

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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: AADPAC@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 Agency’s Web site 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: Agenda:

The committees will discuss supplemental new drug application (sNDA) 021306, for BUTRANS (buprenorphine) transdermal system submitted by Purdue Pharma L.P., evaluating BUTRANS in pediatric patients ages 7 through 16 years for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The committees will be asked to discuss the findings of the clinical study of BUTRANS conducted in pediatric patients, and whether they support additional labeling.

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 Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site 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.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the docket (see **ADDRESSES**) on or before August 30, 2017, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:15 a.m. 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 August 22, 2017. 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 August 23, 2017.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 special accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site 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: August 11, 2017.

Anna K. Abram,

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

[FR Doc. 2017-17303 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-P-0495]

Determination That CORDARONE (Amiodarone Hydrochloride) Tablets, 200 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 or Agency) has determined that CORDARONE (amiodarone hydrochloride) tablets, 200 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Center for Drug

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,