manufactured by Vertex Pharmaceutical, Inc., meets the criteria for a priority review voucher.

TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) is indicated for the treatment of patients with cystic fibrosis aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator gene.

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 TRIKAFTA (elexacaftor/tezacaftor/ivacaftor), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/*.

Dated: September 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20320 Filed 9–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2936]

Recognition and Withdrawal of Voluntary Consensus Standards; Guidance 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 a final guidance entitled ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' This guidance identifies the principles FDA uses for recognizing a standard, and it explains the extent of recognition and other supplementary information. It provides information on how you may request recognition as well as circumstances under which FDA may withdraw recognition. This guidance also responds to a provision of the 21st Century Cures Act (Cures Act) by updating published guidance on these topics.

DATES: The announcement of the guidance is published in the **Federal Register** on September 15, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 the Docket No. FDA–2018–D–2936 for ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' 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 between 9 a.m. and 4 p.m., Monday through Friday.

- 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.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993–0002, 301–796–6287 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's standards recognition program furthers the aim of international harmonization because the same standards (or international equivalents) are relied upon by sponsors to meet other countries' regulatory requirements when appropriate. This guidance describes the procedures that FDA follows and the actions FDA may take to recognize and withdraw recognition from voluntary consensus standards. This guidance provides further clarity and explanation about the regulatory framework, policies, and practices when evaluating requests for recognition. This guidance also responds to section 3053 of the Cures Act by updating published guidance on these topics (Pub. L. 114–255).

FDA generally considers for recognition voluntary consensus standards, which are created by standards development organizations that follow a consensus process. A document issued by the Office of Management and Budget (OMB) entitled ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' commonly called OMB Circular A–119, defines the attributes or elements of a consensus process (Ref. 1). This guidance explains those elements and how they pertain to FDA's consideration of a standard for recognition.

The guidance describes the process leading up to and including recognition. We list common purposes to recognize voluntary consensus standards as well as the essential information that FDA will provide in the supplemental information sheet for the recognition of a standard. This guidance also discusses when FDA may withdraw recognition.

Any interested party may also request that FDA recognize a specific voluntary consensus standard. This guidance recommends the information that should be included in a request for recognition of a standard, and it summarizes the actions we may take to act on such a request.

A notice of availability of the draft guidance appeared in the **Federal Register** of September 14, 2018 (83 FR 46740). FDA considered comments received and revised the guidance as appropriate in response to the comments, including specifying that FDA will provide the rationale for complete and partial recognition and describing considerations for determining the timing of a transition period between versions of standards. This guidance supersedes the guidance ''CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition,'' issued on September 17, 2007.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*. Persons unable to download an electronic copy of ''Recognition and Withdrawal of Voluntary Consensus Standards; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 616 and full title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA guidance have been approved by OMB control number 0910–0120.

Dated: September 3, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–20308 Filed 9–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1861]

Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2017 Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2017 (GDUFA). At the end of September 2022, new legislation will be required for FDA to continue collecting generic drug user fees for subsequent fiscal years for the generic drug program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by October 8, 2020. Stakeholder meetings will be held monthly, and it is anticipated that they will commence in October 2020.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to *GenericDrugPolicy@fda.hhs.gov*. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.