## 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 Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 25 and 26, 2013, from 8 a.m. to 6 p.m.

*Location:* Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301–948–8900.

*Contact Person:* 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). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On April 25, 2013, during session I, 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.

On April 25, 2013, during session II, the committee will 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.

On April 26, 2013, the committee will 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.

*Procedure:* 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 will be scheduled between approximately 9:30 a.m. and 10 a.m. for session I and between 2 p.m. and 2:30 p.m. for session II. Oral presentations from the public will be scheduled between 1 p.m. and 2 p.m. on April 26, 2013. 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.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Conference Management Staff, at *James.Clark@fda.hhs.gov* or 301–796–5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013–04543 Filed 2–26–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0001]**

### Oncologic Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on May 2, 2013, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* During the morning session, the committee will discuss new drug application (NDA) 204408, with the established name tivozanib capsules, submitted by AVEO Pharmaceuticals, Inc. The proposed indication (use) for this product is for the treatment of advanced renal (kidney) cell carcinoma.

During the afternoon session, the committee will discuss NDA 201848, a drug/device combination product with the proposed trade name Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), submitted by Delcath Systems, Inc. The proposed indication (use) for this product is for the treatment of patients with unresectable ocular melanoma that is metastatic to the liver.

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.

*Procedure:* 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 18, 2013. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 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 10, 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 11, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *February 22, 2013.*

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013–04542 Filed 2–26–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0001]**

### Science Board to the Food and Drug Administration Advisory Committee; Amendment of Notice

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration. This meeting was announced in the **Federal Register** of January 30, 2013 (78 FR 6332). The amendment is being made to reflect changes in the *Date and Time, Agenda,* and *Procedures* portions of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:** Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4286, Silver Spring, MD 20993, 301–796–4627, 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.