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.
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 in depth 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]

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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.