Web site at: *http://innovation.cms.gov/initiatives/index.html.* Paper copies can be obtained by writing to Steven Johnson at the address listed in the **ADDRESSES** section of this notice.

II. Collection of Information Requirements

The information collection requirements associated with this notice are subject to the Paperwork Reduction Act of 1995; however, the information collection requirements are currently approved under the information collection request associated with OMB control number 0938–0880 entitled ''Medicare Waiver Demonstration Applicant.'' Applicants must submit the Medicare Waiver Demonstration Application to be considered for this program.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 20, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–02062 Filed 1–31–14; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0053]

Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (''FDA'' or ''we'') is announcing the opening of a docket to obtain comments and scientific data and information that will help us to implement the section of the FDA Food Safety Modernization Act (FSMA) that requires FDA to designate high-risk foods. We are providing an opportunity for interested parties to submit comments and scientific data and information that will help us develop our process for implementing this provision.

DATES: Submit electronic or written comments and scientific data and information by April 7, 2014.

ADDRESSES: You may submit comments and scientific data and information, identified by Docket No. FDA–2014–N–0053, by any of the following methods:

Electronic Submissions

Submit electronic comments and scientific data and information in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments and scientific data and information.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–N–0053 for this notice. All comments and scientific data and information received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments and scientific data and information, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments and scientific data and information received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1914.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA Food Safety Modernization Act Provision Requiring Designation of High-Risk Foods

On January 4, 2011, the President signed the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) into law. Section 204 of FSMA requires, among other things, the designation of high-risk foods. Specifically, section 204(d)(2)(A) of FSMA requires FDA to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health, and to do so not later than 1 year after the date of enactment of FSMA (and thereafter, if necessary). Section 204(d)(2)(B) requires FDA to publish the list of high-risk foods on the Internet Web site of FDA at the time when FDA issues final rules to establish the additional recordkeeping requirements for high-risk foods.

Section 204(d)(2)(A) of FSMA specifically states that the designation of high-risk foods must be based on the: (1) Known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention; (2) likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food; (3) point in the manufacturing process of the food where contamination is most likely to occur; (4) likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination; (5) likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and (6) likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

Through this notice, we are establishing a docket to provide an opportunity for interested parties to provide comments and scientific data and information that will help us refine our draft approach to identifying high-risk foods, as required by section 204(d)(2) of FSMA. Section I.B summarizes our tentative draft approach for the review and evaluation of data to designate high-risk foods. Attached as a reference to this notice is a draft approach document in which we describe the process and methodology we are considering using for designating high-risk foods. After reviewing comments received in response to this notice on the draft approach described here, we plan to further revise the approach as necessary. We also anticipate that the approach will be reviewed by scientific experts (''peer reviewed'').

While section 204(d)(2)(A) of FSMA includes a statutory deadline within 1 year of the enactment of FSMA, FDA is issuing this notice to solicit comments and scientific data and information that will help us refine our draft approach to identifying high-risk foods. In section II.B, there are a number of specific

topics on which we think various stakeholders and the public at large could provide valuable comments and scientific data and information to assist us in implementing section 204 of FSMA. We anticipate that this input will be critical to our effective implementation of section 204 of FSMA.

B. Draft Approach To Implement Section 204(d)(2) of FSMA—Designation of High-Risk Foods

Data and information developed to identify the most significant foodborne contaminants, including data and information regarding the number, severity, and related costs of illnesses, may be used as data inputs for the high-risk foods approach, where applicable and appropriate.

The draft approach would use a multicriteria decision analysis approach, similar to that of Anderson et al., 2011 (Ref. 1), to identify those foods which should be designated as high-risk. This approach would use the specific criteria identified in section 204(d)(2)(A) of FSMA and would implement those criteria within a risk model. For each of the food and hazard pairs identified, we would determine a total risk score by the weighted sum of the score for each of the defined criteria. For foods that have multiple risk scores because they appear in the list associated with more than one hazard, we would determine the total score for that food using each of the individual food-hazard pair total risk scores. Inclusion on the high-risk food list would be based on the total risk score for foods or food categories. We describe our draft approach, criteria, and scoring system, and provide examples, in the document entitled ''FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA'' (Ref. 2). Although the analysis would encompass food-hazard pairs, we do not anticipate this to be a food-hazard list but rather a food list. This draft approach may be further refined pending stakeholder input in response to this notice.

II. Request for Comments and Scientific Data and Information

We invite comments on the draft approach outlined in section I.B and the submission of scientific data and information relevant to high-risk food designation. We anticipate that this general input, along with the more specific input we solicit below, will significantly assist the Agency in fulfilling the requirements of section 204 of FSMA. In particular, we invite comment, scientific data, and information on the following topics:

- Considering available data, uncertainty with the data, and the intended methods, what alternative approaches should we consider to identify high-risk foods?
- What additional criteria should we consider, within the bounds of the factors Congress mandated in section 204(d)(2)(A) of FSMA, to develop the list of high-risk foods? For example, in addition to the public health related economic impact of foodborne illnesses, which the draft approach takes into account, should the approach include nonpublic health economic impact factors, such as costs related to disruption in the food supply following a foodborne illness outbreak? If so, how should we determine these costs given the variety of foods and different market values for various foods?
- What changes should we consider making to the scoring system to ensure the range of possibilities for the foods and hazards is comprehensive and to enhance the scoring?
- What changes should we consider making to the approach to better evaluate risk associated with animal food?
- The draft approach would equally weight the criteria. Should individual weights be assigned to each criterion? If so, which criteria should receive more weight and how should those weights be assigned?
- The draft approach would utilize the food categorization scheme used for the Reportable Food Registry (Ref. 3). What other practical alternatives to this food categorization scheme should we consider in light of the practical constraints of evaluating individual commodities?
- Adverse reactions may occur when allergic consumers are exposed to foods that contain undeclared allergens. Undeclared allergens may be present in a food through either mislabeling or cross-contact during processing and handling. Both situations present a risk to allergic consumers because they lead to incomplete or inaccurate product labels. How should food allergens, including the major food allergens defined in the Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108–282, Title II) (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans), be considered in the development of the high-risk food list?

C. Additional Information and Data Requested

We also are interested in the following types of information and data:

- Scientific data and methods that can be used to assess the public health impact of acute or chronic exposures to pathogens and chemical contaminants in human food or animal food. In particular, scientific data and methods related to chronic exposures to chemical contaminants in food.
- For representative foods in each food category or commodity group to be evaluated:
  - A list of the pathogens and chemical contaminants likely to be found in the food;
  - The percentage prevalence of contaminants in the food;
  - The levels of contaminants in the food;
  - The point in the manufacturing process where the contaminants are likely to be introduced in the food; and
  - The typical steps and control measures taken in the manufacturing process to reduce the possibility of contamination of the food with the pathogen or chemical contaminant.

III. Comments

Interested persons may submit either electronic comments and scientific data and information regarding this document 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 and scientific data and information. Identify comments and scientific data and information with the docket number found in brackets in the heading of this document. Received comments and scientific data and information 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.*

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.* (FDA has 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. Anderson, M., Jaykus, L.-A., Beaulieu, S. et al. ''Pathogen-produce pair attribution risk ranking tool to prioritize fresh produce commodity and pathogen combinations for further evaluation (P^{3}ARRT).'' *Food Control* 22, (2011): 1865–1872. 10.1016/j.foodcont.2011.04.028.

2. Food and Drug Administration. ''FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA.'' 2013. Available at *http://www.fda.gov/*

downloads/Food/GuidanceRegulation/FSMA/UCM380212.pdf.

3. Food and Drug Administration. ''U.S. Food and Drug Administration, Reportable Food Summary Report, Definitions.'' Available at *http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM211534.pdf.* Last Modified April 2012.

Dated: January 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02255 Filed 2–3–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Nucleic Acid-based Compositions and Methods for the Species-Specific Detection of Pathogenic Candida Fungi

Description of Technology: This invention pertains to the development of oligonucleotides for the rapid nucleic acid-based identification of the Candida fungi species *C. haemulonii, C. kefyr, C. lambica, C. lusitaniae, C. norvegensis, C. norvegica, C. rugosa, C. utilis, C. viswanathii, C. zeylanoides, C. dubliniensis,* and *C. pelliculosa* within biological samples. This identification is accomplished by targeting the internally transcribed spacer-2 (ITS2) region that is specific for each species. The assay is sensitive, specific and rapid. Implementation of the technology will facilitate earlier specific diagnoses, and lead to better antifungal therapy implementation for infected patients.

Potential Commercial Applications:

- Directing antifungal drug therapy for improved patient outcomes
- Detection, discrimination of Candida species from biological samples
- Addressing secondary infections of immunosuppressed individuals

Competitive Advantages:

- Easily adapted for use in kits
- High-throughput capable
- Rapid and cost-effective

Development Stage: In vitro data available

Inventors: Christine J. Morrison, Errol Reiss, Cheryl M. Elie, Timothy J. Lott (all of CDC)

Publication: Shin JH, et al. Rapid identification of up to three Candida species in a single reaction tube by a 5' exonuclease assay using fluorescent DNA probes. J Clin Microbiol. 1999 Jan;37(1):165–70. [PMID 9854084]

Intellectual Property: HHS Reference No. E–340–2013/0—

- PCT Application No. PCT/US1998/015840 filed 30 Jul 1998, which published as WO 1999/006596 on 11 Feb 1999
- US Patent No. 6,242,178 issued 05 Jun 2001
- Various international issued patents

Related Technologies:

- HHS Reference No. E–293–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–232–2013/0
- HHS Reference No. E–335–2013/0
- HHS Reference No. E–339–2013/0

Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

Nucleic Acid-based Compositions and Methods for the Detection of Pathogenic Candida or Aspergillus Fungi Species

Description of Technology: This invention pertains to the development of oligonucleotides for the rapid nucleic acid-based identification of Candida or Aspergillus fungi species in biological samples. This identification is accomplished by the targeting the internally transcribed spacer-2 (ITS2) region that are unique to various Candida species. The assay is sensitive, specific and rapid. Implementation of the technology will facilitate earlier specific diagnoses, and lead to better antifungal therapy implementation for infected patients.

Potential Commercial Applications:

- Directing antifungal drug therapy for improved patient outcomes
- Detection, discrimination of Candida and Aspergillus species from biological samples
- Addressing secondary infections of immunosuppressed individuals

Competitive Advantages:

- Easily adapted for use in kits
- High-throughput capable
- Rapid and cost-effective

Development Stage: In vitro data available

Inventors: Christine J. Morrison, Errol Reiss, Brian Holloway, Jong Hee Shin (all of CDC)

Publication: Shin JH, et al. Rapid identification of up to three Candida species in a single reaction tube by a 5' exonuclease assay using fluorescent DNA probes. J Clin Microbiol. 1999 Jan;37(1):165–70. [PMID 9854084]

Intellectual Property: HHS Reference No. E–339–2013/0—

- PCT Application No. PCT/US1997/016423 filed 15 Sep 1997, which published as WO 1998/011257 on 19 Mar 1998
- US Patent No. 6,235,890 issued 22 May 2001
- Various international issued patents

Related Technologies:

- HHS Reference No. E–293–2013/0
- HHS Reference No. E–332–2013/0
- HHS Reference No. E–232–2013/0
- HHS Reference No. E–335–2013/0

Licensing Contact: Whitney Blair, J.D. M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

Nucleic Acid Assays for the Detection and Discrimination of Aspergillus Fungi Species within Biological Samples

Description of Technology: This invention relates to assays for the detection and species-specific identification of Aspergillus fungi. Accurate clinical diagnosis of Aspergillus species has become increasingly important as certain species, such as *A. terreus* and *A. fumigatus,* are resistant to specific commonly employed antifungal compounds. Most contemporary fungal diagnostic methods are time-consuming and inaccurate. This invention directly addresses those inadequacies by providing a method to rapidly and accurately differentiate all medically important species of Aspergillus based on differences in the DNA sequences of the internal transcribed spacer 1 region of ribosomal DNA.

Potential Commercial Applications:

- Directing antifungal drug therapy for improved patient outcomes
- Detection, discrimination of Aspergillus species from biological samples
- Addressing secondary infections of immunosuppressed individuals or asthmatics

Competitive Advantages: