Dated: May 10, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–11323 Filed 5–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0971]

Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers.'' This draft guidance provides recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of infectious disease next generation sequencing-based diagnostic devices for microbial identification and detection of antimicrobial resistance and virulence markers. This draft guidance is neither final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 11, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0971 for ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Heike Sichtig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4526, Silver Spring, MD 20993–0002, 301–796–4574.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices'' for microbial identification and detection of antimicrobial resistance and virulence markers (hereinafter referred to as ''Infectious Disease NGS Dx devices''). Infectious Disease NGS Dx devices are intended for use as an aid in the diagnosis of microbial infection and in selecting appropriate therapies for

which next generation sequencing (NGS) technology can now be used to detect the presence of clinically important pathogenic organisms in human specimens.

In contrast to human sequencing diagnostics, infectious disease sequencing diagnostics carry an absolute need for immediate and actionable results, sometimes within hours, as incorrect initial diagnoses potentially leads to fatalities. Furthermore, the broad range of specimen types (*e.g.,* urine, blood, cerebrospinal fluid (CSF), stool, sputum, etc.) and the large diversity of the infectious disease agents that can be present in the sample do not allow straightforward pre-analytical-, biochemical-, or bioinformatics processes. Each unique specimen type may require a different nucleic acid extraction procedure, a different library preparation protocol, and even a different bioinformatics algorithm to generate the final clinical result. The opportunity for repeat testing is expected to be limited due to a frequently small specimen quantity (*e.g.,* CSF) and the necessity to make a prompt and timely infectious disease treatment decision for the patient.

This draft guidance, when finalized, provides detailed information on the types of studies the FDA recommends to support a premarket application for these devices. This draft guidance specifically addresses Infectious Disease NGS devices that employ targeted or agnostic (metagenomic) sequencing, to identify the presence or absence of infectious disease organisms, and/or to detect the presence or absence of antimicrobial resistance and virulence markers. This draft guidance is not intended to address devices that utilize detection mechanisms other than nucleic acid based approaches. Further, this draft guidance does not apply to devices that are intended to screen donors of blood and blood components as well as donors of human cells, tissues, and cellular and tissue-based products for communicable diseases.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers.'' It neither creates nor confers any rights for or on any person and is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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 ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500016 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously 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; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

Dated: May 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11237 Filed 5–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Class Deviations from the Requirements for Competition and Application Period for the Health Center Program.

SUMMARY: In accordance with the Grants Policy and Administration Manual (GPAM) Part F: Chapter 2.b.34 and Part F: Chapter 3.b.16, the Bureau of Primary Health Care (BPHC) has been granted class deviations from the requirements for competition contained in the GPAM Part F: Chapter 2.a.1 and the requirements for application period contained in the GPAM Part F: Chapter 3.b.3 to expeditiously award funds to new health centers to improve access to services and clinical outcomes for the nation's most vulnerable populations through the patient centered medical home model.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Health Center Program award recipients receiving Health Center Program funding for the first time in fiscal years (FYs) 2012, 2013, 2014, and 2015.

Amount of Competitive Awards: Approximately $10 million will be awarded in FY 2016 through a one-time supplement.

Period of Supplemental Funding: Anticipated 12 month project period is August 1, 2016, through July 31, 2017.

CFDA Number: 93.224

Authority: Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

Justification: Targeting the nation's neediest populations and geographic areas, the Health Center Program supports more than 1,300 health centers that operate over 9,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. Nearly 23 million patients received comprehensive, culturally competent, quality primary health care services through the Health Center Program award recipients in 2014.

The FY 2016 Health Center Program Patient Centered Medical Home Supplement is a one-time supplemental funding opportunity that supports the upfront costs new Health Center Program award recipients face to become patient centered medical homes. Organizational transformation to achieve initial and more advanced levels of patient centered medical home recognition is costly. As of September 2015, data show that among the health centers eligible for this award only approximately 20 percent have achieved patient centered medical home recognition compared to 65 percent across all health centers. The