docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee Amendments of 2012 (MDUFA III), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2012, including PMAs and device BLAs. The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the medical device review process to meet certain performance goals and implement improvements for the medical device review process.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on user fees and refunds for PMAs and device BLAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1681 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

V. 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.*

Dated: March 27, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07577 Filed 4–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1153]

Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice entitled ''Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA To Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food'' that appeared in the **Federal Register** of March 5, 2013 (78 FR 14309). In the notice, FDA requested comments on the findings and recommendations contained in the Institute of Food Technologists (IFT) report to FDA and the submission of information relevant to improving product tracing. The Agency 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 by July 3, 2013.

ADDRESSES: You may submit comments and information, identified by Docket No. FDA–2012–N–1153, 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 way:

- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM 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–2012–N–1153 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 ''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(s), 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 A. McGarry, Office of Foods, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1212, Silver Spring, MD 20903, 301–796–3851.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 5, 2013 (78 FR 14309), FDA published a

notice with a 30-day comment period to request comments on the findings and recommendations contained in the IFT report and the submission of information relevant to improving product tracing. Comments on the findings and recommendations contained in the IFT report and the submission of information relevant to improving product tracing will help FDA as it forms its own recommendations, to be contained in the Agency report to Congress that is required by the FDA Food Safety Modernization Act (FSMA), and as it implements the FSMA provisions relating to the tracking and tracing of food.

The Agency has received requests for a 120-day extension of the comment period for the notice. Each request conveyed concern that the current 30-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 90 days, until July 3, 2013. The Agency believes that a 90-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.*

Dated: March 26, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07580 Filed 4–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0331]

International Consortium of Cardiovascular Registries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''International Consortium of Cardiovascular Registries.'' The purpose of this meeting is to discuss the development of an international consortium of cardiovascular registries with a broad array of interested stakeholders. The initial pilot phase of this effort will be developing relationships and analysis strategies for transcatheter cardiac valve registries, with the understanding that these efforts would be expanded to additional cardiovascular devices in the future.

Date and Time: The meeting will be held on April 22, 2013, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Benjamin Eloff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4210, Silver Spring, MD 20993, 301–796–8528, *Benjamin.eloff@fda.hhs.gov;* or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4110, Silver Spring, MD 20993, 301–796–6689, *Danica.marinac-dabic@fda.hhs.gov.*

Registration: Registration is free and will be on a first-come, first-served basis. Persons interested in attending this public meeting must register online by 5 p.m. on April 11, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 7 a.m.

To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* Select this public meeting from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, mailing address, email address, and telephone number. Those without Internet access should contact Susan Monahan to register (*Susan.Monahan@fda.hhs.gov* or 301–796–5661). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

If you need special accommodations due to a disability, please contact Susan Monahan (*Susan.Monahan@fda.hhs.gov* or 301–796–5661) no later than April 11, 2013.

Streaming Webcast of the Public Meeting: This meeting will also be available via Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on April 11, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after April 16, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public meeting to obtain information on the topics identified in section II. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is May 22, 2013. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please 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