experts, functional areas, and collective regulatory experience across different offices.

II. Objectives of QM CoE

The QM CoE will facilitate and coordinate the continuous evolution and consistent application of QM for drug development and regulatory decision-making to advance therapeutic medical product development, inform regulatory decision-making, and promote public health, by:

- spearheading QM-related policy development and best practices to facilitate the consistent use of QM approaches during the drug development and regulatory assessment;
- providing strategic direction for CDER's QM activities; and
- coordinating CDER's efforts around QM education, training, and community engagement.

III. Anticipated Outcomes of QM CoE

The QM CoE will harmonize existing activities and identify and initiate new activities in the areas of multidisciplinary education and exchange, science policy development and implementation, knowledge management, and community engagement. The centralization of QM efforts across CDER within the CoE will allow for operational optimization and consistent application of QM approaches to advance therapeutic medical product development, inform regulatory decision-making, and promote public health.

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22580 Filed 10–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2314]

Determination That AUGMENTIN XR (Amoxicillin; Clavulanate Potassium) Extended-Release Tablets, 1 Gram; Equivalent to 62.5 Milligram Base, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gram (gm); equivalent to (EQ) 62.5 milligram (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AUGMENTIN (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, is the subject of NDA 050785, held by US Antibiotics, LLC, and initially approved on September 25, 2002. AUGMENTIN XR is indicated for treatment of adults and pediatric patients with community-acquired pneumonia or acute bacterial sinusitis due to confirmed, or suspected beta-lactamase-producing pathogens (*i.e.,* H. influenzae, M. catarrhalis, H. parainfluenzae, K. pneumoniae, or methicillin-susceptible S. aureus) and S. pneumoniae with reduced susceptibility to penicillin (*i.e.,* penicillin minimum inhibitory concentrations EQ 2 microgram/milliliter).

AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Aurobindo Pharma, USA, Inc. submitted a citizen petition dated May 9, 2024 (Docket No. FDA–2024–P–2314), under 21 CFR 10.30, requesting that the Agency determine whether AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AUGMENTIN XR (amoxicillin; clavulanate potassium) Extended-Release Tablets, 1 gm; EQ 62.5 mg base, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been

discontinued from marketing for reasons other than safety or effectiveness. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22572 Filed 10–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4422]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 210934 for Sotagliflozin Oral Tablet

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 Endocrinologic and Metabolic Drugs Advisory Committee (the 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 31, 2024, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation, 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–2024–N–4422. The docket will close on October 30, 2024. 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, 2024. 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 17, 2024, 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–2024–N–4422 for ''Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 210934 for Sotagliflozin Oral Tablet.'' 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 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.