

trial, and the possible consequences of these events?

6. Does the training program need to be validated to ensure that it adequately mitigates such risks, and, if so, how could this be done?

B. Process

Although no statute or regulation requires that separation of functions be applied to this proceeding, the Agency is observing separation of functions as a matter of policy in this matter. As the Center responsible for the action under review, CDRH will be, like EES, a party to the advisory committee meeting and will be responsible for presenting its position at that meeting.

In addition, as a corollary to its decision to observe a separation of functions, until the Commissioner issues an order either affirming or reversing the order denying approval of PMA P080009, the Office of the Commissioner will not engage in any ex parte communication (see 21 CFR 10.3(a)) with anyone participating as a party or any person outside the Agency with respect to the matter under consideration. Any written ex parte communication has been and will continue to be immediately served on the two parties and filed in the docket. Any oral ex parte communication has been and will continue to be immediately memorialized in writing, served on both parties, and filed in the docket.

At the meeting, each party will be provided 2 hours during the first portion of the meeting to present relevant information or views orally. The parties may use the allotted time as desired, consistent with an orderly meeting, and may be accompanied by additional persons, who may present relevant information or views. The parties will subsequently be allowed 15 minutes for rebuttal. During the advisory committee's open discussion, the advisory committee members may pose questions to, or requests for clarification from, EES and/or CDRH. Thereafter, each party will be allocated 15 minutes for summation, after which advisory committee deliberation and voting will occur.

FDA welcomes the public's attendance at this advisory committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you need special accommodations due to a disability, please contact Nancy Braier (see *Contact Person*) 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.

Because this is a public meeting before an advisory committee, it is subject to our regulations concerning the policy and procedures for electronic media coverage of public agency administrative proceedings (§§ 10.200 through 10.206 (21 CFR 10.200 through 10.206)). These procedures are primarily intended to expedite media access to our public proceedings. Representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record our public administrative proceedings, including the testimony of witnesses in the proceedings. Accordingly, the parties and nonparty participants, and all other interested persons, are directed to § 10.200 through 10.206, for a more complete explanation of those regulations' effect on this meeting.

All documents filed or posted in this matter are available for public review under Docket No. FDA-2010-P-0176 in the Division of Dockets Management (see *Registration and Presentations*) between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents at <http://www.regulations.gov>. FDA intends to make background material, including briefing materials for the advisory committee provided by CDRH and EES, available to the public no later than 2 business days before the meeting. If FDA is unable to provide the background material 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 available in the Division of Dockets Management (see *Registration and Presentations*) and at <http://www.regulations.gov> after the meeting.

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

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD.

Dated: November 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0557]

Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice announcing a public meeting for the "Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices" that published in the **Federal Register** of August 8, 2011 (76 FR 48169). In the notice, FDA requested public comments regarding matters to be discussed at the October 13, 2011, meeting, including the performance evaluation of highly multiplexed microbiology/medical countermeasure (MCM) devices, their clinical application and public health/clinical needs, and quality criteria for establishing the accuracy of reference databases. FDA is reopening the comment period to receive comment updates or any new information on the concept paper entitled "Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices," for FDA's proposed evaluation approach for assessing the performance of highly multiplexed microbiology/MCM devices.

DATES: Submit either electronic or written comments and information by December 21, 2011.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Raquel Peat, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5561, Silver Spring,

MD 20993-0002, (301) 796-6218, email: raquel.peat@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 2011, FDA published a notice announcing a public meeting for the “Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices,” and opening of a public docket to seek input and comments from interested stakeholders to discuss the concept paper¹ for FDA’s proposed evaluation approach for assessing the performance of highly multiplexed microbiology/MCM devices, including the following topics:

1. *Clinical Application of Highly Multiplexed Microbiology Devices:* Their clinical application and public health/clinical needs; inclusion of MCM-related pathogens that are expected to be rarely present in the tested specimens; the composition of clinically relevant panels of pathogens; the interpretation of the test results taking into consideration the possible detection of microorganisms that are not clinically relevant, and what is known and unknown about co-infections.

2. *Device Evaluation:* How to evaluate the analytical and clinical performance of highly multiplexed microbiology devices; approaches to device validation when positive specimens are not easily available, which is the case for many MCM pathogens; the sufficiency, feasibility, and practicality of the proposed FDA evaluation approach to establish device performance.

3. *Reference Databases:* Quality criteria for establishing the accuracy of reference databases; methods for curating, maintaining, and updating these databases; what is the current practice for creating and maintaining reference databases.

In the **Federal Register** notice of August 8, 2011, interested persons were originally given until September 13, 2011, to submit comments.

II. Request for Comments

Following publication of the August 8, 2011, **Federal Register** notice and posting of the concept paper, FDA received requests to allow interested persons additional time to comment. The Agency has considered the requests and is reopening the comment period until December 21, 2011.

¹ This concept paper may be found at <http://www.fda.gov/MedicalDevices/NewsEvents/Workshops/Conferences/ucm267410.htm>.

III. How To Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in Section I of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-29937 Filed 11-18-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Gastroenterology and Urology 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: Gastroenterology and Urology 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 January 11, 2012, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel’s telephone number is (301) 977-8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993-0002, Avena.Russell@fda.hhs.gov, (301) 796-3805, or FDA Advisory Committee Information Line, 1-(800) 741-8138 (301) 443-0572 in the Washington, DC

area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 11, 2012, the committee will discuss, make recommendations, and vote on information related to the premarket approval application, sponsored by Torax Medical, Inc., for the LINX Reflux Management System, a sterile, single use, surgically placed device used to treat the symptoms associated with gastroesophageal reflux disease.

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 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 December 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 December 22, 2011. 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 December 23, 2011.