Dated: June 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12249 Filed 6–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–0120]

Determination That BUSPAR (Buspirone Hydrochloride) Capsules, 5 Milligrams, 7.5 Milligrams, 10 Milligrams, and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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has determined that BUSPAR (buspirone hydrochloride) capsules, 5 milligrams (mg), 7.5 mg, 10 mg, and 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA) for buspirone hydrochloride capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 240–402–4318, *Caitlin.Callahan@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, are the subject of NDA 021190, held by Bristol Myers Squibb Co., and initially approved on December 20, 2000. BUSPAR is indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety.

In correspondence dated December 28, 2012, Bristol Myers Squibb Co. requested withdrawal of NDA 021190 for BUSPAR (buspirone hydrochloride). In the **Federal Register** of December 5, 2014 (79 FR 72186), FDA announced that it was withdrawing approval of NDA 021190, effective January 5, 2015.

Epic Pharma, LLC submitted a citizen petition dated January 10, 2023 (Docket No. FDA–2023–P–0120), under 21 CFR 10.30, requesting that the Agency determine whether BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were 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 BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.[1]

Accordingly, the Agency will continue to list BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, 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. ANDAs that refer to BUSPAR (buspirone hydrochloride) capsules, 5 mg, 7.5 mg, 10 mg, and 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. 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: June 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12247 Filed 6–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2136]

Advisory Committee; Antimicrobial Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Antimicrobial Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Antimicrobial Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 7, 2024, expiration date.

[1] FDA previously determined that BUSPAR (buspirone hydrochloride) tablets, 5 mg, 10 mg, 15 mg, and 30 mg, approved under NDA 018731 and held by Bristol Myers Squibb Co. Pharmaceutical Research Institute, were not withdrawn from sale for reasons of safety or effectiveness. See 75 FR 64310 (October 19, 2010), 81 FR 61220 (September 6, 2016).

DATES: Authority for the Antimicrobial Drugs Advisory Committee will expire on October 7, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: She-Chia Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–5343, *AMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Antimicrobial Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/antimicrobial-drugs-advisory-committee-formerly-known-anti-infective-drugs-advisory-committee/antimicrobial-drugs-advisory-committee-formerly-known-anti-infective-drugs-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: June 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12288 Filed 6–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1189]

Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions related to FDA's regulation on importation of prescription drugs.

DATES: Either electronic or written comments on the collection of information must be submitted by August 7, 2023.

ADDRESSES: You may submit comments as follows. 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 August 7, 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.

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–1189 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Importation of Prescription Drugs.'' 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