Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–348–3035.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

CORDARONE (amiodarone hydrochloride) tablets, 200 mg, are the subject of NDA 018972, held by Wyeth Pharmaceuticals, Inc. (a subsidiary of Pfizer, Inc.), and initially approved on December 24, 1985. CORDARONE is indicated for the treatment of the following documented, life-threatening recurrent ventricular arrhythmias when these have not responded to documented adequate doses of other available antiarrhythmics or when alternative agents could not be tolerated: (1) Recurrent ventricular fibrillation and (2) recurrent hemodynamically unstable ventricular tachycardia.

In correspondence dated February 7, 2017, Pfizer, Inc. notified FDA that CORDARONE (amiodarone hydrochloride) tablets, 200 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated January 25, 2017 (Docket No. FDA–2017–P–0495), under 21 CFR 10.30, requesting that the Agency determine whether CORDARONE (amiodarone hydrochloride) tablets, 200 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 CORDARONE (amiodarone hydrochloride) tablets, 200 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CORDARONE (amiodarone hydrochloride) tablets, 200 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CORDARONE (amiodarone hydrochloride) tablets, 200 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.

Accordingly, the Agency will continue to list CORDARONE (amiodarone hydrochloride) tablets, 200 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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: August 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–17302 Filed 8–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3966]

Upsher-Smith Laboratories, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for ZALEPLON

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of an abbreviated new drug application (ANDA) for ZALEPLON Capsules, 5 milligrams (mg) and 10 mg, held by Upsher-Smith Laboratories, Inc. (Upsher-Smith), 6701 Evenstad Dr., Maple Grove, MN 55369. Upsher-Smith has voluntarily requested that approval of this application be withdrawn, and has waived its opportunity for a hearing.

DATES: Effective August 16, 2017.

FOR FURTHER INFORMATION CONTACT: Stefanie Kraus, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6215, Silver Spring, MD 20993–0002, 301–796–9585.

SUPPLEMENTARY INFORMATION: On June 6, 2008, FDA approved ANDA 078706 for ZALEPLON Capsules, 5 mg and 10 mg, submitted by Upsher-Smith. According to annual reports Upsher-Smith filed with the Agency, Upsher-Smith stopped distributing these products by April 6, 2010. In a letter dated August 9, 2011, FDA informed Upsher-Smith that it had concerns about the validity of bioequivalence data submitted with ANDA 078706 from studies conducted by a certain contract research organization, establishing bioequivalence of Upsher-Smith's product to the reference listed drug, SONATA (ZALEPLON) Capsules, 5 mg and 10 mg. In that letter, FDA directed Upsher-Smith to supplement its ANDA with either: (1) New bioequivalence studies or (2) re-assays of the samples from the original bioequivalence studies. Upsher-Smith did not respond to this letter. FDA then sent another letter to Upsher-Smith on August 19,

2016, requesting that Upsher-Smith provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 078706 under section 314.150(d) (21 CFR 314.150(d)).

In a letter dated September 15, 2016, Upsher-Smith informed FDA that it did not intend to submit the requested bioequivalence data and requested that the Agency withdraw approval of ANDA 078706 for ZALEPLON Capsules under section 314.150(d). In that letter, Upsher-Smith also waived any opportunity for a hearing otherwise provided under section 314.150(a).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and 314.150(d), approval of ANDA 078706, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–17301 Filed 8–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Tick-Borne Disease Working Group; Amendment

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; amendment.

SUMMARY: A notice was published in the **Federal Register** on Monday, July 17, 2017 (Vol. 82, No. 135, pages 32711–32712), to solicit nominations of individuals who are interested in being considered for appointment to the Tick-Borne Disease Working Group (Working Group). The nomination period is scheduled to end close of business on August 16, 2017. The notice is being amended to extend the solicitation period for one week to allow more time for interested individuals to submit nominations.

DATES: The solicitation period has been extended. All nominations are due to be submitted on or before August 23, 2017.

ADDRESSES: All nominations should be sent to: CAPT Richard Henry; Office of the Assistant Secretary for Health; Department of Health and Human Services; 330 C Street SW., Suite L100, Washington, DC 20024. Nomination materials, including attachments, also may be submitted electronically to *tickbornedisease@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: CAPT Richard Henry, Office of the Assistant Secretary for Health; Department of Health and Human Services; Telephone: (202) 795–7615; Email address: *richard.henry@hhs.gov.*

Dated: August 10, 2017.

Donald Wright,

Acting Assistant Secretary for Health.

[FR Doc. 2017–17323 Filed 8–15–17; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to *CARB@hhs.gov.* Registration information is available on the Web site *http://www.hhs.gov/ash/carb/* and must be completed by September 5, 2017; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/ash/carb/* on the Meetings page.

DATES: The meeting is scheduled to be held on September 13, 2017, from 9:00 a.m. to 5:00 p.m. ET, and September 14, 2017, from 9:00 a.m. to 3:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the Web site for the Advisory Council at *http://www.hhs.gov/ash/carb/* when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than September 5, 2017; public attendance at the meeting is limited to the available space.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast on the day of the meeting. For more information, visit *http://www.hhs.gov/ash/carb/.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690–5566; email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research