

enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://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.

**Agenda:** On May 2, 2013, the committee will discuss, make recommendations and vote on information related to the premarket approval application for the Juvéderm Voluma XC sponsored by Allergan, Inc. Juvéderm Voluma XC is a dermal filler comprised of hyaluronic acid with lidocaine. Juvéderm Voluma XC is indicated for deep (dermal/subcutaneous and/or submuscular/supraperiosteal) implantation to restore lost volume in the mid-face for aesthetic improvement.

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 <http://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 committee. Written submissions may be made to the contact person on or before April 25, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 2, 2013. 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 April 12, 2013. 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 April 16, 2013.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov), 301-796-5966, 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 <http://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: March 12, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-06167 Filed 3-15-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0233]

#### **Impax Laboratories, Inc.; Withdrawal of Approval of Bupropion Hydrochloride Extended-Release Tablets, 300 Milligrams**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of Bupropion Hydrochloride (HCl) Extended-Release Tablets, 300 Milligrams (mg) (Bupropion HCl Extended-Release Tablets 300 mg), under Abbreviated New Drug Application (ANDA) 77-415, held by Impax Laboratories, Inc. (Impax), 30831 Huntwood Ave., Hayward, CA 94544, and marketed under the name BUDEPRION XL. Impax has voluntarily requested that approval for this product be withdrawn and waived its opportunity for a hearing.

**DATES:** Effective March 18, 2013.

**FOR FURTHER INFORMATION CONTACT:** Carolina M. Wirth, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6282, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** FDA approved ANDA 77-415 for Bupropion HCl Extended-Release Tablets 300 mg (marketed under the name BUDEPRION XL) on December 15, 2006 pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)). Bupropion HCl Extended-Release Tablets 300 mg was indicated for the treatment of major depressive disorder. On September 27, 2012, FDA requested that Impax voluntarily withdraw its Bupropion HCl Extended-Release Tablets 300 mg from the market after results of an FDA-sponsored bioequivalence study showed that Impax's Bupropion HCl Extended-Release Tablets 300 mg are not therapeutically equivalent to the 300-mg strength of the reference listed drug. In a letter dated September 30, 2012, Impax requested that FDA withdraw approval of the 300-mg strength of Bupropion HCl Extended Release Tablets, approved under ANDA 77-415, pursuant to § 314.150(d) (21 CFR 314.150(d)). In that letter, Impax also waived its opportunity for a hearing. The Agency acknowledged Impax's requests in a letter dated November 2, 2012.

Therefore, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the 300-mg strength of Bupropion HCl Extended-Release Tablets under ANDA 77-415 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: March 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-06144 Filed 3-15-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

**Indian Health Professions Preparatory, Indian Health Professions Pre-graduate, and Indian Health Professions Scholarship Programs**

*Announcement Type:* Initial.