4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1082]

Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices." This guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of highly multiplexed microbiological/medical countermeasure in vitro nucleic acid-based diagnostic devices (HMMDs) intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Hobson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5560, Silver Spring, MD 20993-0002, 301-796-5892.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of HMMDs intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. For the purposes of this guidance document, the multiplex level that is used to define HMMDs is the capability to detect ≥20 different organisms/targets, in a single reaction, using a nucleic acid-based technology and involves testing multiple targets through a common process of specimen preparation, amplification and/or detection, and result interpretation. HMMDs are used to aid in the diagnosis of infection or screening for colonization.

The scope of this guidance includes nucleic acid-based devices that employ technologies such as polymerase chain reaction, reverse-transcriptase polymerase chain reaction, bead-based liquid arrays, microarrays, re-sequencing approaches as well as the measurement of individual targets via a common process of sample preparation, target or signal amplification, allele

discrimination, and collective interpretation, and are reported out simultaneously. This guidance is not intended to address devices that utilize detection mechanisms other than nucleic acid-based approaches. The document does not apply to devices that are intended to screen donors of blood and blood components, and donors of human cells, tissues, and cellular- and tissue-based products for communicable diseases.

The draft of this guidance was issued on November 9, 2012 (77 FR 67379). The comment period closed on February 7, 2013. Two sets of comments were received and reviewed by FDA. The guidance was updated to address comments where appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on HMMDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices" may send an email request to CDRH-

Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1803 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

V. 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: August 21, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014-20291 Filed 08/26/2014 at 8:45 am; Publication Date: 08/27/2014]