeting and will not be replayed on meeting day. If FDA is unable to post the background material and/or pre-recorded presentations on its website prior to the meeting, the background

material and/or pre-recorded presentations will be made publicly available on FDA's website at the time of the advisory committee meeting. The meeting will include brief summaries of the pre-recorded presentations. The pre-recorded presentations and brief summaries will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 25, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. eastern time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 17, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 18, 2022.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Takyiah Stevenson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-19159 Filed 9-2-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0441]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cardiovascular and Renal Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 26, 2022, from 9 a.m. to 5:15 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0441. The docket will close on October 25, 2022. Submit either electronic or written comments on this public meeting by October 25, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 25, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 25, 2022. Comments received

by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 12, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-0441 for "Cardiovascular and

Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be 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." FDA 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 the 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:

Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-837-7126, Fax: 301-847-8533, email: CRDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-

741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 216951, for the hypoxia inducible factor prolyl hydroxylase inhibitor, daprodustat tablets, submitted by GlaxoSmithKline, LLC, for the treatment of anemia due to chronic kidney disease in adult patients not on dialysis and on dialysis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 12, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 2:10 p.m. and 3:10 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October

3, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 4, 2022.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Yvette Waples (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-19156 Filed 9-2-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1262]

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 VOXZOGO (vosoritide)

manufactured by BioMarin Pharmaceutical, Inc., meets the criteria for receipt of a priority review voucher.

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: 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 VOXZOGO (vosoritide) manufactured by BioMarin Pharmaceutical, Inc., meets the criteria for a priority review voucher. VOXZOGO (vosoritide) is indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses.

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 VOXZOGO (vosoritide), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: August 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-19155 Filed 9-2-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2721-22; DHS Docket No. USCIS-2022-0007]

Implementation of Employment Authorization for Individuals Covered by Deferred Enforced Departure for Liberians

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security.

ACTION: Notice of Employment Authorization for Individuals Covered by Deferred Enforced Departure (DED).

SUMMARY: On June 27, 2022, President Joseph Biden issued a memorandum to the Secretary of State and the Secretary of Homeland Security (Secretary) determining that it was in the foreign policy interest of the United States to defer, through June 30, 2024, the removal of certain Liberian nationals, and individuals having no nationality who last habitually resided in Liberia, who are present in the United States and to provide them with employment authorization documentation. The memorandum directed the Secretary to make provision for immediate allowance of employment authorization for such individuals. This Notice provides information about Deferred Enforced Departure (DED) for certain eligible Liberian nationals, and individuals having no nationality who last habitually resided in Liberia, and provides information on how eligible individuals may apply for DED-based Employment Authorization Documents (EADs) with USCIS. Through this notice, DHS is providing employment authorization, including procedures for obtaining related documentation, for covered individuals through June 30, 2024, and automatically extending the validity of DED-based EADs bearing a Category Code of A-11 and a “Card Expires” date of March 30, 2020, January 10, 2021, or June 30, 2022, through June 30, 2024. Finally, this Notice provides instructions for DED-eligible Liberians, or individuals without nationality who last habitually resided in Liberia, on how to file for travel authorization.

DATES: The extension and expansion of DED and employment authorization for noncitizens covered by DED for Liberians is effective June 27, 2022, through June 30, 2024. Employment authorization and the procedures for obtaining EADs in this Notice apply to any of the following individuals who are not subject to any of the ineligibilities described in President Biden’s memorandum to the Secretaries of State and Homeland Security: noncitizens who are Liberian nationals, or individuals having no nationality who last habitually resided in Liberia, regardless of country of birth, who were covered by DED as of June 30, 2022; as well as to Liberian nationals, or individuals having no nationality who last habitually resided in Liberia, regardless of country of birth, who have been continuously physically present in the United States since May 20, 2017. Liberian nationals, and individuals