OC201336

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 urine to determine compliance of isoniazid (INH) medication. FDA is seeking panel input on the safety and effectiveness of isoniazid test strips.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

3. On page 13347, in the third column, the section entitled "Procedure" is corrected to read as follows:

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 16, 2013. On April 25, 2013, oral presentations from the public regarding Methotrexate Test Systems will be scheduled between approximately 9:15 a.m. and 9:45 a.m.; regarding phencyclidine (PCP) Test Systems between approximately 1:55 p.m. and 2:25 p.m.; and regarding Isoniazid Test Systems between approximately 4:15 p.m. and 4:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present,

the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 8, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 9, 2013.

Dated: March 27, 2013.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-07568 Filed 04/01/2013 at 8:45 am; Publication Date: 04/02/2013]