Estimated Total Annual Burden Hours: 1,050.

Authority: Sec. 5106, Public Law 111–320, the Child Abuse Prevention and Treatment Act Reauthorization Act of 2010, and titles IV–B and IV–E of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–19228 Filed 9–6–23; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2607]

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 VEOPOZ (pozelimab-bbfg), manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for 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 VEOPOZ (pozelimab-bbfg), approved on August 18, 2023, and manufactured by Regeneron Pharmaceuticals, Inc., meets the criteria for a priority review voucher. VEOPOZ (pozelimab-bbfg) injection is indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

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 VEOPOZ (pozelimab-bbfg), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19287 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1190]

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Sickle Cell Disease

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 Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. On October 31, 2023, the Committee will discuss and make recommendations on biologics license application (BLA) 125787 from Vertex Pharmaceuticals, Inc. for exagamglogene autotemcel (exa-cel). The applicant has requested an indication for the treatment of sickle cell disease in patients 12 years and older with recurrent vaso-occlusive crises. 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 31, 2023, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

The online web conference meeting will be available at the following link on the day of the meeting at *https://youtube.com/live/M90IjjxOdQg.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–1190. The docket will close on October 30, 2023. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 30, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before October 24, 2023, will be provided to the Committee. Comments received after that date and on October 30, 2023, 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–2023–N–1190 for ''Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Sickle Cell Disease, Meeting Date: October 31, 2023.'' 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: Cicely Reese or Marie DeGregorio, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1246, Silver Spring, MD 20993–0002, 301–796–9025, email: *CBERCTGTAC@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 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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On October 31, 2023, the Committee will discuss and make recommendations on BLA 125787 from Vertex Pharmaceuticals, Inc. for exagamglogene autotemcel (exa-cel). The applicant has requested an indication for the treatment of sickle cell disease in patients 12 years and older with recurrent vaso-occlusive crises.

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 and/or video conference meeting 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 and video 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 24, 2023, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 12:35 p.m. and 1:35 p.m. Eastern Time on October 31, 2023. 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, along with the names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on October 16, 2023. 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 6 p.m. Eastern Time on October 18, 2023.

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 Cicely Reece or Marie DeGregorio at *CBERCTGTAC@fda.hhs.gov* (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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this

meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19284 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2607]

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 SOHONOS (palovarotene), manufactured by Ipsen Biopharmaceuticals, Inc., meets the criteria for 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 SOHONOS (palovarotene), approved on August 16, 2023, and manufactured by Ipsen Biopharmaceuticals, Inc., meets the criteria for a priority review voucher. SOHONOS (palovarotene) capsules are indicated for reduction in volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva.

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/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about SOHONOS (palovarotene), go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19289 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–D–3132, FDA–2023–D–3133, and FDA–2023–D–3134]

Modernizing the Food and Drug Administration's Premarket Notification Program; Draft Guidances for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of three draft guidances entitled ''Evidentiary Expectations for 510(k) Implant Devices,'' ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' and ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission.'' FDA is issuing these guidances to improve the predictability, consistency, and transparency of the 510(k) premarket review process. The draft guidances are not final nor are they for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 6, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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 Docket No. FDA–2023–D–3132 for ''Evidentiary Expectations for 510(k) Implant Devices,'' Docket No. FDA–2023–D–3133 for ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' or Docket No. FDA–2023–D–3134 for ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission.'' Received comments 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