

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-0731]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On January 28, 2014, the Agency submitted a proposed collection of information entitled "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0543. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: March 20, 2014.

**Leslie Kux,***Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2014-N-0053]

**Designation of High-Risk Foods for Tracing and for Scientific Data and Information; Extension of Comment Period****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice entitled "Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information" that appeared in the **Federal Register** of February 4, 2014 (79 FR 6596). In the notice, FDA requested comments and scientific data and information that will help us to implement the section of the FDA Food Safety Modernization Act (FSMA) that requires us to designate high-risk foods. FDA is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments on the notice by May 22, 2014.

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

**Electronic Submissions**

Submit electronic comments and information in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments 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 information received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments and information, see the "Request for Comments" heading of the

**SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments 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**

In the **Federal Register** of February 4, 2014 (79 FR 6596), FDA published a notice with a 60-day comment period to request 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 (Pub. L. 111-353). The notice summarized our draft approach for the review and evaluation of data to designate high-risk foods. We invited general comments on the draft approach, along with requests for more specific input on alternative approaches for identifying high-risk foods, whether or not the criteria should be weighted equally, changes in the scoring system, and how foods should be categorized.

FDA has received requests for extension of the comment period for the notice. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.

FDA has considered the requests and is extending the comment period for all interested persons for 45 days, until May 22, 2014. FDA believes that a 45-day extension allows adequate time for interested persons to submit comments.

**II. Request for Comments**

Interested persons may submit either electronic comments 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. 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>.