4160-01-P

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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:

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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 paper[1] 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

[1] This concept paper may be found at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267410.htm.

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

## 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.

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