for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, 240–402–8054, *ctgtac@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, before coming to the meeting, 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.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Committee will meet in open session on both days to discuss the current regulatory expectations for xenotransplantation products. The discussion topics include human cells that have had ex vivo contact with animal cells, and animal organs and cells for transplantation into human subjects. On June 29, 2022, in the morning, under session 1, the Committee will meet to discuss and make recommendations on human cells that have ex vivo contact with animal cells. In the afternoon under session 2, the Committee will begin to discuss and make recommendations on animal organs and cells for transplantation into human subjects and their associated risks. On June 30, 2022, the Committee will continue to discuss and make recommendations on animal organs and cells for transplantation into human subjects.

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 June 22, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Eastern Time on June 29, 2022, and 1 p.m. and 2 p.m. Eastern Time on June 30, 2022. 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 June 16, 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 June 17, 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 Christina Vert (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: May 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11563 Filed 5–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0895]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (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 Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. This meeting will be held to discuss an Emergency Use Authorization (EUA) request by Novavax for a vaccine to prevent COVID–19 in individuals 18 years of age and older. 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 virtually on June 7, 2022, from 8:30 a.m. to 5 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by June 6, 2022. Comments received on or before June 1, 2022, will be provided to the committee. Comments received after June 1, 2022, and by June 6, 2022, will be taken into consideration by FDA.

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. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/DfdMsAqkneE.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0895. The docket will close on June 6, 2022. Submit either electronic or written comments on this public meeting by June 6, 2022. 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 June 6, 2022. 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 June 1, 2022, will be provided to the committee. Comments received June 1, 2022, and by June 6, 2022, 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–2022–N–0895 for ''Vaccines and Related Biological Products Advisory Committee (VRBPAC); 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., Eastern Time 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 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, September18, 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: Prabhakara Atreya or Sussan Paydar, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–506–4946, via email at *CBERVRBPAC@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: Consistent with FDA's regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the VRBPAC as soon as possible is warranted. This notice could not be published 15 days prior to the date of the meeting due to the need for prompt discussion on an EUA request by Novavax for a vaccine to prevent COVID–19 in individuals 18 years of age and older.

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On June 7, 2022, the committee will meet in open session to discuss an EUA request by Novavax for a vaccine to prevent COVID–19 in individuals 18 years of age and older.

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 at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is 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: On June 7, 2022, from 8:30 a.m. to 5 p.m. Eastern Time, the meeting is open to the public. 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 June 1, 2022, will be provided to the committee. Comments received after June 1, 2022, and by June 6, 2022, will be taken into consideration by FDA. 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 email addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before 6 p.m. ET on June 1, 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 June 3, 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 Prabhakara Atreya or Sussan Paydar (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: May 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11668 Filed 5–26–22; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0887]

TG Therapeutics, Inc.; Withdrawal of Approval of New Drug Application for UKONIQ (Umbralisib Tosylate) Tablets, Equivalent to 200 Milligrams Base

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for UKONIQ (umbralisib tosylate) Tablets, equivalent to (EQ) 200 milligrams (mg) Base, held by TG Therapeutics, Inc., 3020 Carrington Mill Blvd., Morrisville, NC 27560. TG Therapeutics, Inc. (TGT) has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of May 31, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 5, 2021, FDA approved NDA 213176 for UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, for the treatment of adult patients with: (1) Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and (2) relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, for MZL and FL included required postmarketing trials intended to verify the clinical benefit of UKONIQ.

On February 3, 2022, FDA issued a Drug Safety Communication about a possible increased risk of death with UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base. FDA's initial review of data from a phase 3, randomized, controlled clinical trial in patients with chronic lymphocytic leukemia (CLL) who were administered UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, in combination with a monoclonal antibody drug compared to the control arm showed a possible increased risk of death in patients receiving the combination of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, and the monoclonal antibody (UNITY–CLL trial). Those patients receiving the combination also experienced more serious adverse events than those in the control arm. FDA considered the data from the UNITY–CLL trial conducted in patients with CLL to have implications for UKONIQ's approved uses for MZL and FL.

On March 10, 2022 (87 FR 13736), FDA published the **Federal Register** notice ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments,'' announcing that UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, would be discussed at an Oncologic Drugs Advisory Committee (ODAC) meeting scheduled for April 22, 2022.

FDA met with TGT on April 14, 2022, to discuss voluntary withdrawal of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, pursuant to § 314.150(d) (21 CFR 314.150(d)) due to the decrement in overall survival and increased serious adverse events observed with UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, in the UNITY–CLL trial. FDA recommended the applicant voluntarily request withdrawal of approval of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, for the follicular lymphoma and marginal zone lymphoma indications pursuant to § 314.150(d) and requested TGT waive its opportunity for a hearing.

On April 15, 2022, TGT submitted a letter asking FDA to withdraw approval of NDA 213176 for UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, pursuant to § 314.150(d) and waiving its opportunity for a hearing. On April 18, 2022, FDA acknowledged TGT's request for withdrawal of approval of the NDA and waiver of its opportunity for a hearing. FDA also cancelled the ODAC meeting scheduled for April 22, 2022, because the meeting was unnecessary considering the applicant's withdrawal request.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 213176 for UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of UKONIQ (umbralisib tosylate) Tablets, EQ 200 mg base, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: May 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11631 Filed 5–27–22; 8:45 am]

BILLING CODE 4164–01–P