INVEGA (paliperidone) extended-release tablet, 12 mg, was discontinued 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at this time, FDA has determined under § 314.161 that INVEGA (paliperidone) extended-release tablet, 12 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that INVEGA (paliperidone) extended-release tablet, 12 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of INVEGA (paliperidone) extended-release tablet, 12 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events to determine whether INVEGA (paliperidone) extended-release tablet, 12 mg, was withdrawn for reasons of safety or effectiveness. We have reviewed the available information and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list INVEGA (paliperidone) extended-release tablet, 12 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 INVEGA (paliperidone) extended-release tablet, 12 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.


Leslie Kux,
Assistant Commissioner for Policy.

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except for those substances which have been traditionally regarded as foods, whose significant function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed. We also consider dehydrated onion and garlic and other dehydrated vegetables used as seasoning to be spices.

The specific microbial hazards and filth in spices that we consider in the draft risk profile include those pathogen and filth adulterants detected in spices, implicated in outbreaks, reported as the reason for recalls, and reported in submissions to the Reportable Food Registry (RFR) (Ref. 3). The draft risk profile focuses on Salmonella, among the pathogens detected in spices, because it is the only spice-associated pathogen linked with human illness, food recalls, and RFR reports in the United States.

We invite comments that can help improve: (1) The data and information used; (2) the analytical analyses employed; and (3) the clarity and the transparency of the draft risk profile.

II. Comments

Interested persons may submit either electronic comments regarding the draft risk profile to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the draft risk profile at either [Ref. 3]. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at http://www.regulations.gov.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at http://www.regulations.gov. (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)


Leslie Kux,
Assistant Commissioner for Policy.


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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Allergenic Products 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: Allergenic Products 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 11, 2013, from 9 a.m. to approximately 3:30 p.m. and on December 12, 2013, from 8:30 a.m. to approximately 2:45 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 31.

For those unable to attend in person, the meeting will also be Webcast. The link for the Webcast is available at: https://collaboration.fda.gov/apac.

Contact Person: Donald W. Juhn or Joanne Lipkind, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, 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: On December 11, 2013, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of Oralair; a sweet vernal, orchard, perennial rye, Timothy, and Kentucky bluegrass mixed pollens allergen extract tablet for sublingual use, manufactured by Stallergenes. On December 12, 2013, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of Grastek, a Timothy grass pollen allergen extract tablet for sublingual use, manufactured by Merck.

FDA intends to make background material available to the public no later than 2 business days prior to 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 December 4, 2013. Oral presentations from the public will be scheduled between approximately 12 p.m. and 12:30 p.m. on December 11, 2013, and between approximately 11:10 a.m. and 11:40 a.m. on December 12, 2013. Those individuals interested in making oral presentations should [Ref. 6].