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

will be posted to the docket at *http://www.regulations.gov.*

*Transcripts:* Transcripts will not be provided.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Cardiovascular procedures are performed in hundreds of thousands of patients every year to treat all manner of cardiovascular disease from coronary artery disease to peripheral vascular disease, intracardiac ablation to surgical interventions, implant of stents to implants of pacemakers, defibrillators, and their associated leads. Information obtained from clinical trials is often limited due to small size, short followup, and lack of generalizability. Observational studies and registries have become increasingly important data sources for assessing the performance of cardiovascular therapeutic medical devices in the real-world setting. However, these registries are often limited in scope and size to a specific country, region, or health care provider system.

Developing a comprehensive understanding of the performance of these devices requires not only an indepth analysis across data sources to link device use to clinical outcomes, but also to incorporate data from international experience with these devices and procedures. FDA is holding this workshop to discuss the development of an international consortium of cardiovascular registries that would allow for broad-based analysis and surveillance of medical device exposure and related clinical outcomes. This effort follows on the successful model of the International Consortium of Orthopedic Registries (ICOR), which has developed a framework for distributed analysis across their member registries around the world. The development of a similar consortium of cardiovascular registries will begin with a narrowed scope incorporating transcatheter valve therapy devices and procedures.

At the end of this workshop, FDA intends that the participants and stakeholders will develop a comprehensive plan for the development of an operational international consortium of cardiovascular registries. This plan will identify specific issues that must be addressed and provide a ''roadmap'' for full implementation.

## II. Topics

Topics to be discussed at this meeting include:

- The role of registry consortia in postmarket surveillance,
- Goals of the International Consortium of Cardiovascular Registries,
- Lessons learned from the development of the ICOR,
- Development of an international consortium of transcatheter valve registries as a pilot phase,
- Analysis of near- and long-term outcomes reported through registries, and
- Discussion of capabilities, challenges, and limitations of existing transcatheter valve registries.

Dated: March 27, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013–07579 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–0001]**

### Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee: Notice of Change of Meeting Schedule

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Wednesday, February 27, 2013 (78 FR 13347). The meeting was shortened to one day, as it was later determined that in order to be more financially prudent all three topics could fit into one day.

**FOR FURTHER INFORMATION CONTACT:** Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993–0002, *Sara.Anderson@fda.hhs.gov,* 301–796–7047, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In FR doc. 2013–04543, appearing on page 13347 in the **Federal Register** of Wednesday, February 27, 2013, the following correction is made:

1. On page 13347, in the first column, under the section entitled ''Date and Time'', the date is corrected to be April 25, 2013.

2. On page 13347, in the second column, the section entitled ''Agenda'' is corrected to read as follows:

*Agenda:* On April 25, 2013, the committee will discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as methotrexate enzyme immunoassays. Methotrexate enzyme immunoassays are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Methotrexate enzyme immunoassays are currently regulated under the heading of ''Enzyme Immunoassay, Methotrexate,'' Product Code LAO, as unclassified under the 510(k) premarket notification authority. Methotrexate enzyme immunoassays are for the quantitative determination of methotrexate. The measurements obtained are used in monitoring levels of methotrexate to ensure appropriate drug therapy. FDA is seeking panel input on the safety and effectiveness of methotrexate enzyme immunoassays.

The committee will also discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as phencyclidine (PCP) enzyme immunoassays and PCP radioimmunoassays. PCP enzyme immunoassays and PCP radioimmunoassays are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. PCP enzyme immunoassays are currently regulated under the heading of ''Enzyme Immunoassay, Phencyclidine,'' Product Code LCM, and ''Radioimmunoassay, Phencyclidine,'' Product Code LCL, as unclassified under the 510(k) premarket notification authority. FDA is seeking panel input on the safety and effectiveness of PCP enzyme immunoassays and PCP radioimmunoassays.

The committee will also discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as isoniazid test strips. Isoniazid test strips are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. Isoniazid test strips are currently regulated under the heading of ''Strip, Test Isoniazid,'' Product Code MIG, as unclassified under the 510(k) premarket notification authority. Isoniazid test strips are a qualitative assay used for detecting isonicotinic acid and its metabolites in