testing results and behaviors and sexual activities. Focus group discussions and in-depth interviews will be used to examine experiences of participants in the RCT.

The duration of the eligibility screener is estimated to be 5 minutes; the study registration process 5 minutes; the baseline survey 15 minutes; the reporting of home-test results 5 minutes; the follow-up surveys 10 minutes; the focus group discussion 1 hour and 30 minutes; and the in-depth interviews 1 hour and 15 minutes.

There is no cost to participants other than their time.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response	Total response burden (hours)
Prospective Participant	Eligibility Screener	24,000	1	3/60	1,200
Enrolled participant	Study Registration	14,000	1	5/60	1,167
Enrolled participant	Baseline Survey for RCT	3,200	1	15/60	800
Enrolled participant	Baseline Survey for HIV-positive group.	300	1	15/60	75
Enrolled participant	Reporting of Home-test Results during study.	1,600	3	5/60	400
Enrolled participant	Follow-up Surveys for RCT	3,200	4	10/60	2,133
Enrolled participant	Follow-up Surveys for HIV positive group.	300	2	10/60	100
Enrolled participants	Reporting of Home-test Results at completion of study.	3,200	1	5/60	267
Enrolled participant	Focus group discussion	216	1	1.5	324
Enrolled participant	Individual in-depth interview guide	30	1	1.5	45
Total					6,511

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–26277 Filed 11–1–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–0775]

Determination That INVEGA (Paliperidone) Extended-Release Tablet, 12 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA) has determined that INVEGA (paliperidone) extended-release tablet, 12 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for paliperidone extended-release tablet, 12 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–3977.

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.

INVEGA (paliperidone) extended-release tablet, 12 mg, is the subject of NDA 21–999, held by Janssen Pharmaceuticals, Inc., and initially approved on December 19, 2006. INVEGA extended-release tablets are indicated for the treatment of schizophrenia and the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants.

Janssen Pharmaceuticals, Inc., has never marketed INVEGA (paliperidone) extended-release tablet, 12 mg. In previous instances (see, e.g., 72 FR 9763, 61 FR 25497), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. The other strengths of INVEGA (paliperidone) that are approved under NDA 21–999 are being marketed.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated June 25, 2013 (Docket No. FDA–2013–P–0775), under 21 CFR 10.30, requesting that the Agency determine whether

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,