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 SKYSONA (elivaldogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the applicant 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 SKYSONA (elivaldogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher. SKYSONA is indicated to slow the progression of neurologic dysfunction in boys 4 to 17 years of age with early active cerebral adrenoleukodystrophy.

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about SKYSONA, go to the Center for Biologics Evaluation and Research Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21851 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on November 10, 2022, from 9 a.m. to 5 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 including information regarding special accommodations due to a disability may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Jarrod Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Jarrod.Collier@fda.hhs.gov,* 240–672–5763, 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 Agency'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 platform. On November 10, 2022, the committee will discuss and make recommendations on the classification of ophthalmic dispensers, which are currently unclassified pre-amendment devices to class I (general controls). This will include a discussion of the known risks and safety/effectiveness concerns and a general classification recommendation for ophthalmic dispensers.

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, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Select 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. Written submissions may be made to the contact person on or before October 20, 2022. Oral presentations from the public will be scheduled on November 10, 2022, between approximately 9:15 a.m. and 10:15 a.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 12, 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 13, 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 Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 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: October 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21831 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0022]

Technical Mapping Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will hold an in-person public meeting with a virtual option on Monday, October 24, 2022, and Tuesday, October 25, 2022. The meeting will be open to the public in-person and via a Microsoft Teams Video Communications link.

DATES: The TMAC will meet on Monday, October 24, 2022, and Tuesday, October 25, 2022, from 8 a.m. to 5 p.m. eastern time (ET). Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held in-person at FEMA Headquarters, 400 C Street SW, Washington, DC 20024, and virtually using the following Microsoft Teams Video Communications link (Monday Link: *https://bit.ly/3qNkBu7*; Tuesday Link: *https://bit.ly/3Lxe2pm*). Members of the public who wish to attend the in-person or virtual meeting must register in advance by sending an email to *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper) by 5 p.m. ET on Thursday, October 20, 2022. For information on services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** caption below as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the **SUPPLEMENTARY INFORMATION** caption below. Associated meeting materials will be available upon request after Monday, October 17, 2022. The draft 2022 TMAC Annual Report Outline will be available for review after Monday, October 17, 2022. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper). Written comments to be considered by the committee at the time of the meeting must be submitted and received by Wednesday, October 19, 2022, 5 p.m. ET identified by Docket ID FEMA–2014–0022, and submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address the email to: *FEMA-TMAC@fema.dhs.gov.* Include the docket number in the subject line of the message. Include name and contact information in the body of the email.
- *Instructions:* All submissions received must include the words ''Federal Emergency Management Agency'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For docket access to read background documents or comments received by the TMAC, go to *http://www.regulations.gov* and search for the Docket ID FEMA–2014–0022.

A public comment period will be held on Monday, October 24, 2022, from 3:30 p.m. to 4 p.m. ET and Tuesday, October 25, 2022, from 11:45 a.m. to 12:15 p.m. ET. The public comment period will not exceed 30 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker by Wednesday, October 19, 2022, 5 p.m. ET.

FEMA is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** caption as soon as possible.

FOR FURTHER INFORMATION CONTACT: Brian Koper, Designated Federal Officer for the TMAC, FEMA, 400 C Street SW, Washington, DC 20024, telephone 202–646–3085, and email *brian.koper@fema.dhs.gov.* The TMAC website is: *https://www.fema.gov/flood-maps/guidance-partners/technical-mapping-advisory-council.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. app.

In accordance with the *Biggert-Waters Flood Insurance Reform Act of 2012,* the TMAC makes recommendations to the FEMA Administrator on: (1) how to improve, in a cost-effective manner, the (a) accuracy, general quality, ease of use, and distribution and dissemination of flood insurance rate maps and risk data; and (b) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States; (2) mapping standards and guidelines for (a) flood insurance rate maps, and (b) data accuracy, data quality, data currency, and data eligibility; (3) how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification; (4) procedures for delegating mapping activities to State and local mapping partners; and (5)(a) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination, and (b) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies. Furthermore, the TMAC is required to submit an annual report to the FEMA Administrator that contains: (1) a description of the activities of the Council; (2) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update Flood Insurance Rate Maps; and (3) a summary of recommendations made by the Council to the FEMA Administrator.

Agenda: The purpose of this meeting is for the TMAC members to discuss and vote on the content of the 2022 TMAC Annual Report Outline. Any related materials will be available upon request prior to the meeting to provide the public an opportunity to review the materials. The full agenda and related meeting materials will be available upon request by Monday, October 17, 2022. To receive a copy of any relevant materials, please send the request to: