DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 1, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Kalyani Bhatt, 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: *PDAC@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 *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: The committee will discuss the efficacy and safety data for new drug application (NDA) 21164, gepirone hydrochloride extended-release tablets, submitted by Fabre-Kramer Pharmaceuticals, Inc., for the proposed indication of major depressive disorder.

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 November 23, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 November 13, 2015. 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 November 16, 2015.

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 accommodations due to a disability, please contact Kalyani Bhatt 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: September 2, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–22593 Filed 9–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–P–0248]

Determination That GLUCAGON (Glucagon Hydrochloride) for Injection, Equivalent to 1 Milligram Base/Vial and Equivalent to 10 Milligram Base/Vial, 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) has determined that GLUCAGON (glucagon hydrochloride) for injection, equivalent to (EQ) 1 milligram (mg) base/vial and EQ 10 mg base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for glucagon hydrochloride for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993, 240–402–0979.

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.

GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, is the subject of NDA 12–122 held by Eli Lilly, and initially approved onNovember 14, 1960. GLUCAGON is indicated for treatment of severe hypoglycemia and as a diagnostic aid in the radiologic examination of the stomach, duodenum, small bowel, and colon.

Under NDA 12–122, GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was produced from animal sources. On September 11, 1998, FDA approved Eli Lilly's NDA 20–928 for GLUCAGON (glucagon rDNA origin), 1mg/vial. Subsequently, Eli Lilly discontinued sales of animal-sourced GLUCAGON in 2002. In 2005, FDA moved animal-sourced GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, to the ''Discontinued Drug Product List'' section of the Orange Book.

Walter G. Jump, on behalf of Cornerstone Regulatory, submitted a citizen petition dated August 7, 2007 (Docket No. FDA–2007–P–0248), under 21 CFR 10.30, requesting that the Agency determine whether animal-sourced GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition, reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal from sale of GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, 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 GLUCAGON (glucagon hydrochloride) for injection, EQ 1 mg base/vial and EQ 10 mg base/vial, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. However, it is the Agency's view that it would be challenging for a prospective applicant to provide adequate data to meet the statutory requirements for an ANDA that relies on NDA 12–122 for GLUCAGON (glucagon hydrochloride) for injection in the absence of comparative data with the animal-sourced glucagon approved in NDA 12–122.

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22673 Filed 9–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1039]

Nonclinical Evaluation of Endocrine-Related Drug Toxicity; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Endocrine-Related Drug Toxicity.'' The purpose of this guidance is to clarify when additional studies are warranted after the standard toxicology tests have been conducted and there is a signal for potential adverse endocrine-related toxicity. This guidance finalizes the draft guidance entitled ''Endocrine Disruption Potential of Drugs: Nonclinical Evaluation'' issued on September 20, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Abby Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 22, Rm. 6474, Silver Spring, MD 20993–0002, 301–796–0174.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Evaluation of Endocrine-Related Drug Toxicity.'' This guidance focuses on nonclinical testing designed to assess the potential for a drug to cause endocrine effects that are