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at this time, FDA has determined under § 314.161 that INVEGA (paliperidone) extended-release tablet, 12 mg, was not withdrawn for reasons of safety or effectiveness.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has identified no data or other information suggesting that INVEGA (paliperidone) extended-release tablet, 12 mg, was withdrawn for reasons of safety or effectiveness.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possible postmarketing adverse events to determine whether INVEGA (paliperidone) extended-release tablet, 12 mg, was withdrawn for reasons of safety or effectiveness. We have reviewed the available information and determined that the product was not withdrawn from sale for reasons of safety or effectiveness.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.

Dated: October 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26283 Filed 11–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1204]

Draft Risk Profile on Pathogens and Filth in Spices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft risk profile entitled ''FDA Draft Risk Profile: Pathogens and Filth in Spices'' (draft risk profile). Our main objectives were to: Describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice; describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States; identify potential additional mitigation or control options designed to reduce the public health risk posed by the consumption of contaminated spices in the United States; and identify data gaps and research needs. The draft risk profile is intended to provide information for FDA risk managers to use in regulatory decision making related to the safety of spices in the U.S. food supply. The information may also be useful to stakeholders and interested parties such as spice producers and importers, spice and food manufacturers, retail food establishments, and consumers.

DATES: Submit either electronic or written comments on the draft risk profile by January 3, 2014.

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

FOR FURTHER INFORMATION CONTACT: Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2927.

SUPPLEMENTARY INFORMATION:

I. Background

In response to recent outbreaks in the United States of human illness associated with consumption of certain spices, as well as other reports in the literature and within FDA suggesting that current pathogen control measures in spices may not adequately protect public health, we developed a draft risk profile on pathogens and filth in spices (Ref. 1). We initiated the draft risk profile in response to a large outbreak of *Salmonella* Rissen infections in 2008 to 2009 associated with the consumption of ground white pepper in the United States (id.). Subsequently, in 2009 to 2010, the United States had a larger outbreak of *Salmonella* Montevideo infections associated with consumption of products containing black and red pepper (id.). The objectives of the draft risk profile are to: (1) Describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice; (2) describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States; (3) identify potential additional mitigation and control options; and (4) identify data gaps and research needs.

Specific risk management questions that are addressed include:

- What is known about the frequency and levels of pathogen and/or filth contamination of spices throughout the food supply chain (e.g., on the farm, at primary processing/manufacturing, at intermediary processing (where spices are used as ingredients in multi-component products), at distribution (including importation), at retail sale/use, and at the consumer's home)?
- What is known about the differences in production and contamination of imported and domestic spices?
- What is known about the effectiveness and practicality of currently available and potential future mitigations and control options to prevent human illnesses associated with contaminated spices (e.g., practices and/or technologies to reduce or prevent contamination, surveillance, inspection, import strategies, or guidance)?
- What are the highest priority research needs related to prevention or reduction of contamination of spices with pathogens or filth?

The draft risk profile has undergone an independent external peer review, and our response to the peer review is available electronically on the FDA Web site (Ref. 2).

For the purpose of the draft risk profile, we consider ''spice'' to mean any dried aromatic vegetable substances in the whole, broken, or ground form,

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 (*http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367337.pdf*) or *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.**)

1. U.S. Food and Drug Administration (2013). ''FDA Draft Risk Profile: Pathogens and Filth in Spices.'' Accessible at *http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367337.pdf.*
2. U.S. Food and Drug Administration (2013). ''FDA Draft Risk Profile: Pathogens and Filth in Spices: Peer Review Report: External Peer Review Comments and FDA Responses.'' Accessible at *http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM367338.pdf.*
3. U.S. Food and Drug Administration (2013). Reportable Food Registry Annual Report. Accessible at *http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm.*

Dated: October 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26119 Filed 10–30–13; 4:15 pm]

BILLING CODE 4160–01–P

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 1.

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. Jehn 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 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 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 formal oral presentations should